EXHIBIT A-B

EXHIBIT B

MO Bureau of Ambulatory Care —Ab Facility Plan of Correction (POC) Instructions

Facility Name	Reproductive Health Services of Planned Parenthood	Survey Exit Date	3/13/19
Facility Address/ City/Zip	4251 Forest Park Avenue, St. Louis, MO 63108	Statement of Deficiencies (SOD): L-tags	L069, L1069, L1076, L1103, L1116, L1131, L1146

- 1. **Include a <u>copy of the first page of the original Statement(s) of Deficiencies</u> for the State (L-tags) <u>signed & dated by administrator</u> or designee, along with associated completed POC forms. If you have any questions, contact BAC at <u>BAC@health.mo.gov</u> or call 573-751-1588.**
- 2. <u>Required elements of an acceptable Plan of Correction</u>. Each deficiency shall be addressed separately by completing the applicable information for all elements below for every citation.

A. (**TAG**):

Indicate the prefix or Tag number for each deficiency indicated on the form Statement of Deficiencies (L1128, L1136, etc.).

B. (CORRECTIVE ACTION):

Fully describe the plan for correcting the deficiency. Address the complete deficiency: several underlying problems may be cited under a single Tag number. Address any processes that lead to the deficiency, and what systemic changes will be made to ensure that the deficiency will not recur. The description must be specific, realistic, and complete. A general statement indicating that compliance will be achieved is not acceptable. The POC should be a **standalone document**, giving sufficient detail to show compliance. Do not attach policies, meeting minutes, or training documentation unless necessary and only include the pertinent sections to answer the deficiency. These documents must be available to the survey team at the revisit. However, it is acceptable to reference a policy as needed describing only what is pertinent to the POC. The POC may provide a brief description of training documentation or meeting minutes to demonstrate compliance.

C. (WHEN):

For each deficiency, indicate date correction will be made on all components for correction put in place. Correction CANNOT be prior to the Exit Date.

D. (WHO):

Refer to the one person responsible for implementing the plan of correction for each deficiency by **job title** only and not proper names.

E. (MONITORING AND/OR TRACKING PROCEDURES):

Describe the **monitoring and/or tracking procedure** that will ensure that the POC is effective and the issue remains in compliance. Include frequency and duration of monitoring, and mechanism of data collection. These monitoring/tracking activities should begin soon after exit and may continue for an extended period of time past the correction date to ensure ongoing compliance. If the person responsible for ongoing monitoring is different than the person named in "D," above then note it here. If you choose to use percentages to describe evidence of compliance, use only 100%. It is acceptable to state "until compliance is achieved" rather than percentages."

F. EVIDENCE/EXHIBIT ATTACHMENTS(s). If written evidence exists to document that corrections have been made, attach the numbered exhibit(s) to this POC and indicate the exhibit number(s) in this column. If documentation is not applicable, indicate "N/A"

MO Bureau of Ambulatory Care — Ab Facility Plan of Correction (POC) Form

A	В	С	D	E	F
(TAG)	(CORRECTIVE ACTION)	(WHEN)	(WHO)	(EVIDENCE OF COMPLIANCE)	
ID/tag	Plan of correction for deficiency noted and	Correction	Title of	Describe monitoring procedure to ensure	Evidence/
number	plan for addressing all related areas	Date	Person	continued compliance, to include:	Exhibit
(L1128)	affected by deficient practice.		Responsible	- Frequency/duration of monitoring	Attachment
			for	- Method of data collection	Numbers
			Correction.	- Who monitors, if different than " D "	or "N/A"
			No names		
L069	In accordance with 19 CSR 30-	4/30/19	Clinical	The facility fire drills shall continue to be an	N/A
	30.020(1)(A)(6) Reproductive Health		Quality	annual obligation of the Compliance Quality	
	Services shall hold an additional Fire Drill to		Improvement	and Risk Management system. RHS shall	
	be documented separately from the Central West End Health Center and Administrative		Manager &	have a separate fire drill and signature sheet	
	Offices to prevent future confusion		Compliance Administrator	from the Administrative Office to prevent misunderstanding of the number of	
	regarding the staff list on the drill and the		Aummstrator	participants. Staff participation shall be	
	separate sign in sheet with Reproductive			audited until compliance has been achieved to	
	Health Center Staff signatures.			satisfy the requirements of the State	
	Tientii Contoi Staii signatures.			Inspection. The audit shall be incorporated in	
	The fire drill evacuation continues to be an			the Quality Assessment and Performance	
	annual requirement.			Improvement (QAPI) program until	
	1			compliance is achieved.	
	Reproductive Health Services shall perform				
	an additional fire drill to ensure all staff has				
	an opportunity to participate and familiarize				
	themselves with their assigned emergency				
	duties. If any staff were not present on the				
	day of the fire drill then a separate fire drill				
	will be held to ensure that all staff have				
	participated.				
	The fire drill shall be newformed no leter				
	The fire drill shall be performed no later than April 30, 2019 to ensure staff who				
	missed the November fire drill have				
	participated. Patient Services Orientation				
	shall continue to include onboarding of the				

