Agency for Health Care Administration

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AC13960123	A. BUILDING: _____ B. WING _____	07/06/2020

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
AMERICAN FAMILY PLANNING	6115 VILLAGE OAKS DRIVE PENSACOLA, FL 32504

(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) COMPLETE DATE
A 000	INITIAL COMMENTS An unannounced Clinic Licensure and complaint survey for allegations contained within complaint numbers 2020010266, 2020010504, 2020006780, 2020006536, 2020006272, 2020006243, and 2020005757 was conducted on at American Family Planning Clinic. The Medical Director was unavailable for interview during the onsite survey, and interview was obtained on . Deficient practice was identified at the time of the survey.	A 000		
A 150 SS=E	59A-9.0225(1), FAC Clinic Supplies/Equip. Stand.-2nd 59A-9.0225 Clinic Supplies and Equipment Standards for Second (1) Each clinic providing second shall provide essential clinic supplies and equipment as required in subsections (1) through (7) when performing second . Any such clinic which is in operation at the time of adoption of this rule and providing second shall be given one year within which to meet these standards as follows: (a) A surgical or examination table(s); (b) A bed or recliner(s) suitable for recovery; (c) with flow meters and masks or equivalent; (d) Mechanical suction; (e) equipment to include, at a minimum, bags and oral airways; (f) Emergency medications, fluids, and related supplies and equipment; (g) Sterile suturing equipment and supplies; (h) Adjustable examination light; (i) Containers for soiled linen and waste materials	A 150		

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A 150	Continued From page 1 with covers; and, (j) Appropriate equipment for the administering of general . . . . . , if applicable. This Statute or Rule is not met as evidenced by: Based on observations, interview with the Director of Operations (DO), and preventive maintenance log review, the clinic failed to maintain required supplies including the . . . . . room exam table, emergency medications and supplies, fluids and suturing equipment. The findings included: Observations of required equipment were made with the Director of Operations on from approximately 10:30 AM to 12:30 PM. Observation of the emergency cart storage found most emergency medications on the cart were expired and had not been removed from the cart. These expired medications included: . . . . . 20 milligrams (mg)/2 milliliters (ml) expired . . . . 1 mg/10ml expired . . . . 125mg/2ml expired . . . . . vial expired . . . . 1mg/1ml expired . . . 25% . . . . . 250mg/ml expired . . . . . -15 in a 1.3 ounce tube expired . . . . . , Observations of emergency supplies and suturing equipment revealed: . . . . . Airway expired . . . . kit for Endometrial Evacuation expired . . . . . collection set with a 25 gauge needle	A 150		

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A 150	Continued From page 2 expired . . . . . . Silver . . applicators expired . . . . . and . . . . . Hypodermic needles, 18 gauge, expired . . . . . , 20 gauge, expired . . . . . . Sterile Disposable Instrument kit, expired Observations in exam . . . # . . revealed three 500 milliliter bags of normal . . . . (. . . . . fluid) which had been opened and partially used and were not labeled with a date when opened. Each bag had a manufacturer label that said, "Single Dose Container." An exam table in the room identified as the intake . . . . . room was ripped, exposing a foam cushion which cannot be . . . . . (photographic evidence obtained) The Director of Operations was present during the observations and acknowledged the expired items. Class III	A 150		
A 154 SS=I	59A-9.0225(5), FAC Clinic Suppl/eqt-2nd Trimest-Sterilization Eq 59A-9.0225 Clinic Supplies and Equipment Standards for Second . . . . . (5) Sterilization Equipment. Sterilizing equipment of appropriate type shall be available and of adequate capacity to properly sterilize instruments and materials. The sterilizing equipment shall have approved control and safety features. This Statute or Rule is not met as evidenced by: Based on observation, policy and procedure	A 154		

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A 154	Continued From page 3 reviews, review of equipment maintenance logs, and interview with the Director of Operations, the clinic failed to maintain sterilization equipment with approved controls and safety features to properly sterilize instruments. The findings included: During a tour of exam . . # on . . . . . at approximately 10:45 AM, sterile instrument packs were observed crowded into drawers and cabinets, several layers of packs deep and numerous sterile packs were observed with water stains, instruments protruding from packaging, and hinged instruments were observed to be in the closed position in the sterile packs, indicating they were not opened during the sterilization process. On at approximately 12:15 PM, during a tour of the clinic, a room located between exam # # with a door open to the hallway was identified by the Director of Operations (DO) as the scrub room where sterilization of instruments takes place. Inside the scrub room, a tabletop model autoclave was observed on a counter sitting on a piece of porous particle board. The metal casing of the autoclave was dented in on the top right corner. A preventive maintenance sticker on the side of the autoclave indicated the last preventive maintenance check was performed and next due . Inside the autoclave were numerous pouches filled with sterilized instruments, stacked on top of each other and so full the DO could not easily remove any of the pouches. On the counter near the sink was a small, uncovered metal dish with a yellow liquid substance and 5 metal instruments soaking in the liquid. The sink in the scrub room contained a shallow metal pan filled	A 154		

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A 154	Continued From page 4 with multiple hinged metal instruments to include clamps, , , and scissors which were in the closed position, and metal speculums, pick-ups, screws, and other metal instruments, soaking in a clear liquid with some of the instruments sticking up out of the liquid due to the pan being too full of instruments. (photographic evidence obtained). During this scrub room observation on [redacted] at approximately 12:20 PM, the DO was asked how long the observed instruments had been soaking, what the instruments were soaking in, and the sterilization process in general. The DO did not provide the requested information regarding the sterilization process, nor did the DO refer to documents hanging on the wall of the scrub room which contained instructions on the sterilization procedures. The DO confirmed the most recent procedures occurred 3 days ago on Saturday, . The DO was asked which staff members were responsible for sterilization and who provided training, but did not provide the names of staff, responding only that "healthcare team members" performed sterilization. A request was made to interview staff who were responsible of the sterilization procedure, and a request was made for written documentation of staff training in sterilization procedures, the types of sterilization products used with manufacturer recommendations, and all logs of preventive maintenance or quality checks for sterilization procedures. The DO was asked repeatedly throughout the survey if she had contacted the administrator or medical director to be available to speak with the surveyors. She stated at 11:46 AM that the Administrator, physicians and clinical staff were not aware of the survey in progress because she had not been able to reach them. At the	A 154		

