IN THE CIRCUIT COURT OF ST. LOUIS CITY, MISSOURI
DIVISION II

REPRODUCTIVE HEALTH SERVICES OF PLANNED PARENTHOOD OF THE ST. LOUIS REGION,	)	
Petitioner,	)	
v.	)	Case No. 1922-CC02395
MICHAEL L. PARSON, in his official capacity of Governor of Missouri, et al.,	)	
Respondents.	)	

AFFIDAVIT OF WILLIAM KOEBEL

1. My name is William Koebel. I am the Section Administrator for the Section for Health Standards and Licensure within the Division of Regulation and Licensure of the Missouri Department of Health and Senior Services (Department), which is responsible for inspecting and licensing abortion facilities in Missouri. In my role I, oversee the inspection and licensing of abortion facilities and assist in performing inspections.

2. A state licensure survey (i.e., inspection) was conducted at Reproductive Health Services of Planned Parenthood of the St. Louis Region (RHS) on March 11 to March 13, 2019.

3. Based on that survey, a Statement of Deficiencies was prepared setting forth areas where RHS was not meeting statutory and regulatory licensing requirements. Among other deficiencies, the Statement of Deficiencies identifies two (2) instances of abortions completed by physicians who did not perform the informed consent with

the patient, as required by Section 188.027.6 RSMo. The Statement of Deficiencies also noted, among other deficiencies, that pelvic exams were not being completed 72 hours before the abortion, at a time that could influence the choice of the procedure and when informed consent for the procedure chosen was required under Section 188.027 RSMo. Ex. A.

4. The Statement of Deficiencies was sent to RHS on March 27, 2019. As in other inspections and other facilities, RHS was required to respond to the Statement of Deficiencies with a Plan of Correction acceptable to the Department.

5. Regarding the medical records collected during the inspection, there were also additional concerns noted that were not cited in the Statement of Deficiencies but required additional investigation. As a result, the Department initiated an investigation of RHS in addition to its annual inspection of RHS.

6. A department-initiated investigation occurs regularly as part of the normal practice of the Department when the Department discovers a potential deficiency on its own, rather than through another means such as a complaint from the public. When such an investigation is initiated, it is nevertheless treated and lodged in the Department's tracking system as a complaint investigation. That is what occurred in this case.

7. Upon the initiation of the complaint investigation, I traveled to RHS's facility on April 2 and April 3, 2019. The investigation included the review of medical records. Seven (7) additional instances were noted where the physician who performed the abortion was not the same physician who provided the informed

consent required by section 188.027.6 RSMo. This revealed a systemic disregard for the requirement. The investigation also revealed significant concerns regarding the safety of patient care provided at the facility, including but not limited to: failure to complete and submit complication reports; failure to communicate with the contracted pathology lab upon discovery of failed abortions; failure to supervise residents performing abortions at the facility, contributing to a complication; failing to ensure the accuracy of medical records; and performing an abortion on a patient who was inappropriate for the care setting at the facility based upon her previous history and a known medical condition.

8. The preliminary investigation findings, as described above, necessitated interviews with the physicians providing care at the facility and their supervising physicians at RHS. Conducting interviews of physicians and others who provide care at healthcare facilities licensed by the Department is a routine part of an investigation and part of standard practice across other licensed facilities at the Department. It also makes the most sense that—when the focus of the investigation is the care provided by the physician—that the investigation include interviews of the physician. This is why such interviews of care providers during investigations is a component of the Department's standard practice.

9. As a result of medical record review and as part of the investigation, on April 3, 2019, I made an unsuccessful attempt to interview Staff A (a physician)[1] at her

[1] All persons generically identified in this affidavit are physicians unless specifically noted.

work location. RHS' Director of Surgical Services informed me that all physicians were unavailable until the week of April 8, 2019.

10. On April 9, 2019, RHS submitted their proposed Plan of Correction in response to the Statement of Deficiencies. With respect to the deficiencies regarding informed consent required under Section 188.027.6 RSMo and pelvic exams, RHS contended that it was following the law and that only minimal correction (with respect to informed consent) was needed to ensure that attending physician's supervisory status was documented. Ex. B.

11. On April 11, 2019, I made email contact with RHS's Interim President and CEO to request interviews with 7 physicians who performed care or supervised care within the medical records reviewed. I requested that interviews be scheduled by the close of business, April 16, 2019. Ex. C.

12. In the April 11 email, I noted that, to protect the integrity of the investigation, it was important to interview Staff A first, followed by Dr. McNicholas. I have 25 years of investigative experience, including 19 years for the State, and the order of interviews can have a definite impact on the reliability of the interviews, which are necessary for an investigation—a truth-seeking process—to most reliably ascertain the truth. It is standard investigative practice and to first interview the person who directly provided the care when the care is the issue being investigated, followed by the person (if necessary) who supervised that care. It would be completely outside the norm and generally unacceptable to complete an investigation into potentially deficient patient care at one of the Department's

licensed facilities without interviewing the person who actually and directly provided the care at issue, absent some circumstance such as that the facility immediately terminated the person's employment after being notified of the deficient care.

