Texas Department of State Health Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	145012	A. BUILDING: _____ B. WING _____	01/30/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
NORTH PARK MEDICAL GROUP	8383 MEADOW ROAD DALLAS, TX 75231

(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 Note: The State Form is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be referred to the Office of the Texas Attorney General (OAG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately. An entrance conference was held with the Clinic Administrator the morning of 1-29-18. The purpose and process of the initial survey were discussed, and an opportunity given for questions. Initial licensure is recommended. An exit conference was held with the Clinic Administrator the evening of 1-30-18. Preliminary findings of the survey were discussed, and an opportunity given for questions.	A 000	REVIEWED MAR 05 2018 BY: Wanda Wilson RN	
A 142	TAC 139.43(1) Personnel Policies The licensee shall develop, implement and enforce policies which shall govern all personnel staffed by the facility using the following minimum criteria: (1) job descriptions, including qualifications for all personnel providing direct or indirect patient care; This Requirement is not met as evidenced by: Based on a review of documentation and interview, the facility failed to ensure that facility	A 142		

[redacted] TITLE Administrator (X6) DATE 03-02-2018

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A 142	Continued From page 1 developed, implemented and enforced policies which shall govern all personnel staffed by the facility using the following minimum criteria: job descriptions, including qualifications for all personnel providing direct or indirect patient care. Findings included: Review of the facility based policy and procedure book revealed there were no policies addressing job descriptions, including qualifications for all personnel providing direct or indirect patient care. In an interview on 01/30/18, staff member #5 confirmed that facility did not have any policies addressing staff job descriptions.	A 142	TAC 139.43(1) Personnel Policies The Clinic Administrator has developed, implemented and will enforce policies addressing job descriptions, including qualifications for all personnel providing direct or indirect patient care. Policy and Procedure will be implemented and placed in Policy and Procedure Manual for all staff positions. See enclosed attachments. The Clinic Administrator will be responsible for the plan of ensuring policies are current for staff job descriptions for areas of work. The plan is to ensure that the Policy and Procedure Manual will have current job descriptions and will be changed as needed. The plan will be implemented upon review of Policy and Procedure Manual. Ongoing compliance will be monitored periodically.	02-19-18
A 158	TAC 139.45(1)(2) Personnel Records An individual personnel record shall be maintained on each person employed by the licensed abortion facility which shall include, but not be limited to, the following: (1) current job description for the employee, which is reviewed and revised as needed; (2) verification of current license and certification of personnel required to have a license and or certification; This Requirement is not met as evidenced by: Based on a review of documentation and interview, the facility failed to ensure that individual personnel records were maintained on each person employed by the licensed abortion facility which included a current job description for the employee, which is reviewed and revised as	A 158		

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A 158	Continued From page 2 needed. Findings included: Review of the personnel files for office personnel revealed that 5 of 6 office personnel did not have job descriptions included in their file. * Staff members #4, 5, 6, 7, and 8 did not have job descriptions in their personnel files. In an interview on 01/30/18 staff member #5 confirmed the above staff members did not have job descriptions in their personnel files.	A 158	TAC 139.45(1)(2) Personnel Records The Clinic Administrator will ensure each employee has current signed job description(s) that will be reviewed and revised as needed. All employees required to have a licensees or certification will be verified and placed in personnel file. The Clinic Administrator will be responsible for the plan of ensuring employees have job descriptions for areas of work. The plan is to ensure once employee has been trained for specific area, employee will have a signed copy of job descriptions placed in employee file. The plan will be implemented upon review of employee file. On going compliance will be monitored at the probation period, yearly review and as needed.	02-19-18
A 197	TAC 139.48(1)(A) Physical & Environmental Requirements The physical and environmental requirements for a licensed abortion facility are as follows. (1) A facility shall: (A) have a safe and sanitary environment, properly constructed, equipped, and maintained to protect the health and safety of patients and staff at all times; This Requirement is not met as evidenced by: Based on a tour of the facility and an interview with staff, the facility failed to maintain a safe and sanitary environment, properly constructed, equipped, and maintained to protect the health and safety of patients and staff at all times. Findings were: During a tour of the facility on 1-30-18, the following was noted:	A 197		

