

EXHIBIT A-H

EXHIBIT H

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	L-1076, L-1103, L-1131

1. **Include a copy of the first page of the original Statement(s) of Deficiencies** for the State (L-tags) **signed & dated by administrator** or designee, along with associated completed POC forms. If you have any questions, contact BAC at BAC@health.mo.gov or call 573-751-1588.
2. **Required elements of an acceptable Plan of Correction.** 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

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ID/tag number (L1128)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date	Title of Person Responsible for Correction. No names	Describe monitoring procedure to ensure continued compliance, to include: <ul style="list-style-type: none"> - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than “D” 	Evidence/ Exhibit Attachment Numbers or “N/A”
L-1076 & L-1103	<p>On May 20, 2019, RHS received a letter responding to the Plan of Correction it timely submitted on April 9, 2019, in response to the Statement of Deficiencies issued by the Department on March 25, 2019. The Department’s May 20 letter seeks additional clarification or information regarding RHS’s Plan of Correction of three cited deficiencies. RHS appreciates this opportunity to provide additional clarification and/or information on these three deficiencies, and understands its Plan of Correction of all other deficiencies identified in the Statement of Deficiency to be acceptable to the Department. As the Department is aware, our license is scheduled to expire on May 31, 2019, and RHS has been endeavoring in good faith to resolve the issues raised by the Department, including by making multiple physicians available for interviews, providing patient records, and otherwise complying with the Department’s investigation. RHS once again asks the Department to renew its license prior to the May 31 expiration date, and to respond to this amended Plan of Corrections by Friday, May 24.</p> <p>RHS takes our responsibility to provide the best possible care for our patients very seriously. We are committed to</p>			See column B (CORRECTIVE ACTION)	N/A

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	<p>the highest medical, legal, and ethical standards. The health and safety of our patients is our top priority. Ensuring the health and safety of our patients is central to our mission and fundamental to every person who works at RHS.</p> <p>RHS adheres to the highest standards, and we take swift action to correct any deficiency if we ever discover that these standards are not being met. As a high-quality health care provider, we constantly strive to improve, and we welcome all opportunities to do so. We always cooperate fully with all Department inspections and quickly address any issues that officials share with us. And we are committed to doing so in the future, because we are committed to our patients and providing them the best care.</p> <p>Under section 188.027.6 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. As RHS observed in the April Plan of Correction, with regard to the two patients identified (#7 and #10), the physician who consented the patient also provided the procedure to the patient. The Department’s May 20 letter appears to acknowledge that there is no deficiency with</p>				

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	<p>regard to these two patients.</p> <p>Nevertheless, the Department references unspecified “additional instances” in which the physician providing the state-mandated information “differed” from the physician who provided the abortion. But in the very next sentence, the letter states that the Department has “been unable to verify the fact or extent of your compliance.” Moreover, the Department expresses concern that a supervising physician who “is merely present in the building without taking any active role in perform or inducing the abortion” is not a physician who performs or induces an abortion within the meaning of section 188.027.6.</p> <p>As RHS noted in its Plan of Correction, the Department advised the Circuit Court of Jackson County in its legal filings that “[w]hen 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 (Oct. 16, 2017). Additionally, as the circuit court found, under the Department’s reading of the statute, “when multiple doctors are involved in the continuum of care before, during, and after a procedure that anyone of those physicians could provide the required information.” Order</p>				

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	<p>at 6, Circuit Court of Jackson County, Missouri, Case No. 1716-CV24109 (Oct. 23, 2017). We believe that attending physicians at RHS have been substantially involved in a patient’s care, including when a fellow or resident is being trained to provide abortions and throughout each patient’s care, and consistent with how physician supervision is understood to function in the context of residency and fellowship regardless of specialty or type of procedure, and therefore, RHS’s practices have been fully compliant with the statute, the Department’s direction and the Court’s order.</p> <p>RHS, however, desires to resolve this issue promptly. To that end, and to ensure Missourians can continue accessing abortion in their home state, RHS will revise its policies to require that when a fellow or resident is providing a procedure under supervision, the supervising physician will provide the state-mandated information required by section 188.027.6, RSMo., at least 72 hours prior and will be physically present in the procedure room during the abortion procedure.</p> <p>Your rejection letter states, inaccurately, that the regulation requires that “[a] pelvic examination must be completed prior to every abortion for the purpose of ‘<i>determining the duration of gestation, identifying</i></p>				