13. On April 12, 2019, an attorney for RHS called and spoke with an attorney for the Department. RHS's attorney asked what the topic of the investigation was about. The Department's attorney responded that the investigation was about the records that the Department obtained during the complaint investigation on April 2 and 3, 2019. The Department's attorney added that the investigation also included any issues stemming from those records related to the licensure requirements of abortion facilities.

14. On April 16, 2019, the attorney for RHS sent me a letter regarding the physician interviews. Although the letter stated that RHS would continue to cooperate with the investigation—even though the physicians had not been produced for interviews—and indicated that the physicians we sought to interview had been contacted, the letter then questioned whether the physicians were legally required to submit to interviews, and even whether RHS was required to cooperate at all. The letter also proposed alternatives to interviewing the physicians; however, these alternatives were determined to be less likely to produce the most reliable results than direct interviews with the physicians, and disclosing the topics of the questions would have compromised the integrity of the investigation. Ex. D.

15. On April 19, 2019, separate counsel contacted me via telephone regarding requests to interview his/her clients, Staff G and Staff F. The attorney asked for specifics regarding the nature of the interview request for their clients. The attorney was informed that the nature of the questioning was in regard to their client's work at RHS and that divulging specifics of the questions may compromise the investigation. They clarified that their clients were not contractors nor employees of RHS but are BJC residents who do rotations through RHS. The attorney indicated that they would be back in touch regarding their clients' willingness to submit to an interview.

16. On April 22, 2019, I contacted attorneys who represented Staff A, Staff B, Staff G, and Staff F, and Dr. Coleen McNicholas and Dr. David Eisenberg regarding conducting interviews with their clients.

17. On April 22, 2019, an email was sent to RHS's attorney responding to a request in the April 16 letter explaining the authority to proceed with the interviews and that, if the investigation was not completed, the license may not be renewed among other possible consequences. Ex. E.

18. On April 24, 2019, the attorney representing Staff B, responded to my April 22, 2019, request for interview and inquired as to the nature of the interview. I responded to the attorney the same day with an explanation for the need to interview Staff B. Ex. F.

19. On April 25, 2019, I was contacted by a new attorney representing Staff G and Staff F. The attorney requested a telephone call on April 26, 2019, to discuss the nature of the requested interviews. Ex. G.

20. On April 26, 2019, I made telephonic contact with the attorney representing Staff G and Staff F, and the attorney representing Staff A, Dr. Coleen McNicholas, Staff H and Dr. David Eisenberg. I informed them of the Department's authority to conduct the investigation of the abortion facility, which includes necessary interviews with their clients, who performed patient care at RHS. I told them the physicians' names were in the medical records reviewed for the investigation. I also told them that I did not work for the Board of Healing Arts or Law enforcement, but I could offer no assurances (because they asked) that their clients would not be referred to either or both agencies based on the findings of the investigation. To emphasize, I never threatened that I would refer my investigative findings to law enforcement or the Board of Healing Arts, but I also could not promise them that a referral would not be made based on what was found in the investigation.

21. On May 2, 2019, I left a voice mail requesting follow up for the attorney who represents Staff B, regarding the Department's interview request for his client.

22. On May 2, 2019, I left a voice mail with counsel requesting follow up regarding the Department's interview request for his clients, Staff A, Dr. Coleen McNicholas, Staff H and Dr. David Eisenberg.

23. On May 3, 2019, an attorney representing RHS sent a letter to a department attorney regarding the physician interviews and the collection of medical records,

the latter regarding a concern for patient privacy. Among other things, the letter requested a response from the Department regarding RHS's Plan of Correction. Ex. H.

24. On May 7, 2019, the attorney representing Staff B contacted this office to notify the Department that Staff B declined the invitation to an interview. Ex. F.

25. On May 7, 2019, an attorney for the Department responded that the Department could not yet confirm a date when RHS could expect a determination on its Plan of Correction because no date had yet been established for when the Department would be able to interview physicians or would be able to collect records. The attorney also had responded on May 6 explaining the Department's authority to review and collect records and the confidentiality afforded by statute of any records collected. Ex. I.

26. On May 8, 2019, I visited RHS to review and collect records. Although I was allowed to inspect records, I was not allowed to copy them, which is a deviation from a long-standing practice with RHS and completely unprecedented. Until this date, the Department had routinely copied records from RHS and other facilities, and not once had RHS raised any concern with patient confidentiality. The Department also routinely copies records when it goes onsite to inspect and investigate other facilities. Copying records—like performing physician interviews regarding direct patient care—is a component of our investigations of all licensed facilities.