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A 154	Continued From page 5 completion of the clinic tour at approximately 12:30 PM, the DO said all other staff members had left the building. At 3:40 PM she stated she had reached the "higher ups" in New Jersey but they did not provide her with the requested information to include the employee training files or documentation related to sterilization equipment and procedures. At approximately 5:16 PM, the DO stated that the administrator was located in New Jersey and comes to the clinic only every few weeks as needed but could not provide an exact date of latest visit. The DO was again asked at this time for staff training and documentation on sterilization procedures. The DO did not provide staff names, did not offer to call any of the staff for a telephone interview, nor did the DO provide staff contact information. When asked who was responsible for staff training, the DO replied that she does the non-medical training and staff A, the clinic registered nurse (RN A) trained the staff. On . . . . . at approximately 5:25 PM, a repeat inspection of the scrub room was performed with the DO who was asked again to explain the procedure for ensuring sterilization of equipment. During this interview, the DO stated that the color change indicators on instrument sterilization pouches and tape used in packaging sterile instruments changed color. The DO stated the clinic does not use spore testing or any other form of biological testing to ensure sterilization equipment is functioning. The DO stated the clinic does not have a copy of the manufacturer's recommendations for maintenance or operating instructions for the autoclave used to sterilize instruments. A handwritten instruction sheet was observed taped to the wall near the autoclave with the title, "How to work Sterilizer Machine." Instructions for using Duo-Check Sterilization	A 154		

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A 154	Continued From page 6 pouches were observed hanging on the wall. The instructions directed that the color change indicator strip on the package "ONLY measure temperature and should be used in conjunction with a multi-parameter indicator strip which measures temperature, for a specified time, and the presence of steam. This procedure, when used in conjunction with weekly biological monitoring (spore testing), provides you with the highest level of sterility assurance." The DO confirmed that no biological testing was performed. (photographic evidence obtained) A review of the policy and procedure manual, last reviewed on [redacted], page 9, paragraph 8, indicated: "To wash soiled instruments the following must be observed: release all catches and joints of instruments, screws and speculums; open instruments are to be placed in the sink covered with enzymatic detergent and water in a deep pan. This will aid in loosening dried [redacted] and other substances which will interfere with sterilization. All [redacted] will be used in a safe and effective manner and in accordance to the product manufacturer's recommendations." Page 14 of the policy and procedure manual regarding equipment and supplies indicated the administrator is responsible for ensuring that all patient equipment is properly maintained, inspected, and calibrated at appropriate intervals (at minimum annually). Page 36 of the policy and procedure manual was an in service training sheet for the scrub station and included the tasks of scrub set-up before session (enzymatic cleaner, bleach, etc.), cleaning, wrapping and sterilization of the instruments, autoclave uses and maintenance, cleaning counter, strainer, scale, and room. A review of the clinic preventive maintenance logs	A 154		

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A 154	Continued From page 7 indicated an item with tag #17083, identified as a Pelton and Crane autoclave, model Delta AF, serial number 6827 passed inspection [illegible] and next due on [illegible]. The Centers for [illegible] Control and Prevention (CDC) Guidelines for [illegible] and Sterilization in Healthcare Facilities (2008), last reviewed [illegible] and retrieved on [illegible] (https://www.cdc.gov/[illegible]/guidelines/di[illegible]/sterilization/sterilizing-practices.html) stated, "The sterilization procedure should be monitored routinely by using a combination of mechanical, chemical, and biological indicators to evaluate the sterilizing conditions and indirectly the microbiologic status of the processed items. ...Once items are cleaned, dried, and inspected, those requiring sterilization must be wrapped or placed in rigid containers and should be arranged in instrument trays/baskets according to the guidelines provided by the AAMI and other professional organizations. These guidelines state that hinged instruments should be opened." Class II	A 154		
A 156 SS=I	59A-9.0225(7), FAC Clinic Suppl/eqp-2nd Trimest-Eqpt Maintenance 59A-9.0225 Clinic Supplies and Equipment Standards for Second [illegible]. (7) Equipment Maintenance. (a) When patient monitoring equipment is utilized, a written preventive maintenance program shall be developed and implemented. This equipment shall be checked and/or tested in accordance with manufacturer's specifications at periodic intervals, not less than annually, to insure proper	A 156		

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A 156	Continued From page 8 operation, and a state of good repair. After repairs and/or alterations are made to any equipment, the equipment shall be thoroughly tested for proper calibration before returning it to service. Records shall be maintained on each piece of equipment to indicate its history of testing and maintenance. (b) All and surgical equipment shall have a written preventive maintenance program developed and implemented. Equipment shall be checked and tested in accordance with the manufacturer's specifications at designated intervals, not less than annually, to ensure proper operation and a state of good repair. (c) All surgical instruments shall have a written preventive maintenance program developed and implemented. Surgical instruments shall be cleaned and checked for function after use to ensure proper operation and a state of good repair. This Statute or Rule is not met as evidenced by: Based on observation, interview with the Director of Operations, review of policy and procedures, and review of preventive maintenance logs, the clinic failed to ensure proper operation of required sterile surgical equipment through a preventive maintenance program, failed to clean equipment, and failed to conduct testing of equipment according to manufacturer's specifications at designated intervals. The findings included: Observations of clinic equipment made on from approximately 10:30 AM to 12:30 PM revealed that equipment requiring annual preventive maintenance had been labeled as last inspected 2 years ago in of 2018 and	A 156		

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A 156	Continued From page 9 were next due on . . . . . Observed equipment with outdated inspection labels included: a centrifuge, viewbox, refrigerators, , units, , , thermometer, ... units, , ... , suction pumps, exam tables, autoclave, exam lights, Automated external defibrillators (AEDs), heating pads, patient scales, patient monitors, and module rack. Observation of the autoclave (machine used to sterilize surgical instruments) revealed the right top corner of the autoclave was dented and observation of the revealed the pads expired on . . . . . . A review of the preventive maintenance completion log confirmed the date of last preventive maintenance as . . . . . and identified the equipment included in the preventive maintenance inspection as a centrifuge, viewbox, refrigerators, , units, , , thermometer, ... units, , ... , suction pumps, exam tables, autoclave, exam lights, Automated external defibrillators (AEDs), heating pads, patient scales, patient monitors, and module rack. The log also identified that one unit, one , and one suction pump failed the preventive maintenance inspection. The and suction pump which failed this inspection were observed in patient exam rooms. On . . . . . at approximately 2:30 PM, the Director of Operations (DO) confirmed the preventive maintenance for equipment was due on and had not been performed since . . . . . . On . . . . . at approximately 5:25 PM, the autoclave was reviewed with the DO. The DO stated the clinic does not have a copy of the manufacturer's recommendations for	A 156		

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A 156	Continued From page 10 maintenance or operating instructions for the autoclave used to sterilize instruments. The DO stated the clinic is not currently utilizing spore testing or any other form of biological testing to ensure sterilization equipment is functioning. A handwritten instruction sheet was observed taped to the wall near the autoclave with the title, "How to work Sterilizer Machine." Instructions for using Duo-Check Sterilization pouches were observed hanging on the wall. The instructions directed that the color change indicator strip on the package "ONLY measure temperature and should be used in conjunction with a multi-parameter indicator strip which measures temperature, for a specified time, and the presence of steam. This procedure, when used in conjunction with weekly biological monitoring (spore testing), provides you with the highest level of sterility assurance." The DO confirmed that no biological testing was performed. (photographic evidence obtained) A review of the policy and procedure manual, dated as last reviewed [redacted], on page 14 indicated preventive maintenance must be done at a minimum annually. Class II	A 156		
A 201 SS=F	59A-9.023( ), FAC Clinic Personnel-2nd Each clinic providing second [redacted] shall have a staff that is adequately trained and capable of providing appropriate service and supervision to the patients. The clinic will have a position description for each position delineating duties and responsibilities and maintain personnel records for all employees performing or monitoring patients receiving a	A 201		

