Missouri Department of Health and Senior Services
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RELAY MISSOURI for Hearing and Speech Impaired and Voice dial: 711

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

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

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	MOA-0014	A. BUILDING: _____ B. WING _____	C 05/28/2019

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
REPRODUCTIVE HEALTH SERVICES / PLANNI	4251 FOREST PARK AVENUE SAINT LOUIS, MO 63108

(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
L 000	Initial Comments An on-site, unannounced state complaint investigation (MO00154375) was conducted from April 2, 2019, to May 28, 2019, in order to determine compliance with applicable statutes and regulations governing abortion facilities, including 19 CSR 30-30.050, 060, and 061 and Chapter 188, RSMo (Regulation of Abortions). The complaint investigation was unable to be completed, due to RHS' refusal to fully cooperate with an ongoing investigation. To date, some physicians who provided the care documented within the medical records reviewed have refused to submit to interviews and requests for copies of patient medical records and relevant policies were initially refused. Requested records have been subsequently provided. Investigation findings include: RHS violated applicable regulation, 19 CSR 30-30.060(1)(A)(8) and state law evidenced by a failure to: -ensure the Department of Health and Senior Services was able to complete an investigation, as required by Chapter 197.230 RSMo, to include failing to induce, encourage, compel, or motivate the physicians who provide patient care at RHS to submit to interviews and failure to ensure the collection of relevant medical records; -ensure the physician performing the informed consent was the same physician performing the abortion, for 8 patients, as required by Chapter 188.027.6 RSMo; -ensure a complication report was completed and filed for a failed abortion for 1 patient, as required by Chapter 188.052.2 RSMo. RHS violated applicable regulation, 19 CSR	L 000		

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L 000	Continued From page 1 30-30.060(1)(A)(1) pertaining to providing care in a safe environment and following standards of care, evidenced by a failure to: -ensure the pelvic examination was completed at the time of the health assessment and in a manner to accurately document the size and orientation of 1 patient's uterus prior to a surgical abortion, which contributed to a failed abortion; -ensure the accuracy of a gross examination of fetal tissue to ensure a completed abortion for 2 patients; -ensure there was communication with the pathology lab after the discovery of failed abortions for 2 patients; -ensure prompt follow up with a patient complaining of continuing pregnancy symptoms for 1 patient; -ensure informed consent was provided to 2 patients prior to the performance of new surgical abortions following failed abortions; -ensure the informed consent process included the seventy-two (72) hour required waiting period for 2 patients; -ensure the appropriateness of nursing care for 1 patient who was instructed to perform a self-fundal massage for post-abortion care at 7 weeks and 1 day gestational age; -ensure an abortion was planned in a safe environment for 1 patient presenting for a therapeutic abortion at 21 weeks and 5 days with a previous history of a C-section and a diagnosis of placenta previa, resulting in an emergency transfer to a hospital, where the patient was described as critically ill and suffering from shock, on pressors (drug for treating hypotension) and suffering massive blood loss. The patient underwent emergency surgery (bilateral uterine artery embolization) to control life-threatening blood loss (2L);	L 000		

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L 000	Continued From page 2 -ensure the appropriate risks and benefits were conveyed to 1 patient of the likelihood of a diagnosis of placenta accreta (a serious pregnancy condition that occurs when the placenta grows too deeply into the uterine wall) at 21 weeks and at term with an ultrasound not showing evidence of an accreta. RHS violated applicable regulation, 19 CSR 30-30.060(3)(B), pertaining to the accuracy of patient medical records, evidenced by a failure to: -ensure medical records were maintained in a manner that accurately documents the time and date a record was created or amended and any specific amendments made to the record; -ensure the medical record accurately identified the identity of the physician inducing a medication abortion for 1 record; -ensure the medical record accurately documents a record of supervision for residents and fellows performing abortions at the facility for 2 records. RHS violated applicable regulation, 19 CSR 30-30.060(3)(H) pertaining to the submission of complication reports, evidenced by a failure to: -ensure a complication report for 1 failed medication abortion was submitted to the department, as required. RHS violated applicable regulation, 19 CSR 30-30.060(8)(C) pertaining to the lack of action taken regarding identified problems with care provided, evidenced by a failure to: - ensure the appropriateness of the care provided at the facility was reviewed regarding the occurrence of 3 failed abortions documented within the medical records from May 26, 2018	L 000		

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L 000	Continued From page 3 through September 5, 2018; -ensure that action was taken regarding problems identified in the medical care provided at the facility, regarding the failed abortions. (Note: The Statement of Deficiencies issued to RHS pursuant to the March 13, 2019 annual inspection showed violations of 19 CSR 30-30.060(D) (L1103) for failure to perform a pelvic examination during the 72-hour preoperative assessment and 19 CSR 30-30.060(1)(A)(8) (L1076) for failure of the facility to ensure the same physician performing the informed consent performs the abortion.)	L 000		
L1069	19 CSR 30-30.060(1)(A)(1) The governing body shall have full legal The governing body shall have full legal responsibility for determining, implementing, and monitoring policies governing a facility's total operation and for ensuring that the policies are administered in a manner to provide acceptable care in a safe environment and in accordance with all legal requirements and standards of care. This regulation is not met as evidenced by: Based on facility record review and review of the standards of medical care, the facility failed to ensure: -the pelvic examination was completed at the time of the health assessment and in a manner to accurately document the size and orientation of 1 patient's (Patient #1) uterus prior to a surgical abortion, which contributed to a failed abortion; -the accuracy of a gross examination of fetal tissue to ensure a completed abortion for 2	L1069		

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patients (Patient #2 and #3);
-there was communication with the pathology lab after the discovery of failed abortions for 2 patients (Patient #2 and #3);
-the prompt follow up with a patient complaining of continuing pregnancy symptoms for 1 patient (Patient #2);
-informed consent was provided to 2 patients (Patient #2 and #3) prior to the performance of new surgical abortions following failed abortions;
-the informed consent process included the seventy-two (72) hour required waiting period for 2 patients (Patient #2 and #3);
-the appropriateness of nursing care for 1 patient (Patient #4) who was instructed to perform a self-fundal massage for post-abortion care at 7 weeks and 1 day gestational age;
-an abortion was planned in a safe environment for 1 patient (Patient #12) presenting for a therapeutic abortion at 21 weeks and 5 days with a previous history of a C-section and a diagnosis of placenta previa, resulting in an emergency transfer to a hospital, where the patient was described as critically ill and suffering from shock, on pressors (drug for treating hypotension) and suffering massive blood loss. The patient underwent emergency surgery (bilateral uterine artery embolization) to control life-threatening blood loss (2L);
-the appropriate risks and benefits were conveyed to 1 patient (Patient #12) of the likelihood of a diagnosis of placenta accreta (a serious pregnancy condition that occurs when the placenta grows too deeply into the uterine wall) at 21 weeks and at term with an ultrasound not showing evidence of an accreta.

Findings included:

1. Review of the medical record for Patient #1

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showed she presented to RHS on August 29, 2018, to provide informed consent for a surgical abortion. The informed consent document is present in the file and is signed by the patient and Staff E. The document is dated August 29, 2018. A transabdominal ultrasound was performed on the patient and gestational age was determined to be 7 weeks and 4 days. The patient agreed to have a vacuum aspiration. The record notes the patient underwent a prior surgical abortion in 2016 and encountered "abnormal bleeding after abortion" as a result of that event.

Patient #1 presented to RHS for a surgical abortion on September 5, 2018. A physical and pelvic examination is documented in the record as conducted by physician resident, Staff F. Staff F documented the uterine orientation as "Ant" and the uterine size as "less than 6 weeks". The procedure was performed at 11:35 a.m. by physician fellow, Staff A. The abortion was not performed under ultrasound. The patient's cervix was dilated to 21 and a 7mm cannula was used for the aspiration. The physician notes that "procedure completed with difficulty MVA activated with no tissue returned." Additional visit comments, entered into the record and dated September 5, 2018, at 12:00 p.m., state, "Uterus anteverted but retroflexed. Dilated to 21Fr and 7mm cannula passed. MVA deployed with no tissue or blood returned. Ultrasound brought to room. Attempted again to pass dilator with visualization with both transvaginal and transabdominal ultrasound views utilized. Unsuccessful in attempt to visualize dilator on US so procedure abandoned. Will plan for medication abortion." A note in the record dated September 5, 2018 at 12:45 p.m., states, "Medication AB teaching completed and HCG drawn. Follow up apt scheduled." The recorded

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entry was made by Staff J, nurse. The record includes a "patient agreement" form for the administration of Mifeprex. The agreement is signed by the patient and Staff E and is dated September 5, 2018 at 12:00p.m. An additional note in the September 5, 2018 record states, "Pt had unsuccessful in clinic procedure. Medication AB initiated. HCG drawn. Pt scheduled for apt for 9-12-2018 for repeat HCG." The entry was made by Staff J, nurse.

An untitled document, referenced to patient #1, generated by Staff E, dated September 5, 2018, at 9:20 a.m., states in part, "Supervising provider review for encounter on 09/05/2018 9:20 AM I was present for the procedure and agree with the treatment and follow up plan(s)." Further, the document noted, "pt. with an very acutely retroflexed uterus and the pregnancy at the fundus. Although the canal and path was able to be appreciated with eth17F Pratt dilator, the angle and traction on the cervix was quite uncomfortable for the patient. The position of the uterus made TA u/S ineffective. TV U/S was able to confirm the path, but given the unique position of the uterus and pts discomfort, coupled with early gestational age, we opted to stop the Sab and proceed with MAB. Discussed and explained with patient. Questions answered."

The record indicates Patient #1 contacted RHS on September 7, 2018 at 12:05 p.m., and spoke to Staff J, nurse. The record documents the patient contact as follows, "Spoke with pt who reports only mild cramping and scant bleeding since taking misoprostol at 530pm last evening. Encouraged pt to wait thru tonight to give misoprostol the full 24 hrs to work and if she still thinks she has not passed the pregnancy tomorrow morning to return to clinic. Pt

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verbalized an understanding of plan and states she will comply. [Staff E] aware and agrees with plan."