27. On May 9, 2019, an attorney for the Department emailed RHS's counsel about not being able to collect the records from the facility, noting that record

collection was a necessary part of the investigation process. Another attorney for RHS later asserted through an email that records were not allowed to be collected—including mere copies of the facility's *policies* that clearly contain no patient information—because of patient-privacy concerns. The Department's attorney explained that records collected during inspections are protected by Section 197.477 RSMo, and RHS later agreed to provide the records. Ex. J.

28. On May 14, 2019, the attorney representing clients: Staff A, Dr. Coleen McNicholas, Staff H, and Dr. David Eisenberg made contact by telephone with the Department in order to decline interview requests on behalf of his clients, Staff A and Staff H. He offered Dr. David Eisenberg for interview at 11:00 a.m. on May 17, 2019, and Dr. Colleen McNicholas at an unspecified time and date during the week of May 20, 2019. By email I declined the interview offer for Dr. Eisenberg at the specified time and date due to our original request to interview him last, as Dr. Eisenberg is the RHS medical director. Ex. K.

29. On May 16, 2019, RHS applied for the renewal of their license. That same day, RHS's counsel emailed the Department and, among other things, requested that the Department respond to its Plan of Correction on or before May 20, 2019, stating that if a response was not received by then, RHS would assume the license was denied. Ex. J.

30. On May 20, 2019, the Department responded to RHS's Plan of Correction, noting that RHS's proposed Plan of Correction with respect to informed consent, pelvic exams, and a deficiency regarding infection-control standards was

unacceptable. The Department also notified RHS that the Department's investigation had revealed more than 30 potential deficient practices, that it would not be able to complete its investigation until we interview the physicians involved in the care provided, and that the Department could not renew its license until we determined compliance with all applicable statutes and regulations. Ex. L.

31. On May 21, 2019, I confirmed through email to the attorney representing Staff G and Staff F that interviews with his clients were still needed and inquired as to the time and date interviews could be scheduled. The attorney responded that he could not recommend that they be interviewed by me so long as I remained committed to interviewing them before interviewing their supervising physicians and without first providing them with the nature of my inquiry. As I have explained previously here, however, providing the specific topics beforehand could compromise the integrity of the investigation. Ex. G.

32. On May 22, 2019, RHS provided a revised Plan of Correction. In the revised Plan of Correction, RHS agreed among other things to begin performing pelvic examinations at least 72 hours before each abortion, at a time when the information could impact the choice of the procedure, and RHS proposed to correct its infection-control deficiency. However, RHS again denied that its practices with respect to the same physician providing informed consent under Section 188.027.6 RSMo were deficient. RHS requested a response to its revised Plan of Correction by May 24, 2019. Ex. M.

33. On May 23, 2019, the Department responded to RHS's revised Plan of Correction, accepting the revised Plan of Correction with respect to pelvic examinations (as long as the proposed changes were implemented and monitored immediately) and infection-control standards. However, the Department again did not accept RHS's position as to the same physician providing informed consent that would perform or induce the abortion as required by Section 188.027.6 RSMo. The Department also reiterated that it needed to interview the physicians at RHS who provided care there and were involved in potentially deficient practices. Because RHS had thus far refused to make the physicians available in the manner that the Department had requested, the Department agreed to interview Dr. Eisenberg and Dr. McNicholas out of order under protest, emphasizing how this deviated from our usual practice with respect to facilities, and clarifying that we were not withdrawing our requests to interview the other physicians. Ex. N.

34. At 5:31 p.m. on May 24, 2019, Dr. Eisenberg's and Dr. McNicholas's attorney stated that both would be available for interview on May 28, 2019, with the first interview (for Dr. McNicholas) scheduled for only one hour. I responded on May 25, 2019, that I would try to be as quick as possible, but I could not guarantee that the interview would only take one hour and that I expected the physicians to be available longer if necessary. Ex. O.

35. I and David Lanigan, the Assistant Section Administrator for the Section for Health Standards and Licensure, interviewed Dr. McNicholas and Dr. Eisenberg on May 28, 2019. Among other topics discussed, Dr. McNicholas 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", which she had 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 stated, "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." The interview lasted approximately 45 minutes, and the interview of Dr. Eisenberg lasted approximately 30 minutes. The findings of the interview conducted with Dr. McNicholas further highlight the necessity to interview resident and fellow staff who performed direct patient care at RHS, and at times, resulted in documented complications.

36. It is unprecedented in my experience for physicians and other health care professionals to refuse to be interviewed regarding health care that they personally provided during a licensing inspection or investigation. This is true regardless of whether these professionals are deemed "employees" or "independent contractors"

by the facility. In the Department's prior inspections and investigations involving RHS, its physicians and health care professionals have always agreed to be interviewed, and the same is true of virtually all facilities regulated by the Department, which includes many hundreds of facilities. *See* Ex. N.

37. All exhibits attached to this affidavit are true and accurate copies of the records that are on file and of record with the Department of Health and Senior Services. It is the regular practice of the Department to inspect medical facilities licensed in Missouri or seeking to be licensed and to create a contemporaneous record of that inspection.