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A 201	Continued From page 11 second . . . . . Any . . . . . clinic which is in operation at the time of adoption of this rule and performing second . . . . . shall be given six months within which to comply with these clinical staff requirements as follows: (1) Physicians. The clinic shall designate a licensed physician to serve as a medical director. (2) Nursing Personnel. Nursing personnel in the clinic shall be governed by written policies and procedures relating to patient care, establishment of standards for nursing care and mechanisms for evaluating such care, and nursing services. (3) Allied health professionals, working under appropriate direction and supervision, may be employed to work only within areas where their competency has been established. This Statute or Rule is not met as evidenced by: Based on staff interviews and record reviews, the clinic failed to provide documentation that staff were adequately trained and capable of providing appropriate services and supervision to the patients for 6 of 6 sampled staff A, B, C, D, E, and F. The clinic failed to provide position descriptions for each position delineating duties and responsibilities and failed to maintain personnel records for all employees performing or monitoring patients receiving a second . The clinic failed to have documentation designating changes in medical directors for 3 of 3 medical directors since . . . . . , physician G, H, J and L. Findings include: Staff Training and Personnel Records:	A 201		

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A 201	Continued From page 12 On . . . . . at approximately 10:15 AM, during entrance conference with the Director of Operations (DO), a list of needed items were requested to include a list of clinic personnel with position title and hire date, personnel files for the Administrator and Financial Officer, and job descriptions. On . . . . . at approximately 12:15 PM, the DO was asked for the names of staff responsible for sterilization of equipment, but refused to provide names when asked, stating only that "healthcare team members" were responsible. The DO was asked to provide documentation of training for each of the staff members who participated in the cleaning and sterilization of equipment. On . . . . . at approximately 12:25 PM, the DO was asked about interviewing other staff members regarding training and job duties. The DO reported all other staff members had left the building and were not available. A request was made for personnel record to include training, job description and hire dates for staff A-F, documentation for the technician's (UT) completion of a course in the operation of equipment, and contact information of all staff members, and to have these ready for review in approximately one hour. The DO verbalized her understanding. On . . . . . at approximately 1:45 PM, a partial training record was provided for 1 employee, Staff A, identified by the DO as the only nurse employed by the clinic. Staff A was a registered nurse (RN). The training record consisted of 3 sheets of paper which included an expired certificate of completion for basic life support . . . . (BLS	A 201		

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A 201	Continued From page 13) issued on and expired on ; an expired certificate of completion for Borne training issued on and expired on ; and a certificate of completion for a course titled "Caring for the Post Patient" completed on . There were no other training or personnel files provided and the DO stated that she had requested them from the office in New Jersey but was having trouble getting them based on time difference and asked if electronic copies were okay. The DO was informed electronic files were fine as long as they could be reviewed and printed if needed, but none were received. On at approximately 3:40 PM, the DO was asked about the expired certification for RN A and was asked if she could provide other training records and an updated certification that was not expired. The DO said there was a class in , 2020 and she would try to get the copies of that. The DO was reminded that other training documentation was also needed for both RN A and the other staff members. At approximately 4:00 PM, the DO provided a list of names for staff who completed training in , but the list did not include the clinic nurse (RN A) and the DO confirmed that RN A didn't attend the training. The DO and 3 other staff members, Staff B, D and E, were identified as the only staff members currently employed who had current training. A review of the policy and procedure manual, pages 28 - 39 comprised Appendix D: In-service Training Plan. The policy manual outlined a staff training program which included trainings in multiple areas such as: Prevention, Sterilization of Equipment, Cleaning, Counseling, Medical Emergencies, Fire protection,	A 201		

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A 201	Continued From page 14 examination, Medications, Licensing regulations and incident reports among others. There was no evidence in the manual that current staff had been trained in these areas. On at approximately 5:16 PM, the DO was referred to the in-service training sections of the clinic's policy and procedure manual and asked again to provide training documentation for the employees, but no additional documentation of training for any employee was provided. When asked who was responsible for staff training, the DO replied that she does the non-medical training and the clinic nurse, RN A, does the rooms and procedures. The DO said that RN A trained the staff. By the conclusion of the survey on at approximately 6:00 PM, the DO had not provided documentation on employee training (except as noted for RN A), position descriptions, or employee contact information. The DO did provide a handwritten list of staff names with their position titles and hire dates. Medical Director: A review of the most recent application for clinic licensure, dated , identified physician H as the clinic Medical Director. A review of correspondence dated from physician H revealed that physician H had removed himself as Medical Director effective . A review of the policy and procedure manual included a cover page, signed on , which indicated that the current Medical Director was	A 201		

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A 201	Continued From page 15 Physician L, while Page 17 of the manual identified physician G as the medical director. On at approximately 10:15 AM, the Director of Operations (DO) was asked to provide information about the current Medical Director, to include name, license and date of . On at approximately 12:25 PM, the DO was asked about interviewing other staff members to include the medical director. The DO reported all other staff members had left the building and were not available. A request was made for documentation designating the Medical Director position approval, the dates each physician served in the position, and contact information. On at approximately 3:00 PM, the DO confirmed that the current Medical Director was physician L, and that physician J had started and ended . The DO stated that physician #H had never performed any procedures at the clinic. On at approximately 5:16 PM, another request to speak with the Medical Director was made. The DO did not offer to call the MD, nor did the DO provide contact information. By the conclusion of the onsite survey on at approximately 6:00 PM, the DO was unable to provide documentation showing changes and dates of Medical Directors. On at approximately 11:21 AM, a telephone interview was conducted with the current Medical Director, physician L, who verified	A 201		

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A 201	Continued From page 16 that she was the current Medical Director (MD) of American Family Planning in Pensacola, Florida. The MD stated that she started there on , and took over from physician J who was the only MD, and verified that she was the only physician currently performing procedures at the clinic. Class III	A 201		
A 202 SS=F	59A-9.023( ), FAC Clinic Personnel-2nd Tri-Orientation/Training (4) Orientation. Each facility shall have and execute a written orientation program to familiarize each new staff member, including volunteers, with the facility and its policies and procedures, to include, at a minimum, fire safety and other safety measures, medical emergencies, and control. (5) In-service Training. In-service training programs shall be planned and provided for all employees including full time, part time and contract employees, at the beginning of employment and at least annually thereafter and will also apply to all volunteers to insure and maintain their understanding of their duties and responsibilities. Records shall be maintained to reflect program content and individual attendance. The following training shall be provided at least annually, and for surgical assistants and volunteers, must include training in counseling, patient advocacy and specific responsibilities associated with the services they provide: (a) control, to include at a minimum, universal precautions against -borne , general sanitation, personal hygiene such as washing, use of masks and gloves,	A 202		

