

EXHIBIT E



Missouri Department of Health and Senior Services

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Randall W. Williams, MD, FACOG
Director



Michael L. Parson
Governor

June 13, 2019

Cathy Williams, Interim President & CEO
Reproductive Health Services of Planned Parenthood
4251 Forest Park Avenue
St. Louis, MO 63108

Re: Complaint Investigation Statement of Deficiencies

Dear Ms. Williams:

As you may be aware, the St. Louis City Circuit Court has issued an order directing the Department to make a decision with respect to RHS's license renewal application by June 21, 2019. The Department is requesting that the Court reconsider that order, but in the meantime, the Department will take steps in good faith to comply with the Order in a timely fashion. In the ordinary course, the Department would pursue the process of progressive discipline under § 197.293, RSMo, before completing a complaint investigation. Accordingly, we are initiating that process now, with the intention of completing it on an accelerated timeline to allow the Department to make a final decision on the renewal application on or before June 21, 2019.

The Department's investigation is reviewing incidents that apparently involved deviations from standard care, resulting in serious patient harm. As you are aware, five physicians who have performed and (in three cases) continue to perform abortions at RHS's facility have refused to cooperate in our investigation, and they have declined to participate in interviews with the Department. We have, therefore, been unable to procure the information needed to draw firm factual conclusions regarding certain deficiencies under investigation. Moreover, in litigation with the Department, RHS and its physicians have made two things abundantly clear: (1) there is no reasonable prospect that the five non-cooperating doctors will agree to participate in interviews in the foreseeable future; and (2) RHS has taken, and will take, *no* affirmative steps to request, encourage, induce, pressure, or otherwise procure the cooperation of the non-cooperating physicians. As RHS's counsel stated in open court, RHS has not taken any steps to ensure the cooperation of its own physicians, and it does not believe that it has an obligation to encourage those doctors to cooperate. RHS's non-cooperation on this point is unprecedented and untenable.

Due to this ongoing non-cooperation, in order to issue a Statement of Deficiencies based on the complaint investigation, we are forced to infer that each physician who declined to participate in an interview has no satisfactory explanation for the conduct under investigation, and we are forced to apply the same presumption to RHS. We are issuing you the attached Statement of Deficiencies in accordance with that inference—*i.e.*, that neither RHS nor its physicians can provide any satisfactory explanation for the deeply troubling instances of patient care that we have reviewed.

You will find enclosed a Statement of Deficiencies, which covers the findings (deficiencies) of the complaint investigation conducted from April 2, 2019, to May 28, 2019, in connection with the licensure

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requirements as they pertain to abortion facilities in Missouri. The enclosed Statement of Deficiencies identifies at least 30 deficient practices arising from our complaint investigation. In this letter, we highlight several of the most serious deficiencies as raising particular concerns, and we insist that any Plan of Correction must clearly and specifically address these deficiencies with a remedial plan that is feasible and readily implemented:

1. A pelvic exam was performed by a medical resident on “Patient 1” prior to a surgical abortion that failed to detect that the uterus was severely retroflexed, increasing the risk of the procedure, including the risk of failed abortion. A physician fellow then attempted a surgical abortion, which failed. RHS then attempted a medication abortion on the same patient, which also failed. A physician then performed a third attempted abortion—a second attempt at surgical abortion—which succeeded. The Department never received a timely complication report for either of the two failed abortions, though RHS claims it prepared one for the failed medication abortion, which the Department first received while onsite for the investigation at RHS on April 2 and 3, 2019. Two of the three physicians involved in this incident—including all those with direct knowledge of the initial failed procedure—have refused to be interviewed. This incident raises a series of grave concerns, including but not limited to:
 - a. It appears clear that the resident who performed the failed pelvic exam was inadequately supervised. If a pelvic exam had been completed by the physician who ultimately performed the successful surgical abortion after the two abortions that failed, the patient likely would not have undergone the two prior abortions. This is a reason why the Department enforces statutes and rules consistent with the standard care as practiced by other physicians to prevent harm to patients. The rule requires a pelvic exam before the procedure is scheduled to help determine what type of procedure to be done and the best way to perform that procedure based on these preoperative findings, including in this case a pelvic exam. This also guides the preoperative counseling provided to the patient regarding risks and benefits for her particular clinical situation.
 - b. Both the failed surgical abortion and the failed medication abortion plainly constituted complications requiring the submission of a complication report, yet the Department never received a complication report as required by law for either failed abortion.
 - c. The physician fellow who performed the failed surgical abortion had another failed surgical abortion within a close timeframe, yet no issue was raised with RHS’s quality assurance.
 - d. As discussed in our prior Statements of Deficiencies, RHS did not comply with the same-physician requirement as to this patient, as well as several other patients.