Affiant

In witness of the above, I have subscribed here my name and affixed my official seal this 29th day of May, 2019.

(Signed)

NOTARY PUBLIC NOTARY SEAL STATE OF MISSOURI

EMILY E. HOLLIS
My Commission Expires
February 7, 2020
Cole County
Commission #12301399

(Seal)

My commission expires:
February 7, 2020

EXHIBIT A

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 _____	03/13/2019

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
REPRODUCTIVE HEALTH SERVICES / PLANNE	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 licensure survey was conducted from 03/11/19 to 03/13/19 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). See below for findings:	L 000		
L 069	19 CSR 30-30.020(1)(A)(6) A written plan shall provide A written plan shall provide for the evacuation of patients, visitors and personnel in the event of fire or other disaster within the facility and for an alarm system to notify personnel. Personnel are to be acquainted with the evacuation plan to properly perform their duties in the event of a fire or disaster. This regulation is not met as evidenced by: Based on policy review, record review, and interview, the facility failed to ensure that all employees participated in a fire drill at least annually. The Abortion Facility does an average of 216 cases per month. On the first day of the survey, there were 21 procedures. Findings included: 1. Review of the facility's policy titled, "Natural Disasters, Chemical Attacks, and Physical Actions," dated 04/18, showed that fire drills are performed at least annually. All staff should be involved. The drill is to familiarize staff with assigned emergency duties. 2. Review of the facility's records of fire drills showed that the most recent fire drill occurred on	L 069		4/30/19

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L 069	Continued From page 1 11/30/18 and the previous drill occurred on 06/02/17. (Note: The time between drills was more than 12 months). The list of staff on the drill from 11/30/18 showed 30 names and 10 were indicated as having been part of the drill. 3. During an interview on 03/11/19 at 4:15 PM, Staff N, Clinical Quality Improvement Manager, stated that she did not know why the fire drills were more than 12 months apart and that no physicians were listed as participating as there were none onsite that day.	L 069		
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 record review the facility failed to ensure all policies were written to maintain compliance with all regulatory requirements for obtaining a complete medical history to include a pelvic examination. Findings included: 1. Licensure regulations at 19 CSR 30-30.060 (2) (D) require a written medical history shall be obtained for each patient. A health assessment including a pelvic examination shall be performed. Pregnancy shall be confirmed by	L1069		4/30/19

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L1069	Continued From page 2 clinical evidence and laboratory tests. This information shall be used in determining the duration of gestation, identifying preexisting medical or other complications, and detecting any factors which could influence the choice of the procedure, anesthesia, or preoperative and postoperative management. If the physician determines gestation is beyond the first trimester, an ultrasound examination shall be performed and results shall be recorded in the patient's medical record. 2. Review of the facility's document titled, "Minutes from RHS (Reproductive Health Services) Provider Training's Regarding SB (Senate Bill) 5 and Corrections for DHSS (Department of Health and Senior Services) Inspection," dated 04/26/18, showed: - Pelvic exams done prior to surgical abortion will continue and should be documented in the surgical abortion template as has been required - current practice. - Pelvic exams will only be done for medical abortion when medically indicated - current practice.	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 policy review, record review and interview, the facility failed to ensure the physician	L1076		4/30/19

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L1076	Continued From page 3	L1076		

who obtained the informed consent was the physician who performed or induced the abortion for two (#7 and #10) of 10 patients' abortion medical records reviewed. The Abortion Facility does an average of 216 cases per month. On the first day of the survey, there were 21 procedures.

Findings included:

1. The physician who is to perform or induce the abortion shall provide the information required in section 188.027.6, RSMo, orally and in person to the patient at least seventy-two (72) hours before the abortion.

2. Review of the facility's policy titled, "Consent and Informed Consent," dated 06/16, showed per Missouri SB (Senate Bill) 793 and SB5 ALL women who request an abortion in Missouri must meet with a Qualified Health Professional and the physician who will provide the abortion procedure for consultation at least 72 hours prior to an abortion procedure (or informed consent may be given by physician only).

3. Review of Patient #7's medical record showed:
- On 11/15/18, Staff GG, Medical Doctor (MD), signed the facility's document titled, "State of Missouri Department of Health and Senior Services Informed Consent Checklist - Abortion."
- On 11/20/18, Staff AA, MD, administered Mifepristone (stops the pregnancy from growing and is the first of two medications administered in a medication-induced abortion).

4. During an interview on 03/12/19 at 1:04 PM, Staff A, Director of Surgical Services, stated that:
- Staff AA was a fellow (physician who has completed their residency and elects to complete further training in a specialty) who worked with

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L1076	Continued From page 4	L1076		

Staff GG.
- The Mifepristone agreement (medication agreement form signed by the patient and provider [physician] that explains that the medications will end the pregnancy, what to expect, and directions) was signed by the patient and Staff AA.