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	emergency procedure to familiarize staff with the fire drill policy and evacuation plan.				
L1069 (#1-2) L1103 (#1-7)	The facility has ensured that the written policy is updated to reflect current practices which comply with all regulatory requirements for obtaining a complete medical history and pelvic examination. The facilities' Medical Standards and Guidelines (MS&Gs), Abortion: Chapter 1, pages 10 and 29 includes specific language indicating that pelvic examinations are performed prior to all abortions, whether medication or surgical. Language stating that a comprehensive medical history must be completed prior to any medication or surgical abortion is included as well. Pregnancy shall be confirmed for any abortion patient by both ultrasound examination and urine hCG testing as required by Missouri regulations. Per the Missouri Department of Health and Senior Services, Statement of Deficiencies and Plan of Correction, Survey dated 03/07/2018, State Form, page 25 of 28, ID Prefix Tag L1163 which specifically states that an ultrasound is "a machine that utilizes high-frequency sound waves to produce images of structures within the body", thereby	Clinical Manager	04/30/2019	Affiliate Medical Standards and Guidelines shall be updated as described in the plan of correction action Column B. This information shall include all components as described; an attachment of the updated MS&Gs Abortion Chapter 1 pages 10 and 29 is included for review. The Clinical Manager shall ensure that the policies are updated and that documentation continues to occur as required by state regulations and the facilities' updated standards and guidelines. The Clinical Manager will review the updated policies in the Quality Assessment and Performance Improvement (QAPI) program.	MS&Gs Chapter 1, page 10 & 29

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	indicating that the utilization of an ultrasound for determination of pregnancy, which is performed on every abortion patient, has the capacity to specifically identify the structure of the uterus, which aids the providing physician the ability to determine the direction and shape of the uterus, and such information can be utilized, in conjunction with the complete medical history and other state-required labs, to decide upon and determine the best procedure, as well as preoperative and postoperative management for each individual patient. Therefore, information from the complete history, health assessment, and required ultrasound shall be utilized to appropriately determine gestation, identify preexisting medical or other complications, and detecting factors which could influence procedure type, anesthesia, or preoperative and postoperative management. Because the health assessment, including a pelvic examination, is completed prior to the procedure, findings from the assessment would influence the choice of the planned procedure and pre-operative management. All required exams and findings, including the pelvic examination, are documented in the patient's medical				

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	record. The documentation includes the date on which the examination is performed. Thus, contrary to Findings #3–5, Tag L1103, the date of the pelvic exam was documented in the medical records of patients #1, #2, #3, #4, #5, #6, #7, #8, #10. Missouri regulations provide that "[a] health assessment including a pelvic examination shall be performed." RHS complies with this requirement by performing a pelvic examination for every surgical and medication abortion patient prior to the procedure. Review of statements from the Missouri Department of Health and Senior Services, Statement of Deficiencies and Plan of Correction, Survey dated 03/07/2018, State Form, page 21 of 28, ID Prefix Tag L1163 specifically states the pelvic examination requirement shall be satisfied as follows: "Ensure a pelvic examination (visual and physical examination of a woman's reproductive organs [the vagina, cervix, fallopian tubes, vulva, ovaries, and uterus] for any abnormalities) was completed prior to the procedure". The statement also provided: "Ensure a physical examination was completed immediately prior to the procedure, in order to evaluate the procedural risks" of the procedure for the				