Patient #1 presented to RHS on September 8, 2018, for post-abortion care. The record, dated September 8, 2018, documents an ultrasound conducted by physician, Staff M. The fetal gestational age was found to be 9 weeks and 0 days. Findings included are identified as, "yolk sac, cardiac motion, fetal pole, gestational sac with double ring sign, single". Staff E performed a physical examination on Patient #1 and determined the uterine orientation to be "post" and a uterine size of "9-10 weeks". (This finding is inconsistent with the findings of Staff F on September 5, 2018.) The visit comment in the record states, "Pt reutrned [sic] to clinic with continuing pregnancy confirmed on sono. Pt desires to have evacuation today if possible. Pt reports only spotting and mild cramping after taking misoprostol at home at 530pm on 9-6-2018 (more than 24 hrs ago). Discussed with [Staff E] who ordered pt receive misoprostol and IV sedation and will attempt in clinic procedure. Discussed with pt who is in agreement. The visit comment is recorded by Staff J, nurse at 11:00 a.m. on September 8, 2018. The procedure was performed at 12:56 p.m. by Staff E. The abortion was performed under ultrasound. The patient's cervix was dilated to 25 and a 9mm cannula was used for the aspiration. The physician notes that the procedure was completed without difficulty [sic]. An additional comment in the record, dated September 8, 2018, 1:05 p.m., from an unknown author, states, "S/p failed Sab 2/2 dicomfotr [sic]and uterune [sic] position. Attempted MAB without success. USe of IVS and U/S guidance was able to evacuate without diffciluty [sic]. Extremely RV and Retroflexed".

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L1069	Continued From page 8 On May 28, 2019, Staff E was interviewed. When asked if she was present during the pelvic examination conducted on Patient #1 by Staff F, Staff E stated, "I don't know." When asked about the difference between the results of the pelvic examination conducted on September 5, 2018, by Staff F, and the pelvic examination conducted by her on September 8, 2018, she stated, "Female anatomy can change from day to day. In addition, there were several weeks between, or there was some time between the first and the second, in which the pregnancy was continuing to grow. One of the biggest drivers of change in female anatomy is change in the size of uterus. So, as the pregnancy grows, the uterus changes size ....In addition, this patient did receive medication in between, which changes both the architecture and the size direction of the uterus". The Department finds this explanation is insufficient to satisfy compliance with this requirement. On May 28, 2019, Staff I, RHS Medical Director was interviewed. When asked if it was his expectation that the supervising physician follow up with a resident who was found to have conducted or documented a pelvic examination inaccurately, he stated, "The residents are not providing the care, because they are not providing the care without that physician present." He stated that the residents never document care that is provided. He further stated, "We are documenting because we are the ones responsible for providing that care." Review of RHS policy 1.1.14, entitled "Medical Screening and Evaluation", table 1.2c states that a "physical examination" must include, "Bimanual exam, including estimation of uterine size and	L1069		

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position and palpation of the adnexa."

Review of Outpatient Gynecologic Surgery (Copyright 1997), by A. Jefferson Penfield, MD, FACOG, Associate Professor of the Department of Obstetrics and Gynecology at the State University of New York showed, " There is no situation in gynecology more fraught with possible confusion and error than a pelvic examination before an intended operative termination of pregnancy. Even those patients who are relaxed and easy to examine, not obese, and with clearly identifiable pelvic structures may lull the gynecologist into a false sense of security. In dealing with abortion under local anesthesia in women who are no more than 10 weeks from conception, it is essential for the operator first to determine the position of the uterus and to outline its dimensions as exactly as possible. With the corpus in an anterior position, estimation of size is not difficult unless the patient is tense or obese. Tension may be relieved by counseling, premedication, and gentleness, but obesity may force the examiner to rely principally on vaginal findings."

Review of the Journal, Obstetrics and Gynecology, by Waldo Fielding, MD FACOG, Shiao-Yu Lee, MD FRCS(C), and Emanuel A. Friedman, MD, ScD, FACOG, from the chapter entitled, Continued Pregnancy After Failed First Trimester Abortion, shows, "Forty-six patients with unintentional continued pregnancy were detected among a series of 65,045 first trimester abortions. Patients at greatest risk are those with very early pregnancy and those with marked uterine anteversion or retroversion or with uterine anomaly...Thus, it appears that judgmental error inherent in the physician's estimation of gestational age constitutes a major component

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underlying continuing pregnancy. Among 30 cases in which reasons could be found (or inferred), physician misjudgment accounted for more than half (53.3%). Anatomic factors constituted the only other important and frequently encountered explanation for failure to abort. Physician culpability here is also acknowledged; for purposes of emphasis, these cases in which technical skills are critical have been separated from those in which judgmental considerations are primary. They accounted for nearly all the remaining reasons among for whom logical reasons could be found. Included among them were 8 patients with uterine malposition (1 markedly anteverted and 7 markedly retroverted), 2 with congenital uterine anomaly (both bicornuate), 2 with leimyomata uteri, and 1 with a tortuous cervical canal. The difficulties of properly evacuating the gravid uterus under these circumstances are well recognized."

To date, some physicians who provided the care documented within the medical records reviewed have refused to submit to interviews.

2. Review of the medical record for Patient #2 showed she presented to RHS on May 21, 2018, to provide informed consent for a surgical abortion. The informed consent document is present in the file and is signed by the patient and Staff B. The document is dated May 21, 2018. A transabdominal ultrasound was performed on the patient and gestational age was determined to be 9 weeks and 4 days. According to the record, Patient #2 demonstrated an understanding and "is prepared for the abortion".

Patient #2 presented to RHS for a surgical abortion on May 26, 2018. A physical examination is documented in the record as

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conducted by Staff B. Staff B documented the uterine orientation as "Mid" and the uterine size as "average". The procedure was performed at 11:00 a.m. by Staff B. The abortion was not performed under ultrasound. The patient's cervix was dilated to 27 and a 9mm cannula was used for the aspiration. The record notes that "procedure completed without difficulty" at the gestational age of "10 weeks and 2 days based on ultrasound". The document indicates that a gross examination of tissue was completed by the physician. "Some" fetal parts were seen by the physician and the report also indicates that the "tissue exam consistent with documented gestational age". Further, the document indicates the "procedure completed without complication".

The record includes a pathology requisition sent to Boyce and Bynum with the sample collected from Patient #2. The document identifies Staff B as the ordering physician and identifies the sample collection time and date as May 26, 2018 at 9:25 a.m. The requisition orders are for "induced gross/micro - dispose" and identifies the sample as "10 w 2 days".

The record includes a pathology report, dated May 31, 2018, read and electronically released by the pathology lab medical director. The gross examination of the sample, as noted on the report, states, "Immature chorionic villi confirming products of conception consistent with 10-11 weeks gestational age. No evidence of villitis, chorioamnionitis, or atypical trophoblastic proliferation. The specimen is received in formalin and consists of tan-pink soft tissue fragments measuring 8.0 x 8.0 x 2.0 cm in aggregate. Placenta and fetal parts are grossly identified. Representative sections are submitted in one block." An additional note, dated May 30,

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2018 indicates, "Additional sections are submitted in three blocks". The microscopic evaluation indicated, "The section demonstrates immature chorionic villi, placental membrane and decidua. 10 weeks 2 days".

The record indicates Patient #2 contacted RHS on June 14, 2018 at 1:05 p.m., and spoke to RHS staff. The record documents the patient contact as follows, "PT called stating "I don't believe the AB worked, my stomach is still getting bigger, I'm still throwing up! I just don't think he got it all." MSA confirmed callback number and gave her the number to the Medical Exchange."

Patient #2 presented to RHS on June 29, 2018, for post-abortion care. The record, dated June 29, 2018, documents an ultrasound conducted by Staff B, with fetal gestational age to be 15 weeks and 1 day. Findings included are identified as, "cardiac motion, fetal pole, fetal movement, gestational sac with double ring sign, single". The clinical impression was documented as, "Continuing pregnancy post-abortion". Examination of the record showed the only informed consent document on file for Patient #2 was dated May 21, 2018.

Patient #2 presented to RHS on June 30, 2018, for an abortion. The record, dated June 30, 2018, documents a physical examination of the patient conducted by Staff B. Staff B documented the uterine orientation as "Mid" and the uterine size as "average". The procedure was performed at 11:38 a.m. by Staff B. The abortion was performed under ultrasound. The patient's cervix was dilated to 39 and a 12mm cannula was used for the aspiration. The physician notes that "procedure completed without difficulty" and "15 weeks 2 days Re-aspiration following surgical

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abortion for on-going IUP". The document indicates that a gross examination of tissue was completed by the physician. "All" fetal parts were seen by the physician and the report also indicates that the "tissue exam consistent with documented gestational age". Further, the document indicates the "procedure completed without difficulty". The following additional visit comments were added to the record on June 30, 2018 at 1:00 p.m., by Staff J, "[Staff B] at bedside, pt c/o severe increase in pain and dizziness, and states when she went to the bathroom had a moderate amount of bleeding/clot. [Staff B] reviewed pts vitals since admitted to clinic. Methergine 0.2 mg given IM. Small amount of bleeding noted on pad since pt returned to bed. Will continue to assess." Another note, documented at 1:15 p.m. by Staff J documents, "Pt clarified that pain she reports is "my tailbone" not uterine cramping, states she has no cramping at present. Pt states dizziness resolved. No additional bleeding noted on pads since last check. [Staff B] at bedside and observed bleeding and spoke with pt. States pt is ok for discharge. He recommended pt RTC for check up in 1-2 weeks, appt scheduled."

Staff B completed a complication report, dated June 30, 2018, for the attempted surgical abortion on Patient #2 on May 26, 2018. The report indicates the reason for the complication was "Failed abortion/pregnancy undisturbed and Incomplete Abortion" The document is signed by Staff B.