5. Review of Patient #10's medical record showed:
- On 08/29/18, Staff FF, Doctor of Osteopathic Medicine (physician whose training focused on emphasizing a whole-person approach to treatment and care), signed the facility's document titled, "State of Missouri Department of Health and Senior Services Informed Consent Checklist - Abortion."
- On 09/05/18, Staff AA attempted a surgical abortion, which was unsuccessful.
- A separate document generated by Staff FF that included:
  * "I was present for the procedure and agree with the treatment and follow up plan(s)."
  * "TV (Trans-vaginal) U/S (ultrasound) was able to confirm the path, but given the unique position of the uterus and patient's discomfort, coupled with early gestational age, we opted to stop the SAB (surgical abortion) and proceed with MAB (medical abortion)."

6. During an interview on 03/13/19 at 1:24 PM, Staff EE, MD, stated that:
- The supervising physician was responsible for care of the patient;
- The supervising physician for Patient #7 was Staff GG;
- Staff GG did not complete a supervisory note for Patient #7;
- Staff AA could administer the Mifepristone without the supervisory physician in the room;

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L1076	Continued From page 5 - Staff GG was in the room during the surgical abortion attempt on Patient #7 (performed by Staff AA); and - The supervising physician for Patient #10 was Staff FF.	L1076		
L1103	19 CSR 30-30.060(2)(D) A written medical history shall be obtained A written medical history shall be obtained for each patient. A health assessment including a pelvic examination shall be performed. Pregnancy shall be confirmed by clinical evidence and laboratory tests. This information shall be used in determining the duration of gestation, identifying preexisting medical or other complications, and detecting any factors which could influence the choice of the procedure, anesthesia, or preoperative and postoperative management. If the physician determines gestation is beyond the first trimester, an ultrasound examination shall be performed and results shall be recorded in the patient's medical record. This regulation is not met as evidenced by: Based on record review and interview, the facility failed to perform the pelvic examination at a time that could influence the choice of the planned procedure and pre-operative management for nine (#1, #2, #3, #4, #5, #6, #7, #8, and #10) of nine patients' abortion medical records reviewed. The Abortion Facility does an average of 216 cases per month. On the first day of the survey, there were 21 procedures. Findings included: 1. 188.027 states that Consent to an abortion is	L1103		4/30/19

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L1103	Continued From page 6 voluntary and informed and given freely and without coercion if, and only if, at least seventy-two hours prior to the abortion: 1(f)- the physician who is to perform or induce the abortion, a qualified professional, or the referring physician informs the woman of the gestational age of the unborn child at the time the abortion is to be performed or induced. 30-30.060 (D) A written medical history shall be obtained for each patient. A health assessment including a pelvic examination shall be performed. Pregnancy shall be confirmed by clinical evidence and laboratory tests. This information shall be used in determining the duration of gestation, identifying preexisting medical or other complications, and detecting any factors which could influence the choice of the procedure, anesthesia, or preoperative and postoperative management. 2. Review of the facility's document titled, "Minutes from RHS (Reproductive Health Services) Provider Trainings Regarding SB (Senate Bill) 5 and Corrections for DHSS (Department of Health and Senior Services) Inspection," dated 04/26/18, showed: - Pelvic exams done prior to surgical abortion will continue and should be documented in the surgical abortion template as has been required - current practice. - Pelvic exams will only be done for medical abortion when medically indicated - current practice. 3. Review of medical records for Patient #1, #2, #3, #4, #5, #6, and #8 with admission dates ranging from 11/17/18 to 02/23/19 for a surgical abortion showed documentation included findings from a pelvic examination, but the date and time	L1103		

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L1103	Continued From page 7 of the pelvic examination were not documented. 4. Review of Patient #7's medical record, dated 11/20/18, showed the patient was admitted for a surgical abortion. The physician's undated and untimed note of the pelvic examination included, "Exam limited by body habitus." A medical record entry, dated 11/20/18 at 1:40 PM, showed Staff B, Registered Nurse, documented, "Per (Staff GG, Medical Doctor [MD]) they were unable to perform in clinic procedure (surgical abortion) so patient will proceed with medication abortion." 5. Review of Patient #10's medical record, dated 09/05/18, showed the patient was admitted for a surgical abortion. Documentation included findings from a pelvic examination, but the date and time of the pelvic examination were not documented. (Note: The surgical abortion was unsuccessful so the plan changed to a medication-induced abortion.) 6. During an interview on 03/13/19 at 11:50 AM, Staff A, Director of Surgical Services, stated that: - The pelvic exam was done after the consenting process and pre-operative phase; - Pelvic exams were done right after the time out (intentional pause immediately before starting the surgical procedure when a final verification is made to confirm the correct patient, surgery, side, implant, and any special requirements); - Right after the pelvic exam, medications were given and then the procedure was completed; and - The medical records did not include the date and time of the pelvic exam. 7. During an interview on 03/13/19 at 1:24 PM, Staff EE, MD, stated that: - Routinely, they performed the time out, the	L1103		