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	patient. The facility's policies are in accord with the regulation, as understood by the Missouri Department of Health and Senior Services. Furthermore, state inspectors observed our physician (Staff EE, MD) perform the pelvic exam prior to the start of a surgical abortion procedure, which is what the regulation requires. Pursuant to Missouri regulation 19 CSR 30-30.060(1)(A)(1), the current facilities' Medical Standards and Guidelines satisfy this regulation as they specifically and purposefully state, per regulations, that all components necessary to be completed are done so in accordance with the law.				
L1076 (#1-6)	The facility rigorously strives to abide by all applicable state and federal laws and regulations, including Chapter 188, RSMo. Under Chapter 188.027 RSMo., "[t]he physician who is to perform or induce the abortion shall, at least seventy-two hours prior to such procedure, inform the woman orally and in person of" the information required in the statute. The facility complies with this requirement in all cases, including in the case of patient #7 and #10. As the Missouri Department of Health and Senior	04/30/2019	Clinical Manager	Attending physician staff shall be educated on the importance of proper documentation and specifically the necessity of signing off as the supervisor for all medical charts. Furthermore, a representative sample of charts shall be audited to ensure adherence to this education until compliance is achieved. The audit shall be incorporated in the Quality Assessment and Performance Improvement (QAPI) program until compliance is achieved.	N/A

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	Services told the Circuit Court of Jackson County in its legal filings: "When there are two or more physicians who are substantially involved in performing or inducing the abortion, any one of those physicians may satisfy section 188.027.6 by providing informed consent." Defendants' Suggestions in Opposition to Plaintiffs' Motion for Temporary Restraining Order at 22, Circuit Court of Jackson County, Missouri, Case No. 1716-CV24109. In the case of medical record #10 the Missouri Department of Health and Senior Services deficiency states that mifepristone was given by a Fellow Physician who was practicing under the supervision of an Attending Physician, and not by the Attending Physician who provided the information required by 188.027.6 RSMo. seventy-two hours prior, which is not correct. The Attending Physician provided the medications to patient #10 and signed the Mifeprex agreement attesting to that fact. The Mifeprex agreement, which is in the patient medical record demonstrates this fact		TVO RUMES		

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	and states: "Mifepristone administered to patient in clinic at xx:xx PM [identifying time redacted] under observation by the Attending Physician, DO [name redacted]". In regards to the case of patient #7, the facility complied with Chapter 188.021.6 RSMo. because the Fellow Physician, who handed the medications to the patient, was practicing under the supervision of the Attending Physician and who was physically present and participated in and supervised the care of the patient. The original documentation from the day of the procedure supports that the Attending Physician was substantially involved in the patient's care. The Attending Physicians on that day physically signed the "Physicians Orders and Medication Administration Record" with the box for mifepristone selected, which was scanned into the medical record. Within the final Visit Summary for the day of the procedure resides proof that the medication was administered as documented under the "Medications Prescribed for this Visit" tab.		TVO HUMES		

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			for Correction. No names	 Method of data collection Who monitors, if different than "D" 	Numbers or "N/A"
	The list of medications prescribed include				
	"Mifeprex 200mg PO administered to pt in				
	clinic, 1 ordered, ordered by Attending				
	Physician, MD [name redacted], transaction				
	category: administered." In addition, Finding				
	#6 observes that the Attending Physician				
	"was in the room" during the procedure. The				
	Attending Physician made an error in				
	documentation by neglecting to sign off the				
	medical record as the supervising provider.				
	However, the Attending Physician did make				
	an addendum at a later date, which states, in				
	part, the following: "I supervised Fellow				
	Physician [name redacted], throughout this				
	clinical encounter, including with the				
	provision of mifepristone for medication				
	abortion as is reflected by my signature on				
	medication documentation from that				
	encounter." The facility will ensure that the				
	Attending Physician will complete a				
	supervisory note in all patient records for				
	whom the Fellow Physician hands the				
	patient the medications, including re-				
	educating the Attending Physician of this				
	requirement. Therefore, the facility is in				