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A 202	Continued From page 17 and instruction to staff if there is a likelihood of transmitting a to patients or other staff members. (b) Fire protection, to include evacuating patients, proper use of fire extinguishers, and procedures for reporting fires; (c) Confidentiality of patient information and records, and protecting patient rights; (d) Licensing regulations; and, (e) Incident reporting. This Statute or Rule is not met as evidenced by: Based on document review, interview with the Director of Operations, and review of policy and procedures, the clinic failed to maintain records documenting staff training attendance upon hire and/or for required annual trainings for 6 of 6 sampled staff A, B, C, D, E, and F. The findings included: On at approximately 10:15 AM, during entrance conference with the Director of Operations (DO), a list of needed items were requested to include a list of clinic personnel with position title and hire date, and staff training. On at approximately 12:15 PM, during a clinic tour the director of operations (DO) was asked for the names of staff responsible for sterilization of equipment, but refused to provide names when asked, stating only that "healthcare team members" were responsible. The DO was asked to provide documentation of training for each of the staff members to include training on sterilization of equipment. On at approximately 12:25 PM, the DO was asked about interviewing other staff members regarding training and job duties. The	A 202		

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A 202	Continued From page 18 DO reported all other staff members had left the building and were not available. A request was made for evidence of staff training, job description and hire dates for staff A-F, documentation for the technician's (UT) completion of a course in the operation of equipment, and contact information of all staff members, and to have these ready for review in approximately one hour. The DO verbalized her understanding. The DO provided a handwritten list of current staff with their position titles and hire dates. Staff A, Registered Nurse (RN), hired in Staff B, Certified Nursing Assistant, hired in Staff C, Certified Nursing Assistant, hired in Staff D, Healthcare Team Member, hired in Staff E, Healthcare Team Member, hired in Staff F, Technician, hired in On at approximately 1:45 PM, a partial training record was provided for 1 employee, Staff A, identified by the DO as the only nurse employed by the clinic. Staff A was a registered nurse (RN). The training record consisted of 3 sheets of paper which included an expired certificate of completion for basic life support (BLS) issued on and expired on ; an expired certificate of completion for Borne training issued on and expired on ; and a certificate of completion for a course titled "Caring for the Post Patient" completed on . There were no other training or	A 202		

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A 202	Continued From page 19 personnel files provided and the DO stated that she had requested them from the office in New Jersey but was having trouble getting them based on time difference and asked if electronic copies were okay. The DO was informed electronic files were fine as long as they could be reviewed and printed if needed, but none were received. A review of the policy and procedure manual, dated , pages 28 - 39 comprised Appendix D: In-service training. The Appendix contained a staff training plan for the following topics: Reception, OSHA and . . . . Prevention, Counseling, Medical Emergencies, Equipment, and Crash Cart/Stat kit, Emergency Preparedness and Fire protection, examination, Procedure room, Scrub, Recovery, Patient advocacy, Confidentiality, HIPAA, Licensing Regulations and Incident Reports. There was no evidence in the manual that current staff had been trained in these areas. On . . . . . at approximately 5:16 PM, the DO was referred to the in-service training sections of the clinic's policy and procedure manual and asked again to provide training documentation for the employees, but no additional documentation of training for any employee was provided. When asked who was responsible for staff training, the DO replied that she does the non-medical training and the clinic nurse, RN A, does the rooms and procedures. The DO said that RN A trained the staff. By the conclusion of the survey on . . . . . at approximately 6:00 PM, the DO had not provided documentation on employee training (except as noted for RN A), or employee contact information. Class III	A 202		

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A 250 SS=I	59A-9.024, FAC Clinic Policies/Procedures-2nd An clinic providing second shall have written policies and procedures to implement policies and to assure that quality patient care shall relate specifically to the functional activities of clinic services. These written procedures shall apply to second and shall be available and accessible to clinic personnel and shall be reviewed and approved annually by the clinic's medical director. Any clinic which is in operation at the time of adoption of this rule and providing second shall be given six months within which to comply with these clinic policies and procedure requirements which shall include but not be limited to the following: (1) Patient admission; (2) Pre- and post- , care; (3) Physician's orders; (4) Standing orders with required signatures; (5) Medications, storage and administration; (6) Treatments; (7) Surgical , ; (8) Medial , ; (9) Sterilization and ; (10) Documentation: Medical records and facility records; (11) Patient discharge; (12) Patient transfer; (13) Emergency measures; (14) Incident reports; (15) Personnel orientation; (16) Inservice education record; (17) ; (18) Equipment and supplies: availability and maintenance; (19) Volunteers; and, (20) Visitors.	A 250		

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A 250	Continued From page 21 This Statute or Rule is not met as evidenced by: Based on observations, interviews with the Director of Operations, and policy review, the clinic failed to implement its policies to assure quality patient care related to medication storage, surgical and medical [illegible], emergency measures, personnel orientation, in-service education, and equipment maintenance and supplies. The findings included: On from approximately 10:30 AM to 12:30 PM, a clinic tour was conducted with the Director of Operations (DO). During this tour, a laboratory area was observed with equipment including a centrifuge and a view box. The DO said a private medical technician does the preventive maintenance for the laboratory equipment. The name and contact information for the medical technician was requested but not provided. Observations made in exam # included: Behind the table was an pole and hanging from the pole was an opened bag of normal , not labeled with a date when opened or any other labeling other than the manufacturer's label which stated, "single dose container". Connected to an canister was a plastic mask and tubing with no covering or opening label/date on it. When asked when this room was last used, the DO stated that she thought it was last used Saturday (3 days ago). Next to the suction equipment was a clear plastic bin, approximately 18 inches long by 9 inches wide and inches deep. The bin was not covered and was filled approximately halfway with a light blue liquid. Near this plastic bin were large	A 250		

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A 250	Continued From page 22 plastic tubes with metal ends. The bin was not labeled, and the DO could not identify the solution in the bin, but was able to describe the purpose of the solution as being used to soak tubing from the suction machine after use for the purpose of cleaning. The DO could not identify when the solution was placed in the bin, how often it was changed, or provide any written materials specifying the protocols for preparing, using, mixing, or discarding the solution. The DO agreed the solution was used to clean contaminated equipment but could provide no further details. (Photographic evidence obtained) The exam room contained numerous packs of sterile instruments stored in cabinets and drawers throughout the room. The sterile instrument packs were very crowded in drawers and cabinets, several layers of packs deep and numerous sterile packs were observed with water stains, instruments protruding from packaging, and hinged instruments were observed to be in the closed position in the sterile packs, indicating they were not opened during the sterilization process. Medications were observed in cabinets, drawers and the crash cart, and they were not locked or sealed in any way to control access. A covered plastic bin with a lid labeled " 1%" and no date, contained pre-filled unlabeled syringes containing a clear fluid. An emergency medication pack was stored on the floor in exam # and contained expired medications. Expired medications included: 20 milligrams (mg)/2 milliliters (ml) expired in 1 mg/10ml expired 125mg/2ml expired vial expired 1mg/1ml expired 25% 250mg/ml expired and -15 in a 1.3 ounce	A 250		