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L1103	Continued From page 8 pelvic exam, administered the medication, and then performed the procedure. - They did the pelvic exam before going into the uterus.	L1103		
L1116	19 CSR 30-30.060(2)(N) Facilities performing surgical,emergency drug Facilities performing surgical procedures shall have emergency drugs, oxygen, and intravenous fluids in the procedure room to stabilize the patient's condition when necessary. A manual breathing bag, suction machine, and endotracheal equipment shall be located in the clinical area for immediate access. This regulation is not met as evidenced by: Based on state statute, nationally-recognized standards, policy review, record review, observation, and interview, the facility failed to ensure: - Staff maintained the necessary endotracheal equipment (equipment used to provide respiration when the patient is unable to breath for themselves) readily available to manage a respiratory emergency; - Staff were familiar with the location and operation of emergency equipment; and - Policies were developed to ensure staff orientation and knowledge validation for the location and use of emergency supplies; The Abortion Facility does an average of 216 procedures per month. On the first day of the survey, there were 21 procedures. Findings included: 1. Review of the 2011 Missouri Revised Statutes TITLE XII PUBLIC HEALTH AND WELFARE	L1116		4/30/19

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L1116	Continued From page 9 Chapter 197 Medical Treatment Facility Licenses Section 197.230 showed: - 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. - In the case of any abortion facility, the department shall make or cause to be made an unannounced on-site inspection and investigation at least annually. Such on-site inspection and investigation shall include, but not be limited to, the following areas: (1) Compliance with all statutory and regulatory requirements for an abortion facility, including requirements that the facility maintain adequate staffing and equipment to respond to medical emergencies. 2. Review of the Association of PeriOperative Registered Nurses "Guideline for Care of the Patient Receiving Moderate Sedation/Analgesia (a condition in which the patient exhibits a mildly depressed level of consciousness and an altered perception of pain but retains the ability to respond appropriately to verbal or tactile stimulation)," dated 2018, showed: - Recommendation III.c.4.	L1116		

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L1116	Continued From page 10 * Monitoring equipment (e.g., pulse oximetry (device that measures the oxygen saturation of arterial blood), Electrocardiogram (ECG - measures electrical activity all over the heart), capnography (the monitoring of the concentration carbon dioxide in the respiratory gases), blood pressure measurement devices, oxygen source, masks and cannulas, suction source, tubing, and tips, and oral and nasal [through the nose] airways) should be working properly, and immediately available in the room where the procedure is being performed. - Recommendation III.e. * Emergency resuscitation equipment and supplies should be immediately available in every location in which moderate sedation is administered. - Recommendation III.e.1. * Emergency equipment and supplies should include: Airway and ventilatory equipment (e.g., laryngoscopes (a diagnostic tool with a blade, light, and mirrors, used to examine the larynx [hollow organ in the throat that forms an air passage to the lungs]), endotracheal tubes (ETT- a breathing tube inserted into the airway to keep the airway open), laryngeal mask airway (LMA - a medical device that keeps a patient's airway open during anesthesia or unconsciousness), oral and nasal airways; 3. Review of the facility's policy titled, "Emergency Response Protocol and Procedure for Emergency Transfer of Patients in Life Threatening Situations," dated 02/19, showed: - When an emergency is recognized by staff they will respond to the patient in crisis and notify physician and Registered Nurse (RN)/Licensed Practical Nurse (LPN). - Basic Life Support (BLS - a level of medical care	L1116		

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which is used for victims of life-threatening illnesses or injuries until they can be given full medical care) services and supportive care will be started as indicated.
- Treating physician will direct patient care and designate team members to carry out tasks as necessary.
 * Be sure to start with the ABCs (Airway, Breathing, Circulation).
- RN/LPN who comes to the room should assess ABCs and should ask treating physician for report regarding any other equipment (e.g. intravenous (small catheter inserted into a vein for administering medication and fluid) access, oxygen, and ultrasound) or medications needed.
(Note: The policy failed to identify the emergency equipment necessary to treat seizures, bleedings, anaphylactic shock, respiratory arrest, and cardiac arrest and other life threatening emergencies and failed to address the need for staff orientation and training on the locations and operation of emergency equipment.)

4. Review of the facility's undated document titled, "Emergency Box: Medication and Supplies," showed the emergency box checklist failed to include suction equipment, i.e., suction device (plastic suction tip used to suction secretions from the mouth and throat) and endotracheal equipment (equipment used to manage an open airway, i.e., endotracheal tubes, endotracheal tube introducers [device used to assist in obtaining an airway] and laryngoscope handle and blades).