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A 197	Continued From page 3 In the ultrasound room: "The ultrasound machine bore no inspection sticker to indicate that it had been inspected and found to be in working order. In procedure room #1: "The suction machine bore an inspection sticker that stated the equipment was due to be inspected 12-2017. "The patient lamp bore an inspection sticker that stated the equipment was due to be inspected 12-2017. "The oral suction machine bore an inspection sticker that stated the equipment was due to be inspected 12-2017. "The hand-held pulse oximeter bore an inspection sticker that stated the equipment was due to be inspected 12-2017. "The mechanical procedure table bore an inspection sticker that stated the equipment was due to be inspected 12-2017. "The AED (automated external defibrillator) model Defibtech DDU-100 checklist indicated only that the expiration dates for the defibrillator pads and the difribrillator were checked on a regular basis. No other routine checks were performed. According to the operating guide for the AED, the ASI (active status indicator) should be checked daily. The ASI, the condition of the unit and accessories and the pad/battery pack expiration dates should be checked monthly. The ASI, condition of the unit and accessories, a manually initiated self-test and pad replacement should all be performed after each use. In the laboratory area:	A 197	TAC 139.48(1)(A) Physical & Environmental Requirements The Clinic Administrator had a scheduled date for the equipment to be inspected on Thursday February 01, 2018. Legacy BioMedical inspected the ultrasound machine, suction machine, patient lamp, oral suction machine, hand-held pulse oximeter, mechanical procedure table, the AED, the Hemocue machine, Rh View Box, the refrigerator in lab, all equipment was found to be satisfactory. The ultrasound machine was new and had not yet inspected. The AED has been checked daily since 01/31/2018 and documented on a daily basis. The battery pack and pads will be checked monthly for expiration dates. Pads will be replaced as needed and after each use. The Clinic Administrator will be responsible for scheduling of the yearly equipment inspection and servicing. The plan will be to ensure the inspection to be performed yearly. The plan will be implemented as needed for inspection, repairs and servicing of equipment. Ongoing compliance will be monitored by Clinic Administrator.	02-01-18

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A 197	Continued From page 4 "The Hemocue machine bore an inspection sticker that stated the equipment was due to be inspected 12-2017. "The Rh View Box bore an inspection sticker that stated the equipment was due to be inspected 12-2017. "The refrigerator used to store equipment controls, Rhogam and Pitocin bore an inspection sticker that stated the equipment was due to be inspected 12-2017. In an interview with staff #5 on 1-30-18, staff #5 confirmed that the above-named equipment was overdue for inspection and that the AED was not being checked at the proper frequency.	A 197		
A 201	TAC 139.48(1)(E)(F) Physical & Environmental Requirements The physical and environmental requirements for a licensed abortion facility are as follows. (1) A facility shall: (E) store hazardous cleaning solutions and compounds in a secure manner and label substances; (F) have the capacity to provide patients with liquids. The facility may provide commercially packaged food to patients in individual servings. If other food is provided by the facility, it shall be subject to the requirements of §§229.161 - 229.171 of this title (relating to Texas Food Establishments); This Requirement is not met as evidenced by: Based on a tour of the facility and an interview with staff, the facility failed to store hazardous cleaning solutions and compounds in a secure manner.	A 201		

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A 201	Continued From page 6 Findings were: During a tour of the facility on 1-30-18, an unlocked supply closet at the end of the patient hallway contained such items as Windex glass cleaner, furniture polish, bleach, laundry detergent, Lysol spray, toilet bowl cleaner and insect spray. In an interview with staff #5 on 1-30-18, staff #5 was asked if the door to the closet was usually locked when patients were in the building. She stated that it was not locked and patients regularly mistook the closet door for the exit door. The above was confirmed in an interview with staff #5 on the evening of 1-30-18.	A 201	TAC 139.48(1)(E)(F) Physical & Environmental Requirements The Clinic Administrator will ensure staff is placing all cleaning solutions and compounds in a secure manner in the supply closet. The door to the supply closet will remain locked. Employees will unlock as needed. All solutions labeled for contents. This will not be stored in patient care areas. The Clinic Administrator will be responsible for ensuring staff locks the Supply Closet door at all times. The plan will be to secure all cleaning solutions from patient reach. The plan will be implemented during monthly in-services as a reminder to staff to keep door locked. Ongoing compliance will be monitored the Clinic Administrator randomly checking for the door to be locked, and to ensure staff is not keeping any cleaning solutions around patients. All staff is aware that they will be written up for leaving solutions out, and/or door unlocked.	02-01-18