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A 250	Continued From page 23 tube expired , ... The DO acknowledged the expired medications and when asked about emergency drills, stated that no emergency drills are performed. (Photographic evidence obtained) The equipment in the room were not clean as evidenced by thick layers of dust on the machine and a dark red-brown substance was dried that had dripped down on the of a white cabinet. There were also dried reddish spots on packaged . . . . . needles in a drawer. These reddish and reddish-brown dried substances were similar in appearance to dried and there was no other liquid substance stored in the room with a similar color. The machine in the room had a transducer with a blue substance dried on it that appeared to be transducer gel and a crack on the outer coating of the transducer. (Photographic evidence obtained). Equipment in the room with preventive maintenance stickers included an adjustable exam light, the defibrillator, the machine, suction equipment, and an automated external defibrillator ( ). The pads for the expired on . . . . . The preventive maintenance stickers for each device identified the last inspection as done . . . . . and next due . . . . . . A review of preventive maintenance logs provided upon request identified the last documented preventive maintenance for all equipment in the clinic as completed . . . . . and due . . . . . . In an interview at approximately 11:30 AM, the DO confirmed the preventive maintenance for equipment was due on and had not been performed since	A 250		

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A 250	Continued From page 24 Observations in exam # included were similar to exam # and included multiple expired medications, sterile instrument packs which were not properly stored, and another unlabeled, uncovered plastic container of blue liquid near the , equipment that was sitting on the table atop an absorbent , with a small, metal tube next to it. (Photographic evidence obtained) Observations in the recovery room included a refrigerator labeled with a biohazard symbol. Inside the refrigerator were drinks - Coke, Monster, and water, and a metal bowl with discolored paper towels which the DO described as used to provide cool relief for patients, but there was no date indicating when they were placed in the refrigerator. There was a desk near the door of the room which had food items, medications, multiple opened and undated vials of , one of which had a needle sticking out of the rubber stopper on the vial, , medications, and were located unsecured on top of the desk. There were boxes of gloves, paper medication cups, pens, , cuffs, basins, a lint roller, air freshener spray, a ketchup packet, saniwipes, a stapler, napkins, and a bottle of misoprostil, a medication used for the termination of , . There were food items and drinks located on the floor which were described by the DO during the tour at approximately 10:45am as items offered to clients. There were wall-mounted cabinets which were not secured with locks and contained bottles of medications including and , medications. There were two bathrooms inside the recovery area. In the first bathroom there was a rectangular open area in the ceiling that appeared to have a missing cover. The DO was not sure what the area was or why it was	A 250		

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A 250	Continued From page 25 open. There was a wall mounted cabinet over the toilet with a missing door which was laying on top of the cabinet. The other bathroom had a similar opening in the ceiling partially covered by a plastic vent. The hallway leading to the recovery area led to a fire exit which was partially obstructed by linen carts. (Photographic evidence obtained) After leaving the recovery area, observations were made at a desk in the hallway between and across from the two exam rooms. On top of the desk was a box containing vials of [illegible], a [illegible] agent also used for termination of [illegible]. There were approximately 10 boxed vials of [illegible] on top of the desk left unsecured. [illegible] is a drug with special storage and handling requirements and is cytotoxic meaning physical contact between the drug and unprotected skin can cause damage. The drug must be stored in a temperature-controlled environment. Special instructions for handling and storage can be found at https://www.pfizermedicalinformation.[illegible]/en-[illegible]/methotrexate/storage-and-stability and https://www.pfizermedicalinformation.[illegible]/en-[illegible]/methotrexate/special-handling-instructions. There was a refrigerator under the desk labeled as "Drugs Only, No Food," which when opened contained medications, a can of sparkling water and a can of V-8. The refrigerator also contained a plastic box with a lid. A piece of tape on the box indicated the date [illegible] and contained approximately sixteen 10cc syringes unlabeled and filled with a clear liquid. (Photographic evidence obtained) Next, observations were made in the scrub room,	A 250		

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A 250	Continued From page 26 an area for sterilization and . . . . . of equipment and supplies. The DO was asked again about the bins containing blue solution in each of the exam rooms and the procedure for sterilizing equipment using chemical and heat (autoclave) sterilization. The DO would not reply with names of staff responsible for sterilization when asked, only stating that "healthcare team members" are responsible. The DO was asked to provide documentation of training for each of the staff members to include training on sterilization of equipment. The DO was also asked to provide the MDS (material data safety) sheets for chemicals used for sterilization. The MDS sheets were not provided and were not observed throughout the tour. (Photographic evidence obtained) Upon completion of tour at approximately 12:30 PM, the DO was asked about interviewing other staff members and said all other staff members and patients had left the building and were not available. The DO was asked to collect all requested documents, to include training, personnel records, contact information of all staff members, sterilization procedures, policy and procedures, equipment maintenance logs and access to the . locker for review. On at approximately 1:45 PM, the DO provided the policy and procedure manual and equipment maintenance binder. Only one a partial training record was provided for 1 employee, Staff A, identified by the DO as the only nurse employed by the clinic. Staff A was a registered nurse (RN). The training record consisted of 3 sheets of paper which included an expired certificate of completion for basic life support . . . . . (BLS) issued on and expired on	A 250		

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A 250	Continued From page 27 ; an expired certificate of completion for Borne training issued on and expired on ; and a certificate of completion for a course titled "Caring for the Post Patient" completed on . There were no other training or personnel files provided and the DO stated that she had requested them from the office in New Jersey but was having trouble getting them based on time difference. On at approximately 3:30 PM, an observation of the controlled substance locker was made in exam # with the DO. A controlled substance log was on a table below the cabinet. The log identified 3 medications as controlled substances - , , , and . The most recent log entry for each of the three medications was initialed but did not have a second set of initials or signature. The medication logs did not have documentation identifying the initials of each person who documented in the log and the initials could not be identified by the director of operations. When the controlled substance locker was unlocked, the locker was found to contain an opened, un-dated multi-use vial of , 1000mcg (micrograms) in 20ml (milliliters) which was only partially full of a clear liquid. There were 19 closed/full vials , 1000mcg in 20ml. There were 12 closed/full vials of 2mg (milligrams) in 2ml and 7 closed/full vials of 500mg in 10ml. The most recent entry on each controlled medication log was dated . The last entry for , indicated the remaining amount was 19 ½ vials, for the entry indicated the remaining amount was 12 vials and the last entry indicated the remaining amount was 6 ½ vials.	A 250		