5. Review of the facility's undated checklist titled, "Quality Management (QM) Site System Review," showed:
- The document was to be completed monthly by the Surgical Services Manager/Delegate and

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included:
- Emergency Equipment
  * Audited by nursing supervisor (blank for initials).
  * Resuscitative equipment; and
  * Cart with emergency supplies & weekly checklist current.
(Note: The checklist failed to contain a list of specific emergency or resuscitative equipment to be checked.)

6. Observation on 03/11/19 at approximately 1:45 PM showed:
- A portable suction machine in supply storage room #2;
- No suction equipment in three of three procedure rooms; and
- No suction equipment in the pre/post procedure area.

7. During an interview on 03/12/19 at 9:25 AM in the pre/post procedure area, Staff O, Advanced Practice Registered Nurse (APRN), Clinical Manager, stated that:
- There was no suction in the procedure rooms or pre/post procedure area.
- She did not know where the suction machine was located.
- Staff needed an in-service on location of emergency equipment.

8. Observation on 03/12/19 at 9:30 AM in the pre/post procedure area showed:
- An emergency box with emergency medications and supplies.
  * The emergency box did not contain suction supplies (suction tips or cannulas) or endotracheal equipment.

During an interview upon the observation, Staff B,

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L1116	Continued From page 13 Registered Nurse (RN), stated that: - There was no suction supplies or endotracheal equipment in the pre/post area. - She did not know what emergency supplies were in the procedure rooms, she was only responsible for the pre/post procedure area. - She had worked at the facility for approximately three years. - She did not know where the suction machine was located. During an interview upon the observation, Staff O stated that she did not know where the endotracheal tubes were located. 9. During an interview on 03/12/19 at 10:05 AM, Staff EE, Physician, stated that: - If they had a patient that needed intubation he would use a LMA. - The LMA's were with the emergency supplies in the procedure rooms. - The facility had LMAs, oxygen, and suction for endotracheal equipment. - Given the facility's proximity to a hospital and EMS response time he had determined those supplies were sufficient for the facility. 10. During an interview on 03/12/19 at 10:10 AM, Staff H, Surgical Scrub Technician (staff member who performs multiple duties including providing the surgeon with the instruments needed to perform a surgery), Patient Flow Coordinator, stated that: - The suction machine was in the sterile supply storage room. - They did not have suction tips or catheters for oral suction of the patient. - She did not know if the facility had laryngoscope handles and blades. - They did not have LMAs.	L1116		

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L1116	Continued From page 14 12. During an interview on 03/12/19 at 10:15 AM, Staff A, Director of Surgical Services, stated that she did not know where the suction tips or laryngoscope handles and blades were located or if they had them. 13. Observation on 03/12/19 at 10:20 AM of procedure room #3 and two sterile supplies closet showed there were no LMA or suction tips available for the facility. 14. Observation on 03/12/19 at 10:35 AM of sterile storage room #2 showed: - The laryngoscope handles and blades were stored together in a factory storage container on the top shelf. - The handles and blades had not been cleaned, high level disinfected, or packaged to prevent cross-contamination. (Note: The handles and blades were not ready for patient use.) During an interview upon the observation, Staff EE, stated that: - The facility purchased laryngoscope handles and blades approximately one year ago. - They were stored on the top shelf in the supply room, still in the original case. - They would never use the laryngoscope handles and blades or the ET tubes. - He did not know the facility did not have any suction tips for oral suctioning. 15. During an interview on 03/13/19 at 11:00 AM, Staff N, Clinical Quality Implementation Manager, stated that: - The only checklist for staff to validate emergency supplies was the document, "Emergency Box," which was used for the	L1116		

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L1116	Continued From page 15 pre/post procedure monitoring area. - The facility did not have an inclusive list of unit emergency supplies and equipment. - The monitoring tool for emergency supplies, "QM Monthly Site System Review Worksheet," did not include a list of emergency supplies and was not a tool to validate staff knowledge of emergency supplies. - The facility did not have a policy that outlined the required emergency supplies to be maintained by the unit; and - The facility did not have a policy that directed staff orientation and knowledge validation for the location and use of emergency supplies.	L1116		
L1131	19 CSR 30-30.060(4)(A) Infection control standards of the facility Infection control standards of the facility must be identified in writing, in compliance with generally-agreed upon national standards such as those of the Centers for Disease Control and Prevention (CDC), Association for Professionals in Infection Control and Epidemiology (APIC), Association of peri-Operative Registered Nurses (AORN), or other standards determined acceptable by the department. This regulation is not met as evidenced by: Based on nationally-recognized standards, policy review, record review, observation, and interview, the facility failed to ensure: - Staff maintained a controlled environment to prevent cross-contamination in sterile processing and decontamination; - Staff followed acceptable sterilization standards and manufacturers instructions for use (IFU) for the monitoring of chemicals used for High-Level Disinfection (HLD) of instruments;	L1131		4/30/19