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	<p><i>preexisting medical or other complications, and detecting any factors which could influence the choice of the procedure, anesthesia, or preoperative and postoperative management.”</i> 19 CSR 30-30.060(2)(D) (emphasis supplied). In fact, that regulation provides in full:</p> <p>A written medical history shall be obtained for each patient. A health assessment including a pelvic examination shall be performed. Pregnancy shall be confirmed by clinical evidence and laboratory tests. This information shall be used in determining the duration of gestation, identifying preexisting medical or other complications, and detecting any factors which could influence the choice of the procedure, anesthesia, or preoperative and postoperative management. If the physician determines gestation is beyond the first trimester, an ultrasound examination shall be performed and results shall be recorded in the patient’s medical record. (Emphasis added.) The regulation does not specify the time when a pelvic exam must be performed, except that it must be performed before the abortion procedure.</p> <p>The letter states that “[i]nspectors found that pelvic examinations were performed immediately prior to the actual abortion procedure,” which the Department now believes is not compliant with the regulation.</p> <p>This change in position is surprising because it has long</p>				

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	<p>been RHS’s practice to perform a pelvic examination in the context of surgical abortion on the day of the procedure, which is when it is medically appropriate and clinically relevant. And although the Department has inspected RHS annually for many years, it has never suggested that the examination be performed at a different time.</p> <p>This change is especially surprising because just last year, RHS’s practices with respect to pelvic examinations were a focus of the Department’s inspection. Specifically, last year the Department cited RHS for failing to ensure a pelvic exam was completed prior to a medication abortion. See Statement of Deficiency (survey date March 7, 2018). This “deficiency” was already an alteration of the Department’s prior understanding of this regulation, because, as the Department is aware, prior to last year, the Department did not enforce the pelvic exam requirement for medication abortion because the requirement was written before approval of medication abortion in the United States, and it is medically unnecessary for that method of abortion. Because the Department changed its interpretation of this regulation last year and now requires a pelvic exam prior to medication abortion, and because RHS’s physicians are not willing to impose on patients an invasive exam that is not medically appropriate in the context of medication abortion, we currently are not providing medication abortion to patients in Missouri.</p>				

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	<p>Most relevantly here, however, in multiple exchanges with RHS over the supposed deficiency for not providing a pelvic exam prior to a medication abortion, the Department at no point indicated when this exam would have to be performed other than prior to the abortion procedure (in either the medication or surgical abortion context).</p> <p>In now taking the position that the pelvic exam cannot be performed on the day of the abortion, the Department has expressed the concern that this timing “does not “meet[] the purpose of the requirement, which ... includes ‘detecting factors which could influence the choice of the procedure.’” This concern is unwarranted. Putting aside that as a result of the medically unnecessary pelvic requirement medication abortion is not available in Missouri (and at any rate is not an option after 10 weeks in pregnancy), a patient and physician can change the abortion method at any time prior to the abortion, in the exceedingly unlikely scenario that a pelvic exam reveals a reason to do so.</p> <p>At any rate, the primary information needed in determining the options that may be available to the patient is gestational age, which in current practice is determined not by a pelvic exam but by an ultrasound examination and medical history. In addition to</p>				

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	<p>determining which procedures the patient qualifies, hemoglobin testing and information on patient preference is considered in determining the choice of procedure. Without significant findings in the above listed evaluations, a pelvic exam provides no additional information that would influence the choice of procedure. The function of a pelvic exam in the abortion context is not to aid in determining type of procedure, but rather to inform the procedural approach in those choosing aspiration abortion. In this context the pelvic exam is critical to determining uterine size and position. Because information obtained from a pelvic examination might change from one day to the next (e.g., the patient’s comfort level may change or her uterus may shift), physicians perform the pelvic exam immediately prior to the surgical procedure so that the information is relevant and not stale. Consequently, the information learned from a pelvic exam is most pertinent immediately prior to the abortion and not days before the procedure.</p> <p>The pelvic exam is also most appropriately done on the day of the abortion procedure in an effort to minimize the occurrences of invasive interventions. Pelvic exams, even in medically indicated situations, are not viewed as pleasant. Indeed, the American College of Obstetricians and Gynecologists has observed there is data to suggest that in asymptomatic patients, it is allowable and even preferable to defer pelvic exams during routine</p>				