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A 250	Continued From page 28 The amount of documented was not correct and the DO confirmed the actual amount on was 7 vials. (Photographic evidence obtained) A review of the policy and procedure manual, last reviewed on found the medication storage and administration policy on pages indicated: Keep all drugs tightly covered and properly labeled. Do not keep medications in any container without proper means of identification. As controlled medications are used, they are recorded. An accurate count is kept at all times. All multi-dose medication vials are dated when opened. Opened, multi-dose vials are usable for 28 days, unless the manufacturer specifies a different (shorter or longer) date for that opened vial. Medications are cared for and stored properly according to the manufacturer's instructions on the label. Refrigerated drugs are kept in a separate refrigerator marked "Drugs Only, No Food." Drug supplies are checked monthly. Outdated drugs are discarded. Page 8-9: Surgical and Medical : All surfaces (counters, exam tables, machinery and lights) are wiped with , solution/wipes between patients and at the end of the day. Sharp items are to be discarded in , resistant containers marked with a biohazard symbol. Surfaces should be cleaned and then decontaminated with appropriate chemical germicide if contaminated with or , . These surfaces should be cleaned and decontaminated at the end of the work day. Page 10, under the heading Emergency Measures, indicated the nurses, administrators, and healthcare team members must know the contents of the crash cart, its location, and where	A 250		

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A 250	Continued From page 29 other emergency equipment is located. Emergency Measures continued on page 11 to state the clinic shall ensure that all appropriate equipment and services are readily accessible to provide appropriate emergency resuscitative and life support procedures. Page 16 included "Sterilizing equipment of appropriate type shall be available and of adequate capacity to properly sterilize instruments and materials. The sterilizing equipment shall have approved control and safety features. Steam sterilization via an autoclave, and appropriate sterilization may be used." The Clinic personnel and training portions of the policy and procedure manual mirror the regulatory requirements and the clinic did not provide evidence of compliance. Pages 28 - 39 comprised Appendix D: In-service training. The Appendix contained a staff training plan for the following topics: Reception, OSHA and Prevention, Counseling, Medical Emergencies, Equipment, and Crash Cart/Stat kit, Emergency Preparedness and Fire protection, ... examination, Procedure room, Scrub, Recovery, Patient advocacy, Confidentiality, HIPAA, Licensing Regulations and Incident Reports. There was no evidence in the manual that current staff had been trained in these areas. Class II	A 250		
A 301 SS=F	59A-9.025(2) and ( ), FAC Medical Screening/eval.-2nd . . . . -Lab Svc 59A-9.025 Medical Screening and Evaluation of Patients Receiving Second . . (2) Laboratory Services.	A 301		

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A 301	Continued From page 30 (a) Laboratory services shall be provided on-site or through arrangement with a laboratory that holds the appropriate federal Clinical Laboratory Improvement Amendments (CLIA) certificate and state of Florida clinical laboratory license issued pursuant to Chapter 483, Part I, F.S. (b) All laboratory services provided on-site shall be performed in compliance with state of Florida clinical laboratory licensure and federal CLIA provisions. (4) factor. testing for negative patients shall be conducted, unless reliable written documentation of type is available. (5) All laboratory test reports shall be placed in the patient's medical record. (6) All laboratory test and storage areas, records and reports shall be available for inspection by the agency. (7) If a person who is not a physician performs an examination, that person shall have documented evidence that he or she has completed a course in the operation of equipment. (8) A test for shall be performed. This Statute or Rule is not met as evidenced by: Based on observation, interview with the Director of Operations and policy and procedure reviews, the clinic failed to provide evidence that the non-physician staff who performed had completed a course in the operation of equipment for 2 of 2 sampled staff members, Staff B and F. The clinic failed to provide preventive maintenance (PM) for the laboratory equipment. Findings include: On from approximately 10:30 AM to	A 301		

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A 301	Continued From page 31 12:30 PM, a clinic tour was conducted with the director of operations (DO). During this tour, in exam . . , . . . gauge needle . . . . collection sets were found expired on . A laboratory area was observed with equipment including a centrifuge and a view box. The DO said a private medical technician performed the preventive maintenance for the laboratory equipment. The name and contact information for the medical technician was requested but not provided. On . . . . . at approximately 12:25 PM, the DO was asked about staff who perform . . . . . , and documentation of training and course completion in the operation of equipment. The DO provided a handwritten list of current staff with their position titles and hire dates which included Staff B, Certified Nursing Assistant and Staff F, . Technician. By the time of survey exit on On at approximately 6:00 PM, evidence of training on . equipment had not been provided for any non-physician employee, to include staff B and F. On at approximately 11:21AM, a telephone interview was conducted with the Medical Director who stated that staff B was very adept and perfomed bedside . . . . . if the technician, staff F, was not in the clinic. Class III	A 301		
A 400 SS=F	59A-9.027, FAC Recovery Rm Stand.-2nd .	A 400		

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A 400	Continued From page 32 Each clinic which is providing second shall comply with the following recovery room standards when providing second (1) Following the procedure, post procedure recovery rooms will be supervised and staffed to meet the patient's needs. A physician or physician assistant, a licensed registered nurse, a licensed practical nurse or an advanced registered nurse practitioner who is trained in the management of the recovery area shall be available to monitor the patient in the recovery room until the patient is discharged. The individual must be certified in basic . A patient in the post- or recovery room shall be observed for as long as the patient's condition warrants. (2) The clinic shall arrange hospitalization if any complication beyond the medical capability of the staff occurs or is suspected. The clinic shall ensure that all appropriate equipment and services are readily accessible to provide appropriate emergency resuscitative and life support procedures pending the transfer of the patient or a viable to the hospital. A physician shall sign the discharge order and be readily accessible and available until the last patient is discharged to facilitate the transfer of emergency cases if hospitalization of the patient or viable is necessary. The clinic medical records documenting care provided shall accompany the patient. These records will include the contact information for the physician who performed the procedure at the clinic. (3) A physician shall discuss Rho (D) with each patient for whom it is indicated and will ensure that it is offered to the patient in the immediate period or that it will be available to the patient within 72 hours	A 400		

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A 400	Continued From page 33 following completion of the procedure. If the patient refuses the Rho (D) , refusal Form 3130-1002, , "Refusal to Permit Administration of (D) ", herein incorporated by reference, shall be signed by the patient and a witness, and shall be included in the patient's medical record. The form can be obtained by written request from the Agency for Health Care Administration, Hospital and Outpatient Services Unit, Mail Stop #31, 2727 Mahan Drive, Tallahassee, Florida 32308, or from the agency website at: http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Hospital_Outpatient/ .shtml. (4) Written instructions with regard to post coitus, signs of possible medical complications, and general aftercare shall be given to each patient. Each patient shall have specific written instructions regarding access to medical care for complications, including a telephone number to call for medical emergencies. The physician will ensure that either a registered nurse, licensed practical nurse, advanced registered nurse practitioner, or physician assistant from the clinic makes a good faith effort to contact the patient by telephone, with the patient's consent, within 24 hours after surgery to assess the patient's recovery. A contact for post- , care from the facility shall be available to the patient on a 24-hour basis. (5) Facility procedures must specify the minimum length of time for recovery as warranted by the procedure type and period. This Statute or Rule is not met as evidenced by: Based on interview with the Director of Operations, interview with the Medical Director and policy and procedure review, the clinic failed	A 400		