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	compliance with current regulations, and the errors in documentation have been appropriately addressed including reeducation of the attending physicians signing off as the supervisor for all medical charts.				
L1116	Reproductive Health Services, in accordance with 19 CSR 30-30.060(2)(N) has emergency drugs, oxygen, and intravenous fluids in the procedure room to stabilize the patient's' condition when necessary. Additionally, manual breathing bag, suction machine and endotracheal equipment shall be located in the clinical area for immediate access by April 30, 2019. The portable suction machine noted in the Reviewers' Summary as located in the storage area will be moved to post procedure area, known as Recovery Room by April 30, 2019 The emergency equipment located in the post procedure area known as the recovery room. The following emergency equipment is kept in the recovery area: • Endotracheal equipment: laryngeal mask airway (LMA), & Ambu bag • Suction machine and necessary	4/30/19	Director of Surgical Services & Clinical Quality Improvement Manager	The updated Emergency Inventory checklists shall continue to be completed weekly. While there was reference to there are no references to AORN within the Missouri regulation 19 CSR 30.30.060 Ongoing Patient Services Staff Orientation to reiterate Patient Services Orientation Checklist under section Medical Emergencies #5 Location & Use of Emergencies Equipment/Supplies during orientation onboarding. Staff shall be retrained on location and operation of emergency equipment. Staff shall be provided an education & training on the emergency box with the emergency medication and supplies location and operations by end of April 2019. The training shall be reviewed in the Quality Assessment and Performance Improvement (QAPI)	Emergency Inventory checklists for procedure rooms and recovery room attached MS&G Chapter 1. Abortions 1.3 Management of Abortion Complications p. 38. Emergency Care Manual, Emergency Medications and Supplies

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	equipment to utilize the machine, including tubing and Yankauer suction tips. Edit the Emergency Inventory procedure rooms and recovery room checklists to include suction tubing and Yankauer. The Yankauer and suction tubing was ordered on 4/5/19. In accordance with 19 CSR 30-30.060(2)(N) Reproductive Health Services shall maintain endotracheal equipment in addition to our Ambu bag noted in the regulations as the manual breathing bag, and a suction machine in a readily available location in the clinical area. LMA equipment was ordered as part of our resuscitation and emergency medical supplies. The emergency medical equipment laryngoscope has been removed from the facility area, as it will not be used as resuscitative equipment at Reproductive Health Services. The Emergency Inventory checklists kept in each procedure room and the Recovery room currently contain the list of specific emergency medical supplies. The Emergency Inventory Log, Any overstock of			"Emergency Inventory Log" attached for authentication of weekly review of emergency and resuscitative equipment in procedure rooms. Recovery room emergency equipment checklist "Emergency Inventory Recovery Room" edited to include Yankauers, Suction Machine, LMA and suction tubes. Continued monthly documentation of QM Site System Review by Director of Surgical Services or designee. Edit Nurse Supervisor for Emergency Equipment to Designee. Edit Emergency Equipment to include resuscitation equipment, and Verify Emergency Inventory Checklist for each Procedure Room & Recovery completed. The Emergency Inventory Checklists include emergency equipment list.	p. 14 Emergency Medications & Supplies List attached

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	Yankauer or suction tubing to be kept in the supply room.				
	Finding #3 confuses the difference of an Emergency Transfer and an Emergency. Medical Standards & Guidelines 1.3 Management of Abortion Complications on page 38 states prior to policy 1.4.c Emergency Response Protocol and Procedure for Emergency Transfer of Patients in Life Threatening Situation, "Refer to ARMS Emergency Manual for management of acute emergencies." Reference to the Emergency Care Manual is currently in the Medical Standards and Guidelines related to emergencies in section 1.3 Management of Abortion Complications. The section referenced in L1116 is specific only to emergency transfers. The Emergency Care Manual contains the emergency equipment necessary to treat seizures, bleedings, anaphylactic shock, respiratory arrest, and cardiac arrest and other life threatening emergencies on the Emergency Medications and Supplies listed on page 14. Staff training will reiterate emergency equipment function and location of equipment.				

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	The Emergency Care Manual's Reproductive Health Services Emergency Medications and Supplies has been updated and included as proof of inclusive list of unit emergency supplies and equipment. Staff will be trained and educated on the emergency box with emergency medications and supplies. Emergency and resuscitative equipment checklist located on a weekly Review titled "Quality Management (QM) Site System Review" to more clearly show that the emergency equipment is listed on the Emergency Inventory Checklist. Laryngoscope has been removed from the facility of Reproductive Health Services area. Training of designated staff to reiterate initialing space provided for Emergency Equipment on the "Emergency Inventory forms" The portable suction machine shall be moved to the Recovery Room location, with				
	moved to the Recovery Room location, with the suction tubes, laryngeal mask airway,				