The record includes another pathology requisition sent to Boyce and Bynum with the sample collected from Patient #2. The document identifies Staff B as the ordering physician and identifies the sample collection time and date as

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L1069	Continued From page 14 June 30, 2018 at 8:10 a.m. The requisition orders are for "G/M/D-REASP" and identifies the sample as "15 weks 2 days". The record includes a pathology report, dated July 6, 2018, read and electronically released by the pathology lab's assistant medical director. The gross examination of the sample, as noted on the report, states, "Immature chorionic villi confirming products of conception consistent with 15-16 weeks gestational age. No evidence of villitis, chorioamnionitis, or atypical trophoblastic proliferation. The specimen is received in formalin and consists of tan-pink soft tissue fragments measuring 8.0 x 8.0 x 5.0 cm in aggregate. Placenta and fetal parts are grossly identified. Representative sections are submitted in one block." The microscopic evaluation indicated, "The section demonstrates immature chorionic villi, placental membrane and decidua. 15 weeks 2 days - Re-Aspiration". A review of records submitted to the DHSS Bureau of Vital Records revealed that a post-abortion care complication report was completed and filed for Patient #2 on July 18, 2018, for post-abortion care she received at the hospital on July 2, 2018. According to the report, Patient #2 presented for the treatment of "endometritis" and was given "IV Antibiotics". The record indicates the post-abortion care was provided at the hospital by RHS Staff O. An amended post-abortion care complication report was submitted to DHSS regarding Patient #2 on July 27, 2018, for care provided to Patient #2 on July 2, 2018, by Staff O. According to the amended report, Patient #2 presented to the hospital for the treatment of "endometritis" and "Hematometra" and as a result was given "IV Antibiotics, D&C".	L1069		

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L1069	Continued From page 15 Review of the hospital medical record for Patient #2 revealed that she presented to the hospital Emergency Room on July 2, 2018. The patient had become septic and had a fever of 104.2 degrees and a pulse of 154. The record indicates, "HPI: 39 yrs G6P6016, POD#2 s/p D&E at 15 weeks at RHS presents with fever, fatigue, abdominal soreness, and a headache. Found to have T of 40 in ED, w/ WBC of 17000, and tachycardic. Procedure was two days ago and per patient report uncomplicated. Since then has been having a normal amount of bleeding (<menses), but has feeling progressively more and more fatigued as well as a progressive headache and lower abdominal pain. She presents now because she is worried about her fever. Of note, she reports that in this same pregnancy she had a termination procedure at 11 weeks and then again 4 weeks later, 6/30/18, at 15 weeks "because they didn't get everything out and the baby still had a heart beat." Both procedures were performed at RHS here in St. Louis by [Staff B]. She was discharged home on Saturday with routine precautions/follow-up." The record indicates that Patient #2 was given IV antibiotics and discharged from the hospital on July 7, 2018. In regard to RHS' failure to ensure prompt follow-up with Patient #2 after the patient called and complained of symptoms of a continuing pregnancy, Staff B declined an interview. On May 28, 2019, Staff I, RHS Medical Director was interviewed. When asked how soon the facility should respond to a patient who reports symptoms of a continuing pregnancy, he stated he would expect that the facility would accommodate the patient, "As soon as we can."	L1069		

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L1069	Continued From page 16 When asked if 15 days was too long a time period, he stated, "Patients have complicated lives ...I do not know why a patient would not come back for 15 days." In regard to the gross examination and identification of "some" fetal parts after the May 26, 2018, failed abortion, Staff B has declined an interview. Review of RHS' Clinical Quality Assurance Committee Meeting" minutes, dated December 19, 2018, revealed, "Reviewed #2 of 6/30 ReAsp visit followed by tx @ hospital D&C &IV Antibiotic, complication report completed at 6/30 visit. Cardiac Motion, 6/29, most likely a pregnancy missed of a twin; ..." The Department finds this explanation is insufficient to satisfy compliance with this requirement. Review of the Journal, Obstetrics and Gynecology, by Waldo Fielding, MD FACOG, Shiao-Yu Lee, MD FRCS(C), and Emanuel A. Friedman, MD, ScD, FACOG, from the chapter entitled, Continued Pregnancy After Failed First Trimester Abortion, shows, "Forty-six patients with unintentional continued pregnancy were detected among a series of 65,045 first trimester abortions. Patients at greatest risk are those with very early pregnancy and those with marked uterine anteversion or retroversion or with uterine anomaly..." Of the identified forty-six patients with unintentional continued pregnancy, none were determined to be twin pregnancies. In regard to Staff B's failure to conduct an informed consent with Patient #2 after she returned to the clinic on June 30, 2018, after a failed surgical abortion on May 26, 2018, Staff B has declined an interview.	L1069		

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L1069	Continued From page 17 On May 28, 2019, Staff I, RHS Medical Director was interviewed. When asked if it was his expectation that there be a new informed consent provided to a patient following a failed abortion and prior to a new surgical abortion procedure, he stated, "My understating is that the informed consent checklist is done once per pregnancy." He confirmed his understanding that if a second physician would treat a continuing pregnancy, they would have to perform a new informed consent checklist. He further confirmed that it was his expectation that a different procedural consent process be completed if the gestational age changes between the time of an initial failed abortion and the performance of a new abortion due to a continued pregnancy. He confirmed he expected the procedural consent to be present in the medical record. (Note: The change in the physiological and anatomical characteristics of the fetus as well as the change in the gestational age of the fetus would require the performance of a procedural consent, noting the changed risks and benefits to the procedure.) Review of RHS policy 1.1.21, entitled, "Early Complications and Problems", table 1.3.a, identifies the management of a "failed abortion" is to "Recounsel patient on pregnancy options". Review of the 2008 Reproductive Health Matters article, entitled, Complications after Second Trimester Surgical and Medication Abortion, by Daniel Grossman, Kelly Blanchard and Paul Blumenthal showed, "Second Trimester abortion is associated with higher rates of complications compared to first trimester terminations. Although the risk of complications is relatively	L1069		

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higher in the second trimester, the absolute risk is low when the termination is performed (in the case of surgical abortion) and managed (in the case of medical induction) by skilled practitioners."

Review of the 2002 book entitled, Women's Heath After Abortion: The Medical and Psychological Evidence, by Elizabeth Ring-Cassidy and Ian Gentles, shows, "The woman who seeks abortion is often promised a relatively painless and simple procedure to eliminate a pregnancy that she does not wish to carry to term. Failed abortion may involve her in a number of unanticipated outcomes. If she changes her mind about "medical" abortion and a child is born with anomalies, maternal grief and guilt may be anticipated and counseling may be necessary. If a second procedure is successful at a late stage of fetal development, where the woman knows that procedures are chosen to ensure that an anticipated live birth cannot occur, grief and guilt may likewise ensue."

Further review of the 2002 book entitled, Women's Heath After Abortion: The Medical and Psychological Evidence, by Elizabeth Ring-Cassidy and Ian Gentles, shows, "In the vast majority of cases of surgical abortion, a failed abortion - meaning that the fetus continues to survive or is not fully expelled - leads to a second surgery which itself raises the possibility of medical complications. Failed abortion is an extremely rare, but possible, result of induced surgical abortion. Nevertheless, in the United States alone, roughly 700 pregnancies a year continue following an initial abortion procedure, and that over the past 25 years about 17,500 women required either a second procedure, or a more serious surgery, or changed their mind and

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continued the pregnancy to term."

On April 3, 2019, Director of Surgical Services, Staff C was interviewed regarding communication with the contracted pathology lab. Staff C confirmed that none of the medical records contain a 24 hour notification from the pathologist of anything but completed abortions. She stated that all communication from the pathologist comes in the form of a pathology report. She stated that if something unusual were to be brought to her attention, she would contact the patient, if necessary. She denied that the pathologist had ever, to her knowledge, made contact with the facility due to a failed or incomplete abortion.

(Note: An interview with Staff E indicated that Staff E denied ever having spoken to a Pathologist at Boyce and Bynum regarding her work at RHS.)

The contract between RHS and Boyce and Bynum Pathology Laboratories was collected and reviewed on April 3, 2019. The contract, dated February 18, 2016, is signed by the former RHS CEO, with delivered services effective on February 5, 2016. In regard to the obligation of the pathologist referenced in Section 188.047.1 RSMo., the document notes, "Provider will comply with all state/federal laws and regulations governing the provision of pathology services and the disposition of fetal remains and tissue (subject to the will of the patient)". An addendum to the contract, dated October 20, 2017, and signed by the lab's Director of Compliance notes, "Boyce and Bynum Pathology Laboratories has reviewed Senate Bill 5, Truly Agreed and Finally Passed in the 99th General Assembly 2017 and will be implementing the necessary process

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changes in order to comply with the provisions identified in 188.047 below ...Effective Monday October 23, 2017 Boyce and Bynum will begin reporting a microscopic exam on all specimens received. The fee for this service will be $30 per specimen submitted."

[Note: On April 18, 2019, a referral was made to the Centers for Medicare and Medicaid Services (CMS) (MO0015502) in regard to CLIA #26D2160160, held by Boyce and Bynum in Columbia, MO. A survey of the facility was conducted on April 25, 2019.

On May 7, 2019, CMS notified Boyce and Bynum and the Medical Director of the following deficient practices at the Condition level: CFR 493.1250 Analytic Systems; CFR 493.1290 Postanalytic Systems; CFR 493.1441 Laboratory Director; and CFR 493.1487 Testing Personnel. A letter to the facility and statement of deficiencies was sent to the facility for response. Boyce and Bynum was notified that they "must take steps to bring any unmet Conditions into compliance immediately". On June 6, 2019, Boyce and Bynum was notified that their submitted plan of correction was deemed acceptable by CMS.]

Review of a "Committee Opinion" from The American College of Obstetricians and Gynecologists (ACOG), number 517, dated February 2012 and reaffirmed in 2016, shows, "Accurate communication of information about a patient from one member of the heath care team to another is a critical element of patient care and safety; it is also one of the least studied and taught elements of daily patient care. One of the leading causes of medical errors is a breakdown of communication. This breakdown may occur between clinicians at any level of the healthcare

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system. Communication failures also have been found to be a leading cause of preventable error in studies of closed malpractice claims. In the era of collaborative care, effective clinician-to-clinician communication is important to facilitate continuity of care, eliminate preventable errors, and provide a safe patient environment."

Review of RHS policy 1.1.17, entitled, "Post Procedure Management" I.A, states, "Tissue evaluation is considered to be complete if all of the following occur: 2. In pregnancies of 10 to 13 weeks gestation, fetal parts are positively identified. 3. In pregnancies greater than or equal to 13 weeks gestation, all fetal parts must be accounted for, i.e., calvarium, spine, and four extremities." I.D.3., states, "Pathology examinations that yield unexpected results will be reported to an abortion provider clinician by phone within 24 hours."

Review of RHS policy 1.1.17 entitled, "Post Procedure Management" I.E, states, "Confirming Complete Abortion in Special Circumstances - in cases of known multiple gestation or known uterine anomalies less than or equal to 10 weeks gestation, must confirm complete abortion by: 1. Identification of 2 or more separate embryos or fetal parts or 2. Use of intra or post-operative ultrasound or 3. Follow-up visit involving ultrasound or hCG to confirm complete abortion."

In regard to the failure of RHS to contact Boyce and Bynum upon discovery of a failed abortion on June 29, 2018, some physicians who provided the care documented within the medical records reviewed have refused to submit to interviews.

3. Review of the medical record for Patient #3

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showed she presented to RHS on July 19, 2018, to provide informed consent for a surgical abortion. The informed consent document is present in the file and is signed by the patient and Staff E. The document is dated July 19, 2018. A transabdominal ultrasound was performed on the patient and gestational age was determined to be 6 weeks and 0 days. According to the record, Patient #3 demonstrated an understanding and "is prepared for the abortion".