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A 400	Continued From page 34 to ensure the recovery area was staffed by a physician or physician assistant, a licensed registered nurse, a licensed practical nurse or an advanced registered nurse practitioner. Findings include: On at approximately 4:00 PM, the Director of Operations (DO) was asked about the recovery area staffing. The DO explained that staff A, the facility Registered Nurse (RN A), goes between the two exam rooms during procedures and "keeps an . . on" the recovery area between assisting with procedures. The DO stated that other healthcare team members were also available during recovery. On at approximately 11:21 AM, a telephone interview was conducted with the Medical Director (MD). The MD stated that she was the only physician currently performing procedures at the clinic, and added that she arrives on a Wednesday, to perform procedures every Thursday, Friday, and Saturday, and leaves sometime on a Sunday, after completing some telemedicine follow-ups, and seeing medical patients. The MD said staff A, the facility Registered Nurse (RN A), was not generally in the facility but was available by telephone. The MD stated that the recovery room was staffed by the DO and staff B, a Certified Nurse Assistant (CNA). The MD said she could easily see the recovery area when she came out of procedure rooms. The MD verified that the RN was not in the facility on the days (Thursday-Saturday) she performed procedures. A review of the policy and procedure manual on page 5 stated: following the procedure, post procedure recovery rooms will be supervised and	A 400		

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A 400	Continued From page 35 staffed to meet the patient's needs. A physician or physician assistant, a licensed registered nurse, a licensed practical nurse or an advanced registered nurse practitioner who is trained in the management of the recovery area shall be available to monitor the patient in the recovery room until the patient is discharged. The individual must be certified in basic [illegible]. A patient in the post-[illegible] or recovery room shall be observed for as long as the patient's condition warrants. Class III	A 400		
CZ817 SS=E	408.810( ) FS; 59A-35.100(1) FAC Minimum Licensure Requirement - Inform AHCA 408.810 Minimum licensure requirements.-In addition to the licensure requirements specified in this part, authorizing statutes, and applicable rules, each applicant and licensee must comply with the requirements of this section in order to obtain and maintain a license. (3) Unless otherwise specified in this part, authorizing statutes, or applicable rules, any information required to be reported to the agency must be submitted within 21 calendar days after the report period or effective date of the information, whichever is earlier, including, but not limited to, any change of: (a) Information contained in the most recent application for licensure. (b) Required insurance or bonds. (4) Whenever a licensee discontinues operation of a provider: (a) The licensee must inform the agency not less than 30 days prior to the discontinuance of	CZ817		

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CZ817	Continued From page 36 operation and inform clients of such discontinuance as required by authorizing statutes. Immediately upon discontinuance of operation by a provider, the licensee shall surrender the license to the agency and the license shall be canceled. (b) The licensee shall remain responsible for retaining and appropriately distributing all records within the timeframes prescribed in authorizing statutes and applicable rules. In addition, the licensee or, in the event of . . . . or dissolution of a licensee, the estate or agent of the licensee shall: 1. Make arrangements to forward records for each client to one of the following, based upon the client's choice: the client or the client's legal representative, the client's attending physician, or the health care provider where the client currently receives services; or 2. Cause a notice to be published in the newspaper of greatest general circulation in the county in which the provider was located that advises clients of the discontinuance of the provider operation. The notice must inform clients that they may obtain copies of their records and specify the name, address, and telephone number of the person from whom the copies of records may be obtained. The notice must appear at least once a week for 4 consecutive weeks. 59A-35.100 Minimum Licensure Requirements. Provider location. A licensee must maintain proper authority for operation of the provider at the address of record. If such authority is denied, revoked or otherwise terminated by the local zoning or code enforcement authority, the Agency may deny or revoke an application or license, or impose sanctions.	CZ817		

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CZ817	Continued From page 37 This Statute or Rule is not met as evidenced by: Based on interview with the Director of Operations, interview with the Medical Director, review of the licensure application and policy and procedure review, the clinic failed to report a change in Medical Director to the Agency for Health Care Administration (AHCA). The clinic had had three different medical directors since their application from , physician H, J and L. Findings include: A review of the most recent application for clinic licensure, dated , identified physician H as the clinic Medical Director. A review of correspondence dated from physician H revealed that physician H had removed himself as Medical Director effective . A review of the policy and procedure manual included a cover page, signed on , which indicated that the current Medical Director was Physician L. On at approximately 12:25 PM, the DO was asked for documentation showing when the new MD, physician L,was appointed, and any documentation indicating notification to AHCA of the change in Medical Director. At approximately 3:00pm the DO confirmed that the current Medical Director was physician L, and that physician J had started and ended . The DO stated that physician H had never performed any procedures at the clinic.	CZ817		

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CZ817	Continued From page 38 The DO was asked repeatedly throughout the survey on if she had contacted the Medical Director to be available to speak with the surveyors. She stated at 11:46 AM that the administrator, physicians and clinical staff were not aware of the survey in progress because she had not been able to reach them. At the completion of the clinic tour at approximately 12:30 PM, the DO said all other staff members had left the building. At approximately 5:16 PM, another request to speak with the Medical Director was made. The DO did not offer to call the MD, nor did the DO provide contact information. By the conclusion of the onsite survey on at approximately 6:00 PM, the DO was unable to provide evidence of Medical Director change notification to AHCA, or board minutes or other documentation showing changes and dates of Medical Directors since . On at approximately 11:21 AM, a telephone interview was conducted with the current Medical Director, physician L, who verified that she was the current Medical Director (MD) of American Family Planning in Pensacola, Florida. The MD stated that she started there on , and took over from physician J who was the previous Medical Director, and verified that she was the only physician currently performing procedures at the clinic. Class III	CZ817		
CZ824	408.811 FS; 59A-35.120 FAC Right of Inspection; Inspection Reports	CZ824		