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[redacted]				
A 355	TAC 139.56(a)(2)(A)(B) Emergency Services (a) A licensed abortion facility shall have a readily accessible written protocol for managing medical emergencies and the transfer of patients requiring further emergency care to a hospital. The facility shall ensure that the physicians who practice at the facility:	A 355		

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A 355	Continued From page 7 (2) provide the pregnant woman with: (A) a telephone number by which the pregnant woman may reach the physician, or other health care personnel employed by the physician or the facility at which the abortion was performed or induced with access to the woman's relevant medical records, 24 hours a day to request assistance for any complications that arise from the performance or induction of the abortion or ask health-related questions regarding the abortion; and (B) the name and telephone number of the nearest hospital to the home of the pregnant woman at which an emergency arising from the abortion would be treated. This Requirement is not met as evidenced by: Based on a review of documentation and interview, the facility failed to ensure that the physicians who practice at the facility provide the pregnant woman with a telephone number by which the pregnant woman may reach the physician, or other health care personnel employed by the physician or the facility at which the abortion was performed or induced with access to the woman's relevant medical records, 24 hours a day to request assistance for any complications that arise from the performance or induction of the abortion or ask health-related questions regarding the abortion. Findings included: Review of the medical records revealed that 29 of 29 patients did not receive a telephone number by which the pregnant woman may reach the physician, or other health care personnel employed by the physician or the facility at which	A 355		

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A 356	Continued From page 8 the abortion was performed or induced with access to the woman's relevant medical records, 24 hours a day to request assistance for any complications that arise from the performance or induction of the abortion or ask health-related questions regarding the abortion. * All 29 patients had aftercare instructions that stated in part, "WARNING SIGNS CALL IMMEDIATELY: On call Nurse [staff member # 10] (phone number provided)". * Medical abortion paperwork included "Aftercare Instructions for Mifepristone Abortion" stated in part, "Managing the Possible side Effects of Misoprostol Drink plenty of fluids and eat lightly the day before on the day you take the Misoprostol pills. Misoprostol may cause nausea, vomiting and diarrhea, and fever, so you need fluids. Spicy or fried foods worsen the distress, if the vomiting and diarrhea are severe, call On call Nurse [staff member # 10] (phone number provided)". * In an interview on 01/30/18, staff member #5 confirmed that staff member #10 does not work at the facility and lives in Houston, therefore this staff member does not have access to the woman's relevant medical records, 24 hours a day. * 19 of 19 abortion patients (#1-11) did not receive an appropriate telephone number. * 11 of 11 medical abortion patients (#1-11) did not receive an appropriate telephone number. In an interview on 01/30/18 staff member #5 confirmed the above findings.	A 355	TAC 139.56(a)(2)(A)(B) Emergency Services The Medical Director has concluded that [redacted] remain as On Call Nurse for patients at North Park Medical Group. [redacted] has been employed by Dr. [redacted] for 16+ years, she has also worked with every physician at North Park Medical Group. [redacted] has direct numbers for the physicians and [redacted] has access to [redacted] the Clinic Administrator, who does have 24 access to patients records in the event of a complication that might arise. Records can be faxed to [redacted] 24/7. The Medical Director will be responsible for ensuring emergency services available for patients who have had a service provided at the facility. The plan will be Nurse [redacted] will still be On Call for any and all emergency services. The plan will be implemented by the Medical Director. Ongoing compliance will be monitored by Medical Director.	02-01-18
A 356	TAC 139.56(b)(c) Emergency Services (b) The facility shall have the necessary	A 356		

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A 356	Continued From page 9 equipment and personnel for cardiopulmonary resuscitation as described in §139.59 of this title (relating to Anesthesia Services). (c) Personnel providing direct patient care shall be currently certified in basic life support by the American Heart Association, the American Red Cross, or the American Safety and Health Institute, or in accordance with their individual professional licensure requirements, and if required in their job description or job responsibilities. This Requirement is not met as evidenced by: Based on a review of documentation and interview, the facility failed to ensure personnel providing direct patient care shall be currently certified in basic life support by the American Heart Association, the American Red Cross, or the American Safety and Health Institute, or in accordance with their individual professional licensure requirements, and if required in their job description or job responsibilities. *Findings Included:* The facility failed to ensure that all direct are staff were competent in cardio-pulmonary resuscitation (CPR) as there was no documented evidence of hands-on skills practice and in-person assessment and demonstration of CPR skills. This presents a risk that staff may not be competent to respond in a medical emergency. Review of the Health & Safety Institute and the National Safety Council website found at http://news.hsi.com/onlineonlycpr reveals that, "No major nationally recognized training program in the United States endorses certification without practice and evaluation of hands-on skills.	A 356		