Patient #3 presented to RHS for a surgical abortion on July 25, 2018. A physical examination is documented in the record as conducted by physician fellow, Staff A. Staff A documented the uterine orientation as "Ant" and the uterine size as "6-8 weeks". The procedure was performed under moderate sedation at 2:48 p.m., by Staff A. The abortion was not performed under ultrasound. The patient's cervix was dilated to 19 and a 6mm cannula was used for the aspiration. The physician notes that "procedure completed without difficulty" and "without complication" at the gestational age of "7Weeks 0 days based on LMP". The document indicates that a gross examination of tissue was completed by the physician with visible villi and membrane/sac. The note indicates the tissue was sent to the pathology lab.

An untitled document, referenced to patient #3, generated by Staff E, dated July 25, 2018, at 8:40 a.m., states, "Supervising provider review for encounter on 07/25/2018 8:40 AM I was present for the procedure and agree with the treatment and follow up plan(s)."

The record includes a pathology requisition sent to Boyce and Bynum with the sample collected from Patient #3. The document identifies Staff E

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as the ordering physician and identifies the sample collection time and date as July 25, 2018 at 8:40 a.m. The requisition orders are for "induced gross/micro - dispose" and identifies the sample as "6 weeks 6 days".

The record includes a pathology report, dated July 27, 2018, read and electronically released by the Medical Director at Boyce and Bynum Pathology Laboratories. The gross examination of the sample, as noted on the report, states, "Immature chorionic villi confirming products of conception consistent with 6-7 weeks gestational age. No evidence of villitis, chorioamnionitis, or atypical trophoblastic proliferation. The specimen is received in formalin and consists of tan-pink soft tissue fragments measuring 5.0 x 5.0 x 0.5 cm in aggregate. Chorionic villi are identified; no embryonic tissue is recognizable. Representative sections are submitted in one block." The microscopic evaluation indicated, "The section demonstrates immature chorionic villi, placental membrane and decidua. 6 weeks 6 days".

The record indicates Patient #3 contacted RHS on August 24, 2018 at 1:35 p.m., and spoke to RHS staff. The record documents the patient contact as follows, "Received call from Call Center spoke w/pt who states she just left her Drs ofc & the Dr states she is 12 weeks pg. ReVac procedure scheduled for Tues 08/28/18. Pre op instructions reviewed w/ pt who voiced understanding."

Patient #3 presented to RHS on August 28, 2018, for an abortion. Staff E performed a physical examination on Patient #3 and determined the uterine orientation to be "Ant" and a uterine size of "12-13 weeks". The procedure was performed under moderate sedation at 10:42 a.m., by Staff

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L1069	Continued From page 24 E. The abortion was not performed under ultrasound. The patient's cervix was dilated to 31 and a 10mm cannula was used for the aspiration. The physician notes that "procedure completed without difficulty" and "without complication" at the gestational age of "11 Weeks 6 days based on LMP". The document indicates that a gross examination of tissue was completed by the physician with "all" fetal parts seen and "consistent with documented gestational age". The note indicates the tissue was sent to the pathology lab. Examination of the record showed the only informed consent document on file for Patient #3 was dated July 19, 2018. Staff E completed a complication report, dated August 28, 2018, for the surgical abortion attempted by physician fellow, Staff A on Patient #3 on July 25, 2018. The report indicates the reason for the complication was "Failed abortion/pregnancy undisturbed" The document is signed by Staff E. The record includes another pathology requisition sent to Boyce and Bynum with the sample collected from Patient#3. The document identifies Staff E as the ordering physician and identifies the sample collection time and date as August 28, 2018, at 8:35 a.m. The requisition orders are for "G/M/D-REASP" and identifies the sample as "gestational age 10 weeks". The record includes another pathology report, dated August 31, 2018, read and electronically released by the Medical Director at Boyce and Bynum Pathology Laboratories. The gross examination of the sample, as noted on the report, states, "Immature chorionic villi confirming products of conception consistent with 10 weeks gestational age. No evidence of villitis or atypical	L1069		

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trophoblastic proliferation. The specimen is received in formalin and consists of tan-pink soft tissue fragments measuring 8.0 x 8.0 x 4.0 cm in aggregate. Placenta and fetal parts are grossly identified. Representative sections are submitted in one block." The microscopic evaluation indicated, "The section demonstrates immature chorionic villi, decidualized endometrial mucosa, and trophoblastic proliferation consistent with implantation site. 10 weeks".

In regard to the gross examination and identification of "visible villi and membrane/sac" after the July 25, 2018, failed abortion, some physicians who provided the care documented within the medical records reviewed have refused to submit to interviews.

On May 28, 2019, Staff E was interviewed. When asked if she is present in the room when a resident that she supervises performs an examination of the products of conception, she stated, "Not always." When asked if she was in the room during the procedure performed on Patient #3, she stated, "I don't know." She further stated, "A patient can have a continuing pregnancy and it still be true that products of conception were identified." She stated that the situation of having an ongoing pregnancy after having an aspiration abortion is "incredibly rare ...Less than 1% of the time do people have an ongoing pregnancy after aspiration abortion."

On May 28, 2019, Staff I, RHS Medical Director was interviewed. When asked if it was his expectation that the supervising physician follow up with a resident who was found to have conducted or documented an examination of fetal tissue / products of conception inaccurately, he stated, "The residents are not providing the care,

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because they are not providing the care without that physician present." He stated that the residents never document care that is provided. He further stated, "We are documenting because we are the ones responsible for providing that care."

In regard to Staff E's failure to conduct an informed consent with Patient #3 after she returned to the clinic on August 28, 2018, after a failed surgical abortion on July 25, 2018, some physicians who provided the care documented within the medical records reviewed have refused to submit to interviews.

On May 28, 2019, Staff I, RHS Medical Director was interviewed. When asked if it was his expectation that there be a new informed consent provided to a patient following a failed abortion and prior to a new surgical abortion procedure, he stated, "My understating is that the informed consent checklist is done once per pregnancy." He confirmed his understanding that if a second physician would treat a continuing pregnancy, they would have to perform a new informed consent checklist. He further confirmed that it was his expectation that a different procedural consent process be completed if the gestational age changes between the time of an initial failed abortion and a re-aspiration due to a continued pregnancy. He confirmed he expected the procedural consent to be present in the medical record.

Review of RHS policy 1.1.21, entitled, "Early Complications and Problems", table 1.3.a, identifies the management of a "failed abortion" is to "Recounsel patient on pregnancy options".

Review of the 2002 book entitled, Women's

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L1069	Continued From page 27 Heath After Abortion: The Medical and Psychological Evidence, by Elizabeth Ring-Cassidy and Ian Gentles, shows, "The woman who seeks abortion is often promised a relatively painless and simple procedure to eliminate a pregnancy that she does not wish to carry to term. Failed abortion may involve her in a number of unanticipated outcomes. If she changes her mind about "medical" abortion and a child is born with anomalies, maternal grief and guilt may be anticipated and counseling may be necessary. If a second procedure is successful at a late stage of fetal development, where the woman knows that procedures are chosen to ensure that an anticipated live birth cannot occur, grief and guilt may likewise ensue." Further review of the 2002 book entitled, Women's Heath After Abortion: The Medical and Psychological Evidence, by Elizabeth Ring-Cassidy and Ian Gentles, shows, "In the vast majority of cases of surgical abortion, a failed abortion - meaning that the fetus continues to survive or is not fully expelled - leads to a second surgery which itself raises the possibility of medical complications. Failed abortion is an extremely rare, but possible, result of induced surgical abortion. Nevertheless, in the United States alone, roughly 700 pregnancies a year continue following an initial abortion procedure, and that over the past 25 years about 17,500 women required either a second procedure, or a more serious surgery, or changed their mind and continued the pregnancy to term." On April 3, 2019, Director of Surgical Services, Staff C was interviewed regarding communication with the contracted pathology lab. Staff C confirmed that none of the medical records contain a report of anything but a completed	L1069		

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abortion. She stated that all communication from the pathologist comes in the form of a pathology report. She stated that if something unusual were to be brought to her attention, she would contact the patient, if necessary. She denied that the pathologist had ever, to her knowledge, made contact with the facility due to a failed or incomplete abortion.

The contract between RHS and Boyce and Bynum Pathology Laboratories was collected and reviewed on April 3, 2019. The contract, dated February 18, 2016, is signed by the former RHS CEO, with delivered services effective on February 5, 2016. In regard to the obligation of the pathologist referenced in Section 188.047.1 RSMo., the document notes, "Provider will comply with all state/federal laws and regulations governing the provision of pathology services and the disposition of fetal remains and tissue (subject to the will of the patient)". An addendum to the contract, dated October 20, 2017, and signed by the lab's Director of Compliance notes, "Boyce and Bynum Pathology Laboratories has reviewed Senate Bill 5, Truly Agreed and Finally Passed in the 99th General Assembly 2017 and will be implementing the necessary process changes in order to comply with the provisions identified in 188.047 below ...Effective Monday October 23, 2017 Boyce and Bynum will begin reporting a microscopic exam on all specimens received. The fee for this service will be $30 per specimen submitted."

[Note: On April 18, 2019, a referral was made to the Centers for Medicare and Medicaid Services (CMS) (MO0015502) in regard to CLIA #26D2160160, held by Boyce and Bynum in Columbia, MO. A survey of the facility was conducted on April 25, 2019.