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CZ824	Continued From page 39 408.811 Right of inspection; copies; inspection reports; plan for correction of deficiencies.- (1) An authorized officer or employee of the agency may make or cause to be made any inspection or investigation deemed necessary by the agency to determine the state of compliance with this part, authorizing statutes, and applicable rules. The right of inspection extends to any business that the agency has reason to believe is being operated as a provider without a license, but inspection of any business suspected of being operated without the appropriate license may not be made without the permission of the owner or person in charge unless a warrant is first obtained from a circuit court. Any application for a license issued under this part, authorizing statutes, or applicable rules constitutes permission for an appropriate inspection to verify the information submitted on or in connection with the application. (a) All inspections shall be unannounced, except as specified in s. 408.806. (b) Inspections for relicensure shall be conducted biennially unless otherwise specified by authorizing statutes or applicable rules. (2) Inspections conducted in conjunction with certification, comparable licensure requirements, or a recognized or approved accreditation organization may be accepted in lieu of a complete licensure inspection. However, a licensure inspection may also be conducted to review any licensure requirements that are not also requirements for certification. (3) The agency shall have access to and the licensee shall provide, or if requested send, copies of all provider records required during an inspection or other review at no cost to the agency, including records requested during an offsite review.	CZ824		

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CZ824	Continued From page 40 (4) A deficiency must be corrected within 30 calendar days after the provider is notified of inspection results unless an alternative timeframe is required or approved by the agency. (5) The agency may require an applicant or licensee to submit a plan of correction for deficiencies. If required, the plan of correction must be filed with the agency within 10 calendar days after notification unless an alternative timeframe is required. (6)(a) Each licensee shall maintain as public information, available upon request, records of all inspection reports pertaining to that provider that have been filed by the agency unless those reports are exempt from or contain information that is exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution or is otherwise made confidential by law. Copies of such reports shall be retained in the records of the provider for at least 3 years following the date the reports are filed and issued, regardless of a change of ownership. (b) A licensee shall, upon the request of any person who has completed a written application with intent to be admitted by such provider, any person who is a client of such provider, or any relative, spouse, or guardian of any such person, furnish to the requester a copy of the last inspection report pertaining to the licensed provider that was issued by the agency or by an accrediting organization if such report is used in lieu of a licensure inspection. 59A-35.120 Inspections. (1) When regulatory violations are identified by the Agency: (a) Deficiencies must be corrected within 30 days of the date the Agency sends the deficiency notice to the provider, unless an alternative	CZ824		

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CZ824	Continued From page 41	CZ824		

timeframe is required or approved by the Agency.
(b) The Agency may conduct an unannounced follow-up inspection or off-site review to verify correction of deficiencies at any time.
(2) If an inspection is completed through off-site record review, any records requested by the Agency in conjunction with the review, must be received within 7 days of request and provided at no cost to the Agency. Each licensee shall maintain the records including medical and treatment records of a client and provide access to the Agency.
(3) Providers that are exempt from Agency inspections due to accreditation oversight as prescribed in authorizing statutes must provide:
(a) Documentation from the accrediting agency including the name of the accrediting agency, the beginning and expiration dates of the provider's accreditation, accreditation status and type must be submitted at the time of license application, or within 21 days of accreditation.
(b) Documentation of each accreditation inspection including the accreditation organization's report of findings, the provider's response and the final determination must be submitted within 21 days of final determination or the provider is no longer exempt from Agency inspection.

This Statute or Rule is not met as evidenced by:
Based on interview with the Director of Operations and record reviews, the facility failed to provide requested documentation of personnel records, staff training, and access to staff for interviews including the administrator and medical director (staff A, B, C, D, E, F).

Findings include:

On at approximately 10:15 AM, during

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AC13960123	A. BUILDING: _____ B. WING _____	07/06/2020

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
AMERICAN FAMILY PLANNING	6115 VILLAGE OAKS DRIVE PENSACOLA, FL 32504

(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) COMPLETE DATE
CZ824	Continued From page 42	CZ824		

an entrance conference, the director of operations (DO) stated procedures were scheduled for the day and asked if the survey team could perform the inspection on another day. The DO was informed of the need for survey and that the survey process would not interrupt operations of the clinic. At that time, several staff members were observed in the clinic, and there were several clients in the waiting room. Later in the day at approximately 12:25 PM, the DO stated that no procedures were scheduled for the day, only intake screening.

A clinic tour was conducted with the DO on ..... from approximately 10:30 AM to 12:30 PM. During an observation of the laboratory area at approximately 10:45 AM, the DO said a private medical technician does the preventive maintenance for the laboratory equipment. The name and contact information for the medical technician was requested but not provided. At approximately 12:15 PM, during an observation of the scrub room for surgical sterilization of equipment, the DO was asked again if the administrator or Medical Director had been notified of the survey in progress and she stated she had not been able to reach anyone. The DO was asked about the staff responsible for sterilization, and evidence of staff training was requested. The DO would not provide the staff names, and only stated that "healthcare team members" were responsible. The DO was also asked to provide the MDS (material data safety) sheets for chemicals used for sterilization. The MDS sheets were not provided and were not observed throughout the tour.

On at approximately 12:25 PM, the DO was asked about interviewing other staff members regarding training and job duties. The

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CZ824	Continued From page 43 DO reported all other staff members had left the building and were not available. A request was made for personnel records to include training, job description and hire dates for staff A-F, documentation for the technician's (UT) completion of a course in the operation of equipment, and contact information of all staff members, and to have these ready for review in approximately one hour. The DO verbalized her understanding. On at approximately 1:45 PM, the DO provided the policy and procedure manual and the equipment maintenance binder. Only one partial training record was provided for 1 employee, Staff A, identified by the DO as the only nurse employed by the clinic. Staff A was a registered nurse (RN). The training record consisted of 3 sheets of paper which included an expired certificate of completion for basic life support (BLS) issued on and expired on ; an expired certificate of completion for Borne training issued on and expired on ; and a certificate of completion for a course titled "Caring for the Post Patient" completed on . There were no other training or personnel files provided and the DO stated that she had requested them from the office in New Jersey but was having trouble getting them based on time difference and asked if electronic copies were okay. The DO was informed electronic files were fine as long as they could be reviewed and printed if needed, but none were received. The DO was asked several times throughout the survey on if she had contacted the Administrator or Medical Director to be available to talk with surveyors. At 11:46 AM she stated	CZ824		

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CZ824	Continued From page 44 that the administrator, physicians and clinical staff were not aware of a survey in progress because she had not been able to reach them. At 3:40 PM she stated she had reached the "higher ups" in New Jersey and was instructed she was not allowed to give a copy of the transfer agreement, nor allow any copies of the agreement to be made by surveyors using a cam scan device. The transfer agreement she provided for review was located in a 3-ring binder with the pages stored in clear plastic sleeves. Across the front page in the plastic sleeve was a piece of paper stating "Do Not Copy." When instructed that the transfer agreement was a regulatory requirement and failure to provide evidence of a transfer agreement would result in a finding of non-compliance, she agreed to allow a copy if needed. On at approximately 5:16 PM, the DO stated that the administrator was located in New Jersey and comes to the clinic only every few weeks as needed but could not provide an exact date of latest visit. During the interview, staff training records were again requested. By the conclusion of the survey on at approximately 6:00 PM, the DO had not provided documentation on employee training (except as noted for RN A), position descriptions, or employee contact information. The DO did provide a handwritten list of staff names with their position titles and hire dates. Unclassified	CZ824		