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A 356	Continued From page 10 According to the Occupational Safety and Health Administration (OSHA) online training alone does not meet OSHA first aid and CPR training requirements." Further guidance can be found at https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=INTERPRETATIONS&p_id=2854 Review of personnel records revealed 1 of 5 direct care staff members (staff member #8) had CPR training through the National Health Care Provider Solutions. * According to the website for National Health Care Provider Solutions found at https://nhcps.com/faq/: "Does your program require a Clinical Skills Check? All of our exams are completely web-based. We do not require an onsite clinical skills check. We have recently added our new Clinical Skills Video Series that is accessible within your account. These Clinical Skills videos demonstrate in detail the correct procedures that would be covered at the onsite clinical skills check." * This training does not meet the National Safety Council recommended criteria of practice and evaluation of hands-on skills. The above findings were confirmed on 01/30/18 in an interview with staff member #5.	A 356	TAC 139.56(b)(c) Emergency Services The Clinic Administrator scheduled a CPR class for the entire staff to participate in to ensure all staff has current hands on skills practice and In-person assessment and demonstration of CPR skills. This was held on Thursday March 01, 2018. Unfortunately one employee was unable to attend due to family emergency. She has scheduled a CPR class to ensure hands on skill assessment and demonstration. The Clinic Administrator will ensure her CPR does meet the National Safety Council recommendation criteria. CPR will be renewed prior to expiration dates. The Clinic Administrator will be responsible for ensuring all staff has current CPR. The plan will be to schedule renewal prior to expiration of current CPR. The plan will be implemented by Clinic Administrator. Ongoing compliance will be monitored reviewing of employee files.	03-01-18
A 399	TAC 139.60(l) Other State and Federal Compliance Rqmts (l) A licensed abortion facility shall not use adulterated or misbranded drugs or devices in violation of the Health and Safety Code, §431.021. Adulterated drugs and devices are described in Health and Safety Code, §431.111.	A 399		

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A 399	Continued From page 11 Misbranded drugs or devices are described in Health and Safety Code, §431.112. This Requirement is not met as evidenced by: Based on a tour of the facility and an interview with staff, the facility used adulterated/misbranded drugs or devices in violation of the Health and Safety Code, §431.021. Adulterated drugs and devices are described in Health and Safety Code, §431.111. Health and Safety Code §431.111 states: SUBCHAPTER E. DRUGS AND DEVICES Sec. 431.111. ADULTERATED DRUG OR DEVICE. A drug or device shall be deemed to be adulterated: (a)(1) if it consists in whole or in part of any filthy, putrid, or decomposed substance; or (2)(A) if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or (B) if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess; or (3) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or (4) if it:	A 399		

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A 399	Continued From page 12 (A) bears or contains, for purposes of coloring only, a color additive that is unsafe under Section 431.161(a); or (B) is a color additive, the intended use of which in or on drugs or devices is for purposes of coloring only, and is unsafe under Section 431.161(a); or (5) if it is a new animal drug that is unsafe under Section 512 of the federal Act; (b) If it purports to be or is represented as a drug, the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standards set forth in such compendium. Such determination as to strength, quality or purity shall be made in accordance with the tests or methods of assay set forth in such compendium, or in the absence of or inadequacy of such tests or methods of assay, those prescribed under the authority of the federal Act. No drug defined in an official compendium shall be deemed to be adulterated under this subsection because it differs from the standards of strength, quality, or purity therefor set forth in such compendium, if its difference in strength, quality, or purity from such standards is plainly stated on its label. Whenever a drug is recognized in The United States Pharmacopeia and The National Formulary (USP-NF), it shall be subject to the requirements of the USP-NF; (c) If it is not subject to Subsection (b) and its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess; (d) If it is a drug and any substance has been: (1) mixed or packed therewith so as to reduce its quality or strength; or (2) substituted wholly or in part therefor; (e) If it is, or purports to be or is represented as, a device that is subject to a performance standard established under Section 514 of the	A 399		