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L1069	Continued From page 29 On May 7, 2019, CMS notified Boyce and Bynum and the Medical Director of the following deficient practices at the Condition level: CFR 493.1250 Analytic Systems; CFR 493.1290 Postanalytic Systems; CFR 493.1441 Laboratory Director; and CFR 493.1487 Testing Personnel. A letter to the facility and statement of deficiencies was sent to the facility for response. Boyce and Bynum was notified that they "must take steps to bring any unmet Conditions into compliance immediately". On June 6, 2019, Boyce and Bynum was notified that their submitted plan of correction was deemed acceptable by CMS.] Review of a "Committee Opinion" from The American College of Obstetricians and Gynecologists (ACOG), number 517, dated February 2012 and reaffirmed in 2016, shows, "Accurate communication of information about a patient from one member of the heath care team to another is a critical element of patient care and safety; it is also one of the least studied and taught elements of daily patient care. One of the leading causes of medical errors is a breakdown of communication. This breakdown may occur between clinicians at any level of the healthcare system. Communication failures also have been found to be a leading cause of preventable error in studies of closed malpractice claims. In the era of collaborative care, effective clinician-to-clinician communication is important to facilitate continuity of care, eliminate preventable errors, and provide a safe patient environment." In regard to the failure of RHS to contact Boyce and Bynum upon discovery of a failed abortion on August 24, 2018, some physicians who provided the care documented within the medical records	L1069		

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L1069	Continued From page 30 reviewed have refused to submit to interviews. On May 28, 2019, Staff E was interviewed. When asked to describe her process for when a pathology report comes back suggesting that no products of conception were seen, she stated, "The patient would be called and asked to come for further evaluation." She further stated, My guess is the only communication with the pathologist is the requisition with the POCs that we send. We don't typically have any communication with the pathologist." She denied any communication with the pathologist in regard to Patient #3. She denied ever communicating with a pathologist about any abortion she performed. On May 28, 2019, Staff I, RHS Medical Director was interviewed. When asked if it was his expectation that there be communication with the pathology lab upon a physician's discovery of a failed abortion, he stated, "If I become aware of a patient who has had a continuing pregnancy, despite an induced abortion being performed at Planned Parenthood, at RHS, we do discuss with pathology and review the pathology that was obtained at the time of the initial index abortion." When asked about the frequency of the occurrence of speaking with the pathologist regarding a failed abortion, he stated, "I honestly don't know. It's a regular occurrence in the practice of medicine." 4. Review of the medical record for Patient #4 showed she presented to RHS on July 26, 2018, to provide informed consent for a surgical abortion. The record indicates the physician portion of the 72 hr. informed consent was completed by Staff H. A transabdominal	L1069		

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ultrasound was performed on the patient and gestational age was determined to be 6 weeks and 5 days. According to the record, Patient #4 demonstrated an understanding and "is prepared for the abortion".

Patient #4 presented to RHS for a surgical abortion on August 1, 2018. A physical examination is documented in the record as conducted by physician resident, Staff G. Staff G documented the uterine orientation as "Ant" and the uterine size as "6-8 weeks". The record indicates the surgical time-out, to confirm correct patient identity, site and procedure "prior to the surgical procedure" was conducted by physician fellow, Staff A. However, the record identifies that the procedure was performed at 9:47 a.m., by Staff G. The abortion was not performed under ultrasound. The patient's cervix did not require dilation. A 7mm cannula was used for the aspiration. The physician notes that "procedure completed without difficulty" and "without complication" at the gestational age of "7 Weeks 1 day based on LMP". The document indicates that a gross examination of tissue was completed by the physician with visible villi and membrane/sac. According to the record, the physician saw no fetal parts. However, the physician noted that "Tissue exam consistent with documented gestational age." The note indicates the tissue was sent to the pathology lab.

The record indicates Patient #4 contacted RHS on August 2, 2018 at 8:49 a.m., and spoke to RHS staff. The record documents the patient contact as follows, "Pt is concerned with some bloating in her stomach, MSA confirmed call back number." An additional note in the record, documented by Staff J, on August 2, 2018 at 11:55 a.m., states, "Returned pts call. Pt

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concerned bc earlier today her stomach felt "bloated" and she is worried that she will need a re-vac bc "I needed one last time." Pt reports bloating has resolved, states she is eating well, drinking plenty of fluids, passing gas. Pt reports very little bleeding and no pain. Advised to do frequent fundal massage and call for heavy bleeding, pain unrelieved by massage and OTC meds, or fever. Advised OTC remedies for gas/bloating. Comfort/ reassurance offered. Emergency precautions reviewed. Qestions answered."

On April 24, 2019, at approximately 10:55 a.m., an in-person interview was conducted with Staff J at the office of RHS' attorney in St. Louis, Missouri. Staff J confirmed that she was a Registered Nurse and had been employed by RHS for approximately 3 years and 8 months. She reports directly to a nurse supervisor for medical issues and Director of Surgical Services, Staff C for administrative issues at RHS. Her normal job duties include providing informed consent to patients on "informed consent days" and providing other medical care as assigned on "procedure days". Her assigned job duties also include making follow-up patient contact by telephone, should patients call in with medical concerns. She characterized her patient follow-up calls as: complaints of bleeding; pain; or anything the patient would consider a complication. During normal daytime operation of the facility, patient calls are received from the call center on the lower level of the facility and after hours, a third party call center transfers patient calls to her when she is "on call" and has the call phone. She stated she has access to the medical advice of a Nurse Practitioner or Physician when performing her duties related to patient follow-up calls. Staff J was provided the

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"Patient Communication" record, dated August 2, 2018, for Patient #4 for her review. Staff J confirmed she wrote the "Additional Visit Comments" dated August 2, 2018 at 11:55 a.m. When asked about her direction to the patient to perform "frequent fundal massage", she stated the following:

- Fundal massage is appropriate direction for a patient complaint of bleeding and cramping.
- She originally thought that the direction was appropriate for any gestational age but was recently informed by a physician (could not identify) that a fundal massage may not make a difference for a gestational age of 8 weeks or under.
- She demonstrated how she instructs patients to perform a fundal massage on themselves by placing her fist low on her abdomen and twisting her knuckles into her lower abdomen as if she was "kneading dough".
- She has observed other nurses performing a fundal massage on patients in the RHS recovery room. She described the procedure the same and stated that the advantage of having a nurse perform the massage on the patient is that the nurse can massage from different angles.
- She did not recall ever observing a physician performing a fundal massage.
- At no time has she observed a physician or nurse place their hand in a patient's vagina to perform a fundal massage.

5. Review of the medical record for Patient #12 showed she presented to RHS for an abortion on April 24, 2019. The medical record includes an informed consent, signed by the patient and Staff H on April 16, 2019. However, Staff H included a note within the medical record to indicate, "Patient had 72 hour consent signed with this

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writer at Washington University at 13:54 on 4/16/19". The record showed that Staff H conducted a transabdominal ultrasound, "at WashU". However, no ultrasound results are within the RHS record. The physician notes, "I intend to perform a procedure using aspiration and/or removal of the fetus in multiple parts with multiple passes." A time-out is documented in the record as, "Time-out confirming correct patient identity, correct site and procedure to be done was performed prior to the surgical procedure by Staff N. The record notes that Patient #12 had a prior C-Section on August 30, 2017 and "known placenta previa". A physician note within the record documents Patient 12's complication as follows: "37 G4P2, h/o prior c/s x1 with known placenta previa admitted earlier this week with vaginal bleeding who presents today for day 1 of 2 day AB procedure. Pt has formal U/S at WashU which did not show e/o morbidity adherent placenta, complete previa. On placement of cervical dilators, by 3rd dilapan started having bright red bleeding. Continued placement of dilators did tamponade bleeding. Total EBL 200cc. Vag pack placed. Plan to transfer to BJH by EMS for in-hospital D&E. Pre-op Hgb 10.2 EMS called."

Review of the hospital medical record for Patient #12, dated April 16, 2019, regarding the ultrasound conducted on the patient, the note indicates, "Anterior placenta previa - cannot exclude possible accreta on the basis of this scan, but there are no highly suspicious findings for such".

Further review of the hospital record for Patient #12 on April 16, 2019, showed Staff H conducted a transvaginal and transabdominal ultrasound and dated the gestational age at 20 weeks and 4

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days with a "Suspected uterine abnormality, Previous cesarean delivery". The record notes Patient #12 was diagnosed with, "Placenta accreta in second trimester".

The record contains an "Emergency Transfer Form" for Patient #12. Patient #12 was transferred from RHS at 3:10 p.m., on April 24, 2019 to Barnes Jewish Hospital. Staff H requested the transfer.

Review of the hospital medical record for Patient #12, under "Assessment and Plan", dated April 24, 2019, states, "Placenta previa in second trimester: she desires induced therapeutic abortion by standard D&E. She was counseled on pregnancy options and desires to proceed with termination of pregnancy. Consents were signed. I intend to perform a standard D&E."

Further review of the hospital medical record for Patient #12 revealed an informed consent was completed prior to the emergency surgery. The document states, in relevant part, "Options for the pregnancy were discussed with the patient, including continuation of pregnancy, medically induced abortion by labor induction, and surgically induced abortion by dilation and evacuation (D&E). Given the increased risk to maternal health or life endangerment from placenta previa, history of cesarean section, and possible placenta accreta, the patient desires not to continue the pregnancy. She is requesting an abortion by standard D&E."

Review of the medical record for Patient #12 revealed an Anesthesia note, prior to the emergency surgery on April 24, 2019, stated, "PPH Bleeding requiring Uterine artery embolization. Patient lost around 2 to 2.5 litre of

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blood in OB operating room during termination of 23 week pregnancy. Received 1 unit of blood and 4 litre of crystalloids. 2 units of cross matched blood is on its way. Patient is already intubated and under general anesthesia."

Review of the hospital record for Patient #12 on April 24, 2019, documented the ICU History and Physical as follows, "37 y.o. female presented to BJH today 4/24 from planned parenthood s/p laminaria placement with brisk vaginal bleeding (EBL 200ml) requiring vaginal packing (patient was 21 w 5d with pregnancy complicated by placenta previa. Due to this, she desired to have therapeutic termination of pregnancy). On arrival to BJH hemostasis had been achieved. She was taken to OR by Gynecology for a standard D&E. Her operative course was complicated by post-abortion hemorrhage with EBL of 1800ml. She was given 4L of crystalloid, 2 units of pRBCs, 1g TXA. Vaginal packing was inserted and a intrauterine foley balloon was placed. She was taken to IR for bilateral uterine artery embolization. The patient was sent to 7800 SICU for close monitoring and serial CBCs. The patient arrived hemodynamically stable and unsupported."

Review of the medical record for Patient #12, under "Description of Procedure", states, "The lower uterine segment was atonic and the area of her prior cesarean delivery on the anterior and posterior walls of the lower uterine segment was noted to be thin but intact. 0.2mg IM Methergine, 250mcg Hemabate, 800mcg Misoprostol, and 30U IV Pitocin were administered sequentially with minimal improvement in uterine tone. The suction curette was introduced again with further evacuation of clot. The endometrium was noted to have gritty texture in all 4 quadrants."