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	<p>gynecologic visits. ACOG Committee Opin. No. 754 (Oct. 2018), https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Gynecologic-Practice/The-Utility-of-and-Indications-for-Routine-Pelvic-Examination. Minimizing the number of pelvic exams, specifically restricting them to instances in which there is clear medical benefit, is important for all patients but especially for those who find vaginal exams particularly distressing, including because they have experienced sexual or other trauma.</p> <p>Although RHS believes its existing practices are consistent with the regulation and with good patient care, RHS desires to resolve this issue promptly. To that end, and to ensure Missourians can continue accessing abortion in their home state, RHS will revise its policies to require that a pelvic exam must be performed on the same day the patient receives the state-mandated information, at least 72 hours before the abortion.</p> <p>RHS notes that forcing patients to receive a pelvic exam on the same day she receives the state-mandated information will result in the patient receiving two pelvic exams, because as discussed above, the pelvic exam is needed immediately prior to the abortion to ascertain factors that could influence how the procedure should be performed. RHS will advise all patients that the first exam is medically unnecessary but required by the State of</p>				

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	<p>Missouri.</p> <p>Finally, the rejection letter states that RHS’s policy with regard to the pelvic exam and medication abortion does not comply with the regulation, because the policy states that a pelvic exam would be performed before a medication abortion “when indicated (e.g., vaginal bleeding, or abdominal/pelvic pain, <i>or as required by Missouri regulation</i>).” (Emphasis added.) As the policy clearly states, and as RHS stated last year to the Department, a pelvic exam will be performed “as required by Missouri regulation.” The Department interprets this statement as “suggest[ing] that there may be times when a pelvic examination would not be required by Missouri regulations.” This is not the intent of the policy, and RHS will revise its policy to state: “As required by Missouri regulation, a pelvic exam must be completed before a medication abortion.”</p> <p>The Department’s letter states that it “cannot complete our investigation until it interviews the physicians involved in the care provided in the potential deficient practices ... at the facility,” and that the “investigation needs to be completed and any deficiencies resolved before the expiration of RHS’s license on May 31, 2019.”</p>				

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	<p>As the Department is aware, all care at RHS is supervised by an attending physician. The Department has asked to interview two of the RHS attending physicians: Dr. Eisenberg who is a co-medical director, and Dr. McNicholas. Although those physicians are not RHS employees, their counsel offered to make them available for interviews, but the Department rejected that offer. It is, therefore, not true that the Department is unable to interview the physicians involved in the care the Department is investigating.</p> <p>Rather, the Department has stated that it will not proceed with any further interviews unless they are in a specified order. This is contrary to the way the Department previously proceeded with this investigation, as on April 11, the Department asked to interview 8 individuals (7 physician and 1 registered nurse), and then proceeded to interview that nurse—the only person identified who is an RHS employee, and who RHS accordingly was able to produce promptly for an interview, despite that she was listed seventh on the Department’s list.</p> <p>It was only on May 15 that the Department said it would not interview the attending physicians because interviews needed to be conducted in a specific order. Those physicians remain willing to talk to the Department, and RHS urges the Department to interview them. Again, as supervising physicians, these physicians were responsible</p>				

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	<p>for the care provided at RHS, and it is unreasonable to refuse to proceed with the investigation by not speaking with them. This is especially true because, as the Department is well aware, the physicians whose counsel have declined for them to be interviewed are not RHS employees, and therefore, we are unable to compel them to sit for an interview—particularly a free-ranging interview and under circumstances in which the Department has indicated it could make criminal referrals or referrals to the board of registration for the healing art. And this demand is even more unreasonable as to the Barnes Jewish hospital residents, who have not provided care at RHS since September 2018, when their clinical rotation at RHS ended.</p> <p>Finally, we note that the letter states that the Department has identified potential deficiencies, and included among them are those issues discussed in the letter and addressed above. As RHS has previously offered, RHS is willing to answer any questions the Department may have, including addressing any potential deficient practice if the Department will identify those issues. This is what § 197.293, RSMo., contemplates: a back and forth in which the Department identifies any issues with compliance and Planned Parenthood then outlines what action it will take to bring its practices in line with the Department’s view—and this is precisely what we have done with the above issues and would do for any of the potential deficiencies.</p>				

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	For these reasons and because the Department’s refusal to proceed with its investigation in a reasonable manner threatens to close the sole remaining abortion provider in the state, thereby denying Missouri women their constitutional right to abortion, RHS respectfully requests the Department to reconsider its position—for the benefit of the Missourians it is supposed to serve.				
L-1131	Provide more specific information regarding the frequency and type of audits that will be completed to ensure compliance is maintained.			2019 Tag L1131 Audit to be completed weekly for 4 weeks, monthly for 5 months and once more after a year to report that tagged items remain compliant. The Infection Prevention Audit completed on a monthly basis includes as one of its checks: Check documentation for HDL Log completed prior per use.	L1131 Audit Infection Prevention Audit