2. A surgical abortion was performed on “Patient 2” by a physician. The fetus was at 10 weeks’ development. The physician who performed the abortion noted in the medical records that he or she identified some fetal parts to confirm the success of the abortion. The pathology lab also confirmed the presence of fetal parts. Yet the surgical abortion had failed, resulting in a continuing pregnancy. The patient contacted RHS approximately three weeks later, reporting the continuing pregnancy. RHS did not schedule a second attempt at abortion for over two weeks, during which time the pregnancy progressed from first trimester to second trimester. RHS performed the second abortion attempt without providing any additional informed consent, even though the five weeks’ delay resulted in material changes, both in the degree of risk to the patient, and in fetal development. RHS’s quality assurance process reported that the first failed attempt was likely to the presence of a “twin,” even though no twin was detected in a pre-abortion ultrasound. In a peer-

reviewed study of 65,045 first-trimester surgical abortions, there were 46 failed abortions, a rare complication, reviewed, in which none were cited as twin pregnancies. There was no evidence of quality control to assess the multiple failed abortions at RHS, limiting the opportunity to prevent failed abortions from occurring in the future. Two days after the second abortion attempt, the patient was admitted to the hospital via the Emergency Department and became septic because of complications that arose subsequent to the second abortion after the previous failed abortion. The physician involved in this incident has refused to be interviewed. This incident raises a series of grave concerns, including but not limited to the following:

- a. The affirmative but incorrect report by the physician that fetal parts were identified raises grave concerns about the accuracy of reporting.
 - b. The same concern is raised by the pathology lab's affirmative but incorrect report.
 - c. There was no communication with the pathology lab whatsoever after the continuing pregnancy was identified.
 - d. Because this physician travels to St. Louis from out of town, the delay in scheduling the second attempt appears to have been driven by the physician's convenience, rather than the patient's best interest.
 - e. The failure to provide an updated informed consent before the second attempt at surgical abortion violates both Missouri law and basic medical standards.
 - f. The quality assurance review of this incident by RHS failed to provide a satisfactory explanation of the incident.
3. A similar series of events happened with respect to "Patient 3" after a failed surgical abortion. Both the physician who performed the failed abortion—who was the same fellow who performed the failed abortion on Patient 1—and the pathology lab incorrectly reported that the abortion had been successful after reviewing the products of conception. The patient returned to RHS with a continuing pregnancy about 5 weeks later. No updated informed consent process was provided to the patient prior to the second surgical abortion. No communication occurred with the pathology lab to seek an explanation for this second failure to detect a failed abortion. The physician fellow involved in this incident has refused to be interviewed. This incident raises several grave concerns similar to those discussed above with respect to "Patient 2." In addition, as discussed in our prior Statements of Deficiencies, RHS also violated the same-physician requirement in this incident.
 4. The treatment provided to "Patient 12" raises particularly grave concerns. Patient 12 was recommended to have a therapeutic abortion after 21 weeks' gestation. The patient was examined by an RHS physician at a hospital, who concluded that the patient had placenta previa—which in the majority of cases resolves as the uterus grows and the placenta moves up—and/or placenta accreta, along with a history of C-section. An ultrasound was performed which did not have findings to completely exclude or confirm placenta accreta. If a surgical abortion is to be performed, given the high risks of such a procedure, an ACOG Committee Opinion states that a second-trimester abortion on such a patient should be performed at a facility with blood products and the capacity for interventional radiology and/or hysterectomy; RHS lacks all three. For unexplained reasons, the physician nevertheless referred the patient to RHS's facility for the second-trimester abortion, where that physician attempted the abortion at a gestational age of 21 weeks and five days. The abortion attempt failed, and it resulted in massive uncontrolled bleeding and an emergency transfer of the patient to the hospital. The patient lost over two liters of blood, underwent a uterine artery embolization, and was described in hospital records as "critically ill."

This complication was both life-threatening and potentially preventable, and the physician's conduct appears to have potentially deviated from standard care in a manner that inflicted serious patient harm. The physician involved in this incident has refused to be interviewed, and no other physician has first-hand knowledge of the treatment.

In addition to these deficiencies in patient care, it is *imperative* that your Plan of Correction must address the failure of RHS and its physicians to cooperate in this investigation, which is unprecedented and unacceptable. Refusal of health care providers to cooperate in the Department's investigations thwarts the Department's ability to conduct meaningful review of troubling instances of patient care, and obstructs the Department's ability to ensure that problems will not be repeated.

We expect that your Plan of Correction will provide specific, detailed, and feasible remedial measures to address each of these grave concerns, as well as all other deficiencies identified in the Statement of Deficiencies. I have included detailed instructions for the Plan of Correction for your review. Because of the accelerated timeline imposed by the Court's order, we request that you provide a complete Plan of Correction no later than close of business on Tuesday, June 18, 2019.

Sincerely,



William Koebel, Administrator
Section for Health Standards and Licensure
Missouri Department of Health and Senior Services