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L1069	Continued From page 37 The record notes that Patient #12 was discharged from the hospital on April 26, 2019. Review of RHS policy 1.1.12, entitled, "Contraindications and Special Conditions - Surgical Abortion", in the treatment table labeled 1.2b, the condition of "Insertion of osmotic dilators, if required" states, "Must evaluate and determine the appropriate management or referral." The same table lists the requirement for treating the uterus condition of "scarred" as, "All patients greater than or equal to 14 weeks gestation with scarred uterus and placenta previa and/or a placenta overlying the incision site must be evaluated for placenta accreta/increta/percreta. Studies sufficient for diagnosing an invasive placenta in a patient less than 14 weeks gestation can be performed at the affiliate with the appropriate equipment, training and skill to do so. Patients with a reassuring evaluation may have an outpatient D&E by surgeon experienced in these types of procedures. Experience is determined by the medical director or program director." Review of a Practice Bulletin from The American College of Obstetricians and Gynecologists (ACOG), entitled, Second-Trimester Abortion number 135, dated June 2013 and reaffirmed in 2015, shows, "Women with prior cesarean deliveries are at an increased risk of placenta accreta and warrant special attention, particularly if ultrasonography indicates a low-lying placenta or placenta previa. When there is a suspicion of abnormal placentation, D&E is the preferred abortion method, and preparations should be made for possible hemorrhage by ensuring the procedure is performed at an appropriate facility with accessibility to blood products, interventional	L1069		

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radiology, and the capability to perform a hysterectomy if necessary. Because the positive predictive value of ultrasonography to diagnose placenta accreta may be as low as 65%, preoperative uterine artery embolization is not generally recommended. Although the diagnostic accuracy of magnetic resonance imaging is similar to ultrasonography for placenta accreta, magnetic resonance imaging may be useful to confirm accreta and identify patients who should be referred to a tertiary care center that has interventional radiology and surgical services immediately available."

Review of an Article, dated August 7, 2018, in the Society for Maternal-Fetal Medicine (SMFM), entitled, Clinical Diagnosis of Placenta Accreta and Clinicopathological Outcomes, by: Rosenbloom; Hirshberg; Stout; Cahill; Macones and Tuuli, states, "There were 50 cesarean hysterectomies performed for suspected abnormal placentation from 2000 to 2016. Of these 34 (68%) had a diagnosis of accreta preoperatively and 16 (32%) were diagnosed intraoperatively at the time of cesarean delivery."

To date, some physicians who provided the care documented within the medical records reviewed have refused to submit to interviews.

On May 28, 2019, Staff I, RHS Medical Director was interviewed. He denied RHS has a blood bank. He denied that RHS has interventional radiology capabilities. He denied that RHS has the capability to perform a hysterectomy. When asked if RHS was an appropriate setting for a planned abortion for a patient at 21 weeks and 5 days gestational age with a previous history of a C-section and a diagnosis of placenta previa, he stated, "We have very careful evidenced based

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L1069	Continued From page 39 guidelines about how we practice medicine and it is without a doubt safe to do an abortion in the second trimester even with a patient who has had a previous C-Section when that patient has been properly assessed for the clinical appropriateness for the location of care." When asked if a proper assessment include an MRI for the described patient's medical condition, he stated, "It depends on the circumstances. Generally, no."	L1069		
L1076	19 CSR 30-30.060(1)(A)(8) The governing body, ensure abortion facility The governing body, through the administrator, shall ensure that the abortion facility abides by all applicable state and federal laws and regulations. This shall include, but not be limited to, compliance with Chapter 188, RSMo. This regulation is not met as evidenced by: Based on facility record review and state law, the facility failed to ensure: - the Department of Health and Senior Services was able to complete an investigation, as required by Chapter 197.230 RSMo to include failing to induce, encourage, compel, or motivate the physicians who provide patient care at RHS to submit to interviews and failing to ensure the collection of relevant medical records; - the physician performing the informed consent was the same physician performing the abortion, for 8 patients (Patients: #1 #3; #4; #6; #8: #9; #10; and #11), as required by Chapter 188.027.6 RSMo; - a complication report was completed and filed for a failed abortion for 1 patient (Patient #1), as required by Chapter 188.052.2 RSMo.	L1076		

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L1076	Continued From page 40 Findings included: 1. Chapter 197.230.1 RSMo. states, "The department of health and senior services shall make, or cause to be made, such inspections and investigations as it deems necessary. The department may delegate its powers and duties to investigate and inspect ambulatory surgical centers or abortion facilities to an official of a political subdivision having a population of at least four hundred fifty thousand if such political subdivision is deemed qualified by the department to inspect and investigate ambulatory surgical centers. The official so designated shall submit a written report of his or her findings to the department and the department may accept the recommendations of such official if it determines that the facility inspected meets minimum standards established pursuant to sections 197.200 to 197.240." DHSS inspectors conducted an unannounced, onsite complaint investigation at RHS on April 2 and April 3, 2019. At that time, a request was made to conduct an in-person interview with Staff A (Physician-fellow). RHS Director of Surgical Services, Staff C denied the request and told inspectors she would work to reschedule the interview for a more convenient time. A request was also made for telephonic contact information for Staff B (Out of state physician). Staff C also denied the request and stated that if telephonic contact was required, she would allow inspectors to be present when Staff B was contacted by the RHS Interim CEO, Staff D. On April 3, 2019, an attempt was made to conduct an in-person interview with Staff A at her alternate work location. Staff A was "in-clinic" and	L1076		

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unavailable for interview at that time. Contact information for the DHSS was left at Staff A's work place and telephonic contact was requested.

On April 3, 2019, at approximately 3:00 p.m., Staff C was interviewed via telephone and stated that all RHS physicians were unavailable for interview during the week of April 1, 2019, due to their primary work schedules at the hospital. She agreed to coordinate dates and times the physicians would be available during the week of April 8, 2019, and make contact regarding their availability for interview.

On April 11, 2019, an email was sent to the RHS Director of Surgical Services, Staff C and the RHS Interim CEO, Staff D, requesting they make the following practitioners available for interview: Staff A (Physician- fellow); Staff B (Physician-Out of State); Staff E (Physician); Staff F (Physician-resident); Staff G (Physician - resident); Staff H (Physician); Staff I (Physician- Medical Director); and Staff J (Nurse). They were asked to respond by the close of business on April 16, 2019.

On April 16, 2019, DHSS became aware through contact with RHS' attorney that each of the requested physicians were represented by outside counsel. Multiple documented unsuccessful attempts were made to arrange for in-person interviews with facility physicians. At the date of this writing, Staff A, Staff B, Staff F, Staff G and Staff H have declined an invitation to submit to interviews. These physicians provided the care documented within the medical records reviewed.

An excerpt from a letter received from RHS' attorney, dated May 3, 2019, showed, "Further,

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the Department cited no authority allowing its employees to "collect" protected patient records and remove them from RHS' facility (rather than just "inspecting" them onsite). As you are aware, patient medical records are of the upmost sensitivity and that is even more the case when we are talking about women who exercised their constitutional right to privacy. Therefore, we also request that prior to the Department removing any additional files from RHS, you provide your authority permitting Department employees to remove protected patient records from RHS' facility".

On May 8, 2019, an announced, onsite visit to RHS was conducted at approximately 10:00 a.m., in order to collect and review additional relevant facility records. A written request for copies of the following records was given to facility staff: the patient roster for September 5, 2018; medical record and informed consent document for each patient seen on September 5, 2018; the RHS policy and procedure manual; informed consent document for the procedure performed on patient #2 on June 30, 2018; and the informed consent document for the procedure performed on patient #3 on August 28, 2018. RHS Clinical Manager, Staff K and Clinical Quality Manager, Staff L refused to make copies of the requested records, citing patient privacy concerns and the advice of RHS' attorney. When asked about the privacy concerns regarding providing a copy of the policy and procedure manual, they again refused to provide a copy and referred the request to RHS' attorney. They agreed to allow a visual review of the electronic records requested.

On May 11, 2019, RHS provided electronic copies of the requested medical records and policy manual to the Department.

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L1076	Continued From page 43 Review of DHSS electronic records showed that between April 4, 2001 and May 29, 2018, there were 19 complaint investigations completed and 16 licensure / revisits completed at RHS. Interviews with facility staff, including physicians and the collection of facility medical records and policies are documented regularly and routinely throughout the inspection record. Inspectors have not previously been denied requested records or interviews with staff, as deemed necessary. On May 24, 2019, at 5:30 p.m., the attorney representing Staff E and Staff I agreed to permit their clients to submit to interviews on May 28, 2019. 2. Chapter 188.027.6 states, "The 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: (1) The immediate and long-term medical risks to the woman associated with the proposed abortion method including, but not limited to, infection, hemorrhage, cervical tear or uterine perforation, harm to subsequent pregnancies or the ability to carry a subsequent child to term, and possible adverse psychological effects associated with the abortion; and (2) The immediate and long-term medical risks to the woman, in light of the anesthesia and medication that is to be administered, the unborn child's gestational age, and the woman's medical history and medical conditions. Medical records were obtained and reviewed for the following patients: Patient #1 was previously cited on the SOD dated, March 13, 2019.	L1076		

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L1076	Continued From page 44 Patient #3 signed an informed consent on July 19, 2018. The physician who was to perform the abortion, Staff E, also signed the document. Patient # 3 initialed the document to confirm, "I have been provided the name of the physician who is to perform or induce the abortion and a contact number where the physician may later be reached if I have questions". Patient #3 further confirmed, "I have had the opportunity to ask any questions of the physician who is to perform or induce the abortion concerning the abortion." Additionally, Patient #3 confirmed, "I certify that the physician who is to perform or induce the abortion informed me orally and in person, at least 72 hours prior to the procedure, of ..." the requirements of Chapter 188.027.6. Patient # 3 presented to the facility for a surgical abortion on July 25, 2018. The procedure was performed by Staff A. The medical record for Patient #4 indicated the informed consent was completed on July 26, 2018. The informed consent document was not present in the medical record. However, the record documented the physician who was to perform the abortion, Staff H, provided the informed consent for Patient #4. Patient # 4 presented to the facility for a surgical abortion on August 1, 2018. The procedure was performed by a physician resident, Staff G. The following patient records were requested and initially refused. However, DHSS inspectors were able to view the records on-site and obtained the redacted records on May 11, 2019: Patient #6 signed an informed consent for an abortion with Staff E on August 23, 2018. Physician (resident), Staff F performed the	L1076		