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	and the Yankauer. Each procedure room will be stocked with suction tubing, Yankauer suction tip. In addition, staff in-service training on the equipment location and operation to be completed in April 2019.				
L1131	Reproductive Health Services Infection Control standards, in accordance with 19 CSR 30-30.060(4)(A) shall maintain a controlled environment and follow all manufacturer's instructions and guidelines concerning High-Level Disinfection (HLD). HLD Log edited to include: - Date and time of HLD disinfection - HLD solution lot number - HLD solution shelf-life date - HLD solution activation date - HLD solution reuse-life date - Results of solution test strip testing - HLD solution temperature	4/30/2019	Director of Surgical Services	Staff shall be educated by April 30, 2019 on the edits to the High-Level Disinfection Log. The Director of Surgical Services shall audit for compliance to the updated standards by checking the logs weekly for adherence. Reproductive Health Services has updated the Quality Management Site System review to include the audit of wall hand sanitizer to ensure none are expired. Staff educated on marking the new canisters appropriately. Furthermore, wall hand sanitizers are included in the monthly log for review as items to be checked to ensure compliance with not being	N/A

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(TAG)	(CORRECTIVE ACTION)	(WHEN)	(WHO)	(EVIDENCE OF COMPLIANCE)	
ID/tag number (L1128)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice. - HLD solution exposure time	Correction Date	Title of Person Responsible for Correction. No names	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "D" expired.	Evidence/ Exhibit Attachment Numbers or "N/A"
	 Quantity and description of the device or item Identity of the person performing high-level disinfection. All Reproductive Health Services staff will be trained to document the required monitoring controls for HLD regarding the disinfection of instruments as directed in the manufacturer's instructions. Each log shall include each disinfection use including the item(s) sterilized and the quantity. Temperature of the HLD solution shall be verified with a thermometer calibrated within the applicable range according to the manufacturer's instructions. Labeling of sterile instruments and packages. Log edited to include: -The sterilizer identification number (machine 1 or machine 2) A detailed list of contents (i.e. 2 LAM Packs, 4 two pack dilators) The person who assembled the package The date of sterilization The cycle number All staff shall be trained to follow the acceptable sterilization standards and facility			Staff shall be trained to keep the proper window and doors closed in the decontamination area in order to prevent cross-contamination and to adhere to best practices. Director of Surgical Services shall review with the Quality Assessment and Performance Improvement (QAPI) program Infection Control standards in accordance with 19 CSR 30-30.060(4)(A) changes until compliance is achieved.	

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			for Correction. No names	 Method of data collection Who monitors, if different than "D" 	or "N/A"
	policy for labeling of sterile instruments and packages.				
	Expired wall hand sanitizers were removed and disposed of. New and non-expired hand sanitizers were placed in the wall holders, and the date of expiration was marked on the side of the canister in bold lettering.				
	Reproductive Health Services currently has a physical separation of decontamination area from areas where clean items are handled to minimize the risk of crosscontamination. A smaller autoclave has been ordered to reorganize the sterilization room to be able to close the door properly. The current pass-through window shall remain closed except when passing clean/disinfected equipment from the decontamination area to the sterilization room. Both doors to the decontamination room and the sterilization room shall remain closed at all times				
L1146	Reproductive Health Services shall follow all applicable laws pertaining to controlled substances pursuant to 19 CSR 30-1.048(1)(3). The controlled substance logs shall be updated to include the addresses of patients who received controlled substances.	4/30/19	Clinical Manager, Quality Manager	Regular audits shall be performed of the updated controlled substance logs in order to ensure compliance to best practice standards and documentation by adding it to the monthly QM System Site Review checklist. The audit shall be incorporated in the Quality	Attachment Controlled Substance Administration & Disposal Log

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number	plan for addressing all related areas	Date	Person	continued compliance, to include:	Exhibit
(L1128)	affected by deficient practice.		Responsible	- Frequency/duration of monitoring	Attachment
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			Correction.	- Who monitors, if different than " D "	or "N/A"
			No names		
	The controlled substance logs, in accordance			Assessment and Performance Improvement	
	with subsection list (1)(A)-(E), shall be			(QAPI) program until compliance is achieved.	
	recorded separately from patient medical				
	records.				
	Reproductive Health Services, has updated				
	the Missouri Department of Health & Senior				
	Services Bureau of Narcotics and Dangerous				
	Drugs Controlled Substance Dispensing or				
	Administration Log to be in compliance with				
	19 CSR 30-1.048 & 19 CSR 30-1.78(5)				
	including reason for wastage.				
	C4-C5-1-11 1-4-2-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-				
	Staff shall be trained on the updated log,				
	including documenting the reason for				
	wastage. Staff shall be trained in the practice				
	of including patient addresses on the edited Controlled Substance Administration and				
	Disposal Log				