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(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 399	Continued From page 13 federal Act, unless the device is in all respects in conformity with the standard; (f)(1) If it is a class III device: (A)(i) that is required by a regulation adopted under Section 515(b) of the federal Act to have an approval under that section of an application for premarket approval and that is not exempt from Section 515 as provided by Section 520(g) of the federal Act; and (ii)(I) for which an application for premarket approval or a notice of completion of a product development protocol was not filed with the United States Food and Drug Administration by the 90th day after the date of adoption of the regulation; or (II) for which that application was filed and approval was denied or withdrawn, for which that notice was filed and was declared incomplete, or for which approval of the device under the protocol was withdrawn; (B) that was classified under Section 513(f) of the federal Act into class III, which under Section 515(a) of the federal Act is required to have in effect an approved application for premarket approval, that is not exempt from Section 515 as provided by Section 520(g) of the federal Act, and that does not have the application in effect; or (C) that was classified under Section 520(l) of the federal Act into class III, which under that section is required to have in effect an approved application under Section 515 of the federal Act, and that does not have the application in effect, except that: (2)(A) In the case of a device classified under Section 513(f) of the federal Act into class III and intended solely for investigational use, Subdivision (1)(B) does not apply to the device during the period ending on the 90th day after the date of adoption of the regulations prescribing the procedures and conditions required by Section	A 399		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	140012	A. BUILDING: _____ B. WING _____	01/30/2018

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NORTH PARK MEDICAL GROUP	8363 MEADOW ROAD DALLAS, TX 75231

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A 399	Continued From page 14 520(g)(2) of the federal Act; and (B) In the case of a device subject to a regulation adopted under Section 515(b) of the federal Act, Subdivision (1) does not apply to the device during the period ending on whichever of the following dates occurs later: (i) the last day of the 30-day calendar month beginning after the month in which the classification of the device into class III became effective under Section 513 of the federal Act; or (ii) the 90th day after the date of adoption of the regulation; (g) If it is a banned device; (h) If it is a device and the methods used in, or the facilities or controls used for its manufacture, packing, storage, or installations are not in conformity with applicable requirements under Section 520(f)(1) of the federal Act or an applicable condition as prescribed by an order under Section 520(f)(2) of the federal Act; or (i) If it is a device for which an exemption has been granted under Section 520(g) of the federal Act for investigational use and the person who was granted the exemption or any investigator who uses the device under the exemption fails to comply with a requirement prescribed by or under that section. Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989. Amended by Acts 1993, 73rd Leg., ch. 440, Sec. 2, eff. Sept. 1, 1993. Amended by: Acts 2015, 84th Leg., R.S., Ch. 1 (S.B. 219), Sec. 3.0968, eff. April 2, 2015. Findings were: During a tour of procedure room #1 on 1-30-18, 2 bottles of Ativan were found in a locked medication closet. One of the bottles was	A 399		

Texas Department of State Health Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	140012	A. BUILDING: _____ B. WING _____	01/30/2018

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A 399	Continued From page 15 factory-labeled as 2 mg (milligram) tablets and the other bottle was factory-labeled as 1 mg tablets. When the contents were examined, the bottle marked as containing 2 mg tablets contained whole tablets. The bottle marked as containing 1 mg tablets contained irregular tablet fragments. In an interview with staff #5 on 1-30-18, staff #5 stated that the tablet fragments represented Ativan 2 mg tablets that had been split in half with a pill cutter to make a 1 mg dose for patient use. The tablet fragments were of irregular shape and size, did not represent uniform tablet halves and could not be guaranteed to each contain Ativan 1 mg. No narcotic count sheet for either bottle of Ativan could be located by staff #4 or staff #5. Ativan is classified as a Schedule IV controlled substance and its use and quantity should be closely monitored. The above was confirmed in an interview with staff #5 on the evening of 1-30-18.	A 399	TAC 139.60(i) Other State and Federal Compliance Report The Clinic Administrator ordered Ativan 1mg to dispense and will not split the Ativan 2mg. The altered Ativan was disposed of to avoid administering wrong dosage. The Clinic Administrator along with the physician on staff will ensure narcotic count sheet for Ativan 1mg and Ativan 2mg. All Ativan will be given under the direction of the physician on staff. The Clinic Administrator and Physician on staff will be responsible for narcotic count sheet and dispensing of medication to patients. The plan will be to ensure patients are receiving proper medication dosage. The plan will be implemented by Clinic Administrator and Physician on staff daily. Ongoing compliance will be monitored by Clinic Administrator and Physician on staff.	02-20-18