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L1076	Continued From page 45 procedure on September 5, 2018. Patient #8 signed an informed consent for an abortion with Staff E on August 27, 2018. Physician (resident), Staff F performed the procedure on September 5, 2018. Patient #9 signed an informed consent for an abortion with Staff E on August 29, 2018. Physician (resident), Staff F performed the procedure on September 5, 2018. Patient #10 signed an informed consent for an abortion with Staff E on August 29, 2018. Physician (fellow), Staff A performed the procedure on September 5, 2018. Patient #11 signed an informed consent for an abortion with Staff E on August 30, 2018. Physician (fellow), Staff A performed the procedure on September 5, 2018. Review of RHS policy 1.2 , section II.C.5. shows, "The providing physician must inform the woman orally and in person: a. The immediate and long term medical risks to the woman associated with the proposed abortion method including, but not limited to, infection, hemorrhage, cervical tear or uterine perforation, harm to subsequent pregnancies or the ability to carry a subsequent child to term and possible adverse psychological effects. b. Immediate and long term risks of in light of anesthesia and medication that is to be administered, the gestational age and the woman's medical history and medical conditions." To date, some physicians who provided the care documented within the medical records reviewed have refused to submit to interviews.	L1076		

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L1076	Continued From page 46 On May 28, 2019, Staff E was interviewed. When asked when she conducts informed consent with a patient, if she has knowledge that she will not be performing the abortion, she stated, "I intend to perform every abortion for every consent that I sign ...I consider all the abortions performed when I am supervising them to be abortions that I performed." Staff E admitted that she was not always physically present in the procedure room during an abortion procedure, performed by a resident or fellow she supervises. When asked the meaning of "I was present for the procedure and agree with the plan", as noted in the medical records reviewed, she stated, "It means I was available in the surgical suite at the time the procedure was performed or may have been in the room ..." She further confirmed that she provided informed consent to multiple patients, knowing that she may not later perform the actual abortion. When asked if the physician who performed the abortion was present in the room for the informed consent, she stated, "No. I can't be sure, but no ... They are rarely, if ever in the room with us during consent". She further explained how providing informed consent to a patient, while knowing that she may not perform the abortion is consistent with the requirement, by stating, "As the Supervising Physician, I am ultimately responsible for the care of the patient and that can mean I have any varying degrees of hands-on experience in the actual room ...In general, given that I am the supervising and ultimately responsible attending physician, that is how I would say it's consistent." On May 28, 2019, Staff I, RHS Medical Director was interviewed. When asked if it was his expectation that the physician performing the informed consent would be the same physician who performs the abortion procedure, he stated,	L1076		

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"The physicians who perform the consent are responsible for the care that's provided on the procedure day and they are performing the procedures that are provided under their name and under their supervision." When asked if it was his expectation that the supervising physician be physically present in the room during an abortion procedure performed by a resident or fellow, he stated, "It depends on the circumstances. The attending physician is responsible for the care that is provided by the team of physicians that day. They are present in the building. They are present in the room at times. But there is a graduated level of responsibility and privileging for our fellows that allows them to provide some care without, um, present in the room is not always required."

Review of the medical record for Patient #12 revealed an institutional knowledge of the requirement. In relevant part, the informed consent portion of the record indicated, "She is aware that should she need to reschedule her abortion procedure to be provided by a different physician that she will need to meet with the physician performing the abortion in person at least 72 hours prior to the procedure ..."

(Please note: On May 28, 2019, at approximately 11:30 a.m., RHS submitted a Plan of Correction for this identified deficiency. After review, the submitted plan was found to be acceptable.)

3. Medical record review for Patient #1 showed she presented to RHS on August 29, 2018, to provide informed consent for a surgical abortion. The informed consent document is present in the file and is signed by the patient and Staff E. Patient #1 presented to RHS for a surgical abortion on September 5, 2018. Staff A

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performed the procedure at 11:35 a.m. The abortion was not performed under ultrasound. The patient's cervix was dilated to 21 and a 7mm cannula was used for the aspiration. The physician notes that "procedure completed with difficulty MVA activated with no tissue returned." Additional visit comments, entered into the record and dated September 5, 2018, at 12:00 p.m., state, "Uterus anteverted but retroflexed. Dilated to 21Fr and 7mm cannula passed. MVA deployed with no tissue or blood returned. Ultrasound brought to room. Attempted again to pass dilator with visualization with both transvaginal and transabdominal ultrasound views utilized. Unsuccessful in attempt to visualize dilator on US so procedure abandoned. Will plan for medication abortion." A note in the record dated September 5, 2018 at 12:45 p.m., states, "Medication AB teaching completed and HCG drawn. Follow up apt scheduled." The record includes a "patient agreement" form for the administration of Mifeprex. The agreement is signed by the patient and Staff E and is dated September 5, 2018 at 12:00p.m. No complication report for the failed surgical abortion is within the medical record.

On April 3, 2019, during an interview with RHS' Director of Surgical Services, Staff C, when asked about the existence of a complication report for the failed surgical abortion attempt on Patient #1, she stated that the procedure was not considered a complication.

On May 28, 2019, Staff E was interviewed. When asked if she considered the abandonment of a surgical abortion a complication, she stated, "I consider that we weren't able to complete the abortion at that time." When asked if she considered what happened to Patient #1 a failed

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abortion, she stated, "No, because then we had a plan for medication abortion. We still had a plan to complete the procedure for her." When asked if she knew if a complication report was filed regarding the surgical abortion, she stated, "I don't know, but I don't consider that to be a complication, so I wouldn't necessarily expect one to be". The Department finds this explanation is inconsistent with RHS' own policy manual and insufficient to satisfy compliance with this requirement.

On May 28, 2019, Staff I, RHS Medical Director was interviewed. When asked if it was his expectation that a complication report be completed for an abandoned surgical abortion, he clarified, "So the decision to change the route of the termination from surgical to medication abortion? No. My understanding of when a post abortion complication report is required is after the abortion is completed." He confirmed knowledge of the statutory requirement to complete and file an abortion complication report for every complication. He further stated, "We follow that requirement."

Review of RHS policy 1.1.21, entitled, "Early Complications and Problems", table 1.3.a, identifies "cervical stenosis / inability to dilate" and "false passage" as complications.

19 CSR 30-30.050(1)(D) defines a complication as including, "but is not limited to, incomplete abortion, hemorrhage, endometritis, parametritis, pyrexia, pelvic abscess, uterine perforation, failed abortion, cervical lacerations, retained products, or diagnosable psychiatric condition;"

To date, some physicians who provided the care documented within the medical records reviewed

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L1076	Continued From page 50 have refused to submit to interviews.	L1076		
L1119	19 CSR 30-30.060(3)(B) The facility shall maintain a medical record The facility shall maintain a medical record according to professional standards for each patient. This regulation is not met as evidenced by: Based on facility record review and interview, the facility failed to ensure: - the medical records were maintained in a manner that accurately documents the time and date a record was created or amended and any specific amendments made to the record; - the medical record accurately identified the identity of the physician inducing a medication abortion for 1 record; - the medical record accurately documents a record of supervision for residents and fellows performing abortions at the facility for 2 records. Findings included: 1. Medical records reviewed during the course of this investigation showed significant documented differences between the "Encounter date" and the "Current date". The following records were collected and reviewed: - Patient #1 presented to RHS for a surgical abortion on September 5, 2018. The medical record recording the visit notates an "encounter date" of September 5, 2018 and a "current date" of September 13, 2018. - Patient #1 presented to RHS on September 8, 2018, for post-abortion care. The medical record	L1119		

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recording the visit notates an "encounter date" of September 8, 2018 and a "current date" of September 12, 2018.
- A medical record, referenced to patient #3, generated by Staff E, dated July 25, 2018, at 8:40 a.m.(approximately 6 hours prior to the start of the procedure), states, "Supervising provider review for encounter on 07/25/2018 8:40 AM I was present for the procedure and agree with the treatment and follow up plan(s)."
- Patient #3 presented to RHS on August 28, 2018, for post-abortion care. The medical record recording the visit notates an "encounter date" of August 28, 2018 and a "current date" of September 6, 2018.
- Patient #4 presented to RHS for a surgical abortion on August 1, 2018. The medical record recording the visit notates an "encounter date" of August 1, 2018 and a "current date" of January 3, 2019.
- A medical record, referenced to patient #4, generated by Staff H, dated August 1, 2018, at 8:40 a.m.(approximately 1 hour prior to the start of the procedure), states, "Supervising provider review for encounter on 08/01/2018 8:40 AM I was present for the procedure and agree with the treatment and follow up plan(s)."

On April 3, 2019, Staff C stated that the "encounter date" represents the date the patient was seen. She explained that each time a patient "checks out" after their appointment, the electronic record is locked and no one can get into the medical record without unlocking the record. The "current date" represents when the record was last unlocked and relocked. She stated that the "current date" may be different due to a number of reasons: The front desk clerk failed to check a patient out from their original appointment or a correction was made to the visit

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summary (spelling, grammar), which would require "running" a new visit summary. She denied that a medical record can be amended without an addendum being added to the record and no physicians have access to unlock the records. She identified herself, two staff nurses and a front desk clerk who have access to "unlock" the records. She is able to determine who was in the record but not for what purpose.

In regard to the record for Patient #1 on September 5, 2018, she stated that the "system does not show me that anyone was in there. The front desk clerk must have just checked her out on September 13th".

In regard to the record for Patient #1 on September 8, 2018, she stated that the front desk clerk was in the record on September 12, 2018. She could not determine the clerk's purpose for being in the record.

In regard to the records for Patients #3 and Patient #4, she stated that the system shows that she was in the records and could not recall the purpose of unlocking the records.

On May 28, 2019, Staff E was interviewed. When asked to explain the difference between the "encounter date" and the "current date" within the medical record, she stated, "I have no idea. That's an informational technology thing. It's how documents are generated. I don't know the answer to that." Staff E denied changing the record. She denied that she had access to "unlock" a record to change the record.

For records scanned into the system and not created within the electronic medical record, such as complication reports and informed consent

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documentation, Staff C stated that there is no way to determine at what date and time the record was scanned into the medical record.

2. Review of the medical record for Patient #1 showed she presented to RHS for a surgical abortion on September 5, 2018. A physical and pelvic examination is documented in the record as conducted by physician resident, Staff F. Staff F documented the uterine orientation as "Ant" and the uterine size as "less than 6 weeks". The procedure was performed at 11:35 a.m. by physician fellow, Staff A. The abortion was not performed under ultrasound. The patient's cervix was dilated to 21 and a 7mm cannula was used for the aspiration. The physician notes that "procedure completed with difficulty MVA activated with no tissue returned." Additional visit comments, entered into the record and dated September 5, 2018, at 12:00 p.m., state, "Uterus anteverted but retroflexed. Dilated to 21Fr and 7mm cannula passed. MVA deployed with no tissue or blood returned. Ultrasound brought to room. Attempted again to pass dilator with visualization with both transvaginal and transabdominal ultrasound views utilized. Unsuccessful in attempt to visualize dilator on US so procedure abandoned. Will plan for medication abortion." A note in the record dated September 5, 2018 at 12:45 p.m., states, "Medication AB teaching completed and HCG drawn. Follow up apt scheduled." The recorded entry was made by Staff J. The record includes a "patient agreement" form for the administration of Mifeprex. The agreement is signed by the patient and Staff E and is dated September 5, 2018 at 12:00p.m. The section of the record entitled, "Medications Prescribed During this Visit" indicate that a 200 mg Mifeprex was "po administered to pt. in clinic" by [RHS Medical Director, Staff I].

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L1119	Continued From page 54 On May 28, 2019, Staff E was interviewed. When asked about the medication abortion of Patient #1, she stated, "I handed her the pill and watched her take it." When asked why the record reflects that Staff I administered the pill to induce the abortion, she stated, "So, [Staff I] as the Medical Director, often times the scheduling, it's a scheduling issue. Under which, it has nothing to do with him actually physically giving the medication ....As the Medical Director, he would be the one for whom the medication is ordered from for the clinic, so he would be the dispensing to me who was the person who administered the medication." On May 28, 2019, Staff I, RHS Medical Director was interviewed. When asked if it was his expectation that the medical record accurately reflect the role of each practitioner and are timed and dated accurately, he stated, "So the medical record should be accurate, period. It should be complete. It should reflect the medical care that is provided. There are elements of the medical record that require time stamps, based on clinical utility that should be included." 3. Review of the medical record for Patient #1 showed she presented to RHS for a surgical abortion on September 5, 2018. The abortion was performed at 11:35 a.m. by physician fellow, Staff A. A complication occurred during the performance of the surgical abortion and the procedure was abandoned. A medication abortion was initiated. An untitled document, referenced to patient #1, generated by Staff E, dated September 5, 2018, at 9:20 a.m., states in part, "Supervising provider review for encounter on 09/05/2018 9:20 AM I	L1119		

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was present for the procedure and agree with the treatment and follow up plan(s)." Further, the document noted, "pt. with an very acutely retroflexed uterus and the pregnancy at the fundus. Although the canal and path was able to be appreciated with eth17F Pratt dilator, the angle and traction on the cervix was quite uncomfortable for the patient. The position of the uterus made TA u/S ineffective. TV U/S was able to confirm the path, but given the unique position of the uterus and pts discomfort, coupled with early gestational age, we opted to stop the Sab and proceed with MAB. Discussed and explained with patient. Questions answered."

On September 8, 2018, Staff E performed a successful surgical abortion on Patient #1.

On May 8, 2019, medical records were reviewed for all procedures completed on September 5, 2018, at RHS. Staff K and Staff L initially refused to provide copies of the records. The requested records were provided on May 11, 2019. Review of the records showed:

- Patient #13 signed an informed consent for an abortion with Staff E on August 29, 2018. Staff E performed the procedure at 1:14 p.m., on September 5, 2018. The record does not denote a procedure end time.

- Patient #8 signed an informed consent for an abortion with Staff E on August 27, 2018. Physician resident, Staff F performed the procedure at 1:15 p.m., on September 5, 2018. The procedure ended at 1:19 p.m. The records contains a supervisory note. The note pertaining to the supervision of Patient#8's abortion is dated September 5, 2018, at 9:05 a.m. The note indicates Physician E was "present for the

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L1119	Continued From page 56 procedure and agree the treatment and follow up plan(s)." On May 28, 2019, Staff E was interviewed. When asked to explain why the supervisory record for Patient #1 was documented as completed over an hour prior to the procedure taking place, she stated, "The document is generated based on the patient's appointment time. So, if we looked, her appointment time would have been 9:20 a.m." On May 28, 2019, Staff I, RHS Medical Director was interviewed. When asked if it was his expectation that the medical record accurately reflect the time the supervising physician was present in the room during the abortion procedure, he stated, "I don't know that I have an expectation regarding the time." To date, some physicians who provided the care documented within the medical records reviewed have refused to submit to interviews.	L1119		
L1129	19 CSR 30-30.060(3)(H) The facility shall ensure, complication reprt The facility shall ensure that an individual complication report for any complication care provided via the facility is submitted to the department within forty-five (45) days of the care as required by section 188.052, RSMo, and 19 CSR 10-15.020. This regulation is not met as evidenced by: Based on Department and facility record review and interview, the facility failed to ensure: - a complication report for 1 failed medication abortion was submitted to the department, as	L1129		

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required.

Findings included:

1. Medical record review for Patient #1 showed she presented to RHS on August 29, 2018, to provide informed consent for a surgical abortion. The informed consent document is present in the file and is signed by the patient and Staff E. Patient #1 presented to RHS for a surgical abortion on September 5, 2018. Staff A performed the procedure at 11:35 a.m. The abortion was not performed under ultrasound. The patient's cervix was dilated to 21 and a 7mm cannula was used for the aspiration. The physician notes that "procedure completed with difficulty MVA activated with no tissue returned." Additional visit comments, entered into the record and dated September 5, 2018, at 12:00 p.m., state, "Uterus anteverted but retroflexed. Dilated to 21Fr and 7mm cannula passed. MVA deployed with no tissue or blood returned. Ultrasound brought to room. Attempted again to pass dilator with visualization with both transvaginal and transabdominal ultrasound views utilized. Unsuccessful in attempt to visualize dilator on US so procedure abandoned. Will plan for medication abortion." A note in the record dated September 5, 2018 at 12:45 p.m., states, "Medication AB teaching completed and HCG drawn. Follow up apt scheduled." The record includes a "patient agreement" form for the administration of Mifeprex. The agreement is signed by the patient and Staff E and is dated September 5, 2018 at 12:00p.m.

The record indicates Patient #1 contacted RHS on September 7, 2018 at 12:05 p.m., and spoke to a nurse, Staff J. The record documents the patient contact as follows, "Spoke with pt who

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reports only mild cramping and scant bleeding since taking misoprostol at 530pm last evening. Encouraged pt to wait thru tonight to give misoprostol the full 24 hrs to work and if she still thinks she has not passed the pregnancy tomorrow morning to return to clinic. Pt verbalized an understanding of plan and states she will comply. [Staff E] aware and agrees with plan."

Patient #1 presented to RHS on September 8, 2018, for post-abortion care. The record, dated September 8, 2018, documents an ultrasound was conducted. Findings included are identified as, "yolk sac, cardiac motion, fetal pole, gestational sac with double ring sign, single". The visit comment in the record states, "Pt returned to clinic with continuing pregnancy confirmed on sono. Pt desires to have evacuation today if possible. Pt reports only spotting and mild cramping after taking misoprostol at home at 530pm on 9-6-2018 (more than 24 hrs ago). Discussed with [Staff E] who ordered pt receive misoprostol and IV sedation and will attempt in clinic procedure. Discussed with pt who is in agreement. The visit comment is recorded by Staff J at 11:00 a.m. on September 8, 2018. The procedure was performed at 12:56 p.m. by Staff E. The abortion was performed under ultrasound. The patient's cervix was dilated to 25 and a 9mm cannula was used for the aspiration. The physician notes that the procedure was completed without difficulty. An additional comment in the record, dated September 8, 2018, 1:05 p.m., from an unknown author, states, "S/p failed Sab 2/2 dicomfotr and uterune position. Attempted MAB without success. USe of IVS and U/S guidance was able to evacuate without diffciluty. Extremely RV and Retroflexed".

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L1129	Continued From page 59 The record contains a completed complication report, dated September 8, 2018, for the MAB attempted on Patient #1 on September 5, 2018. The report indicates the reason for the complication was "Failed abortion/pregnancy undisturbed" The document is signed by Staff E. On April 3, 2019, a review of records received by the DHSS Bureau of Vital Records from RHS was conducted. Review of the records showed no complication report submitted for Patient #1. On April 3, 2019, at approximately 11:00 a.m., the Clinical Quality Manager, Staff L was interviewed regarding the process for submitting a complication report to the State of Missouri. Staff L stated that the process is manual, in that each form is paper and not electronic. She further noted that each complication report is bundled, by month and sent via certified mail to the BVR within the allowable timeframe. Staff L provided a copy of the bundled record that she provided to BVR representing complications that occurred in September 2018. Contained within the bundle is the complication report for Patient #1. Staff L signed the cover letter sent to the BVR and the letter is dated October 18, 2018. The certified mail receipt is stamped as received at BVR on October 25, 2018.	L1129		
L1169	19 CSR 30-30.060(8)(C) The QAPI program shall show evidence of actio The QAPI program shall show evidence of action the facility took regarding problems identified and shall identify opportunities for improvement. This regulation is not met as evidenced by:	L1169		

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L1169	Continued From page 60 Based on facility record review and review of the standards of medical care, the facility failed to ensure: - the appropriateness of the care provided at the facility was reviewed regarding the occurrence of 3 failed abortions documented within the medical records from May 26, 2018 through September 5, 2018; - that action was taken regarding problems identified in the medical care provided at the facility, regarding the failed abortions. Findings included: 1. See referenced evidence of facility deficient practices at: 19CSR30-30.060(1)(A)(1); 19CSR30-30.060(1)(A)(8); 19CSR30-30.060(3)(B); and 19CSR30-30.060(3)(H). To date, some physicians who provided the care documented within the medical records reviewed have refused to submit to interviews. Review of RHS' Clinical Quality Assurance Committee Meeting" minutes, dated December 19, 2018, revealed, "Reviewed #2 of 6/30 ReAsp visit followed by tx @ hospital D&C &IV Antibiotic, complication report completed at 6/30 visit. Cardiac Motion, 6/29, most likely a pregnancy missed of a twin; ..." The Department finds this explanation is insufficient to satisfy compliance with this requirement. Between July 25, 2018, and September 5, 2018, Staff A performed at least 2 failed abortions, as documented within the medical records reviewed. As of the date of this writing, Staff A has refused to submit to an interview with DHSS Inspectors. On May 28, 2019, Staff E was interviewed. When	L1169		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	MOA-0014	A. BUILDING: _____ B. WING _____	C 05/28/2019

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
REPRODUCTIVE HEALTH SERVICES / PLANNI	4251 FOREST PARK AVENUE SAINT LOUIS, MO 63108

(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
L1169	Continued From page 61 asked about the frequency of failed abortions, she stated, "A failed abortion is less than 1% of all the abortions that we take care of and I would say that's consistent with what I have seen." When asked about the frequency of complications at RHS, she stated, "You have to have a denominator. This is still incredibly rare and consistent with the expected amount of failed abortions, 1% or less."	L1169		