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L1131	Continued From page 16 - Staff followed acceptable sterilization standards for the maintenance of logs to document the required monitoring controls for HLD of instruments; - Staff followed acceptable sterilization standards for the maintenance of logs to document the required monitoring controls for steam sterilization; - Staff followed acceptable sterilization standards and facility policy for the labeling of sterile instruments and packages; and - Ensure expired supplies were not available for use. The Abortion Facility does an average of 216 procedures per month. On the first day of the survey, there were 21 procedures. Findings included: 1. Review of the facility's policy titled, "Managing Infection Prevention at Affiliates," dated 07/09/18, showed: - All staff is responsible for adhering to and incorporating infection prevention practices with service provision. - The facility uses as a reference: * The Affiliate Risk Management Services infection Prevention Manual; * Centers for Disease Control and Prevention; * HealthCare Infection Control Practices Advisory Committee Guidelines; - Other resources are listed in the attachment section of this manual: * Association for the Advancement of Medical Instrumentation (AAMI); * Association of PeriOperative Registered Nurses (AORN); * Association of Professionals in Infection and Epidemiology (branch of medicine which deals with the incidence, distribution, and possible	L1131		

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control of diseases and other factors relating to health); and
* Occupational Safety and Health Administration.

2. Review of the AORN "Perioperative Standards and Recommended Practices for Instrument Cleaning," dated 2018, showed:
- Recommendation V.
* Instruments should be cleaned and decontaminated in an area separate from locations where clean items are handled.
* Physical separation of decontamination areas (area of a health care facility designated for collection, retention, and cleaning of soiled and/or contaminated items) from areas where clean items are handled minimized the risk of cross-contamination.
* Droplets and aerosols created during cleaning of soiled instruments can cause cross-contamination of any nearby clean items or surfaces.
- Recommendation V.a.
* The sterile processing area should have:
- Separate clean and decontamination spaces, which may be rooms or areas;
- Decontamination and clean spaces that are separated by one of three methods: A wall with a door or pass-through, a partial wall or partition that is at least 4 feet high and at least the width of the counter, or a distance of 4 feet between the instrument washing sink and the area where the instruments are prepared for sterilization.
- Recommendation VI.
* Contaminated instruments are a potential source of transmissible pathogens.

3. Review of the American National Standards Institute (ANSI) and AAMI document titled, "ANSI/AAMI ST79:2017, Comprehensive Guide to Steam Sterilization and Sterility Assurance in

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Health Care Facilities," dated 2017, showed:
3.3.6.1.1 Design considerations: The decontamination area/room should be physically separate from all other processing areas and from areas in which clean or sterilization procedures are carried out, with any connecting doors and pass-through windows remaining closed.

4. Observation on 03/11/19 at 1:30 PM of the sterile processing area showed:
- The pass through window between sterile processing and decontamination was open.
- Staff F, Surgical Scrub Technician (ST, staff member who performs multiple duties including providing the surgeon with the instruments needed to perform a surgery), was cleaning contaminated instruments in the decontamination room in direct proximity to the pass through window.
- The door to the sterile processing room was propped open.
- Two sterilizers along the wall adjacent to the door that protruded past the door frame and prevented the door from being closed.

During an interview upon the observation, Staff A, Director of Surgical Services, stated that the sterilizers blocked the door to sterile processing from closing.

5. Observation on 03/12/19 at 9:28 AM showed the doors to sterile processing and decontamination and the pass through window were open.

6. Observation on 03/12/19 at 11:25 AM showed the door to sterile processing and the pass through window was open.

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L1131	Continued From page 19 7. During an interview on 03/13/19 at 9:15 AM, Staff A stated that the door to decontamination and the pass through window were to remain closed at all times. 8. Review of the ANSI/AAMI document titled, "ANSI/AAMI ST79:2017, Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities," dated 2017, showed: - E.6 Quality control in chemical disinfection (chemical substances which are used to kill or deactivate pathogenic microorganisms [capable of causing illness in humans]) * Dilution and minimum effective recommendation (MEC) / minimum recommended concentration (MRC) monitoring: The disinfectant is diluted by water remaining on surfaces and in the lumens of devices immersed in the disinfectant. Dilution can be very significant in the long-term use and reuse of a chemical disinfectant and can potentially reduce the concentration of the chemical agent to a level too low to be effective in killing a sufficient number of certain microorganisms in the recommended exposure time. To avoid dilution of the disinfectant, excess moisture should be removed after cleaning. Disinfectant solutions must not be used at concentrations below the MEC or MRC stated on the label. As part of a health care facility's quality control program, Liquid Chemical Sterilants (LCS)/HLD solutions such as glutaraldehyde (Cidex OPA [brand] - high level disinfectant for semi-critical medical devices) solution should be monitored upon activation and before each use in order to detect unexpected dilution of the solution. 9. Review of the AORN "Guideline for Manual	L1131		

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Chemical High-Level Disinfection," dated 2018, showed:
- Recommendation IV.d.
 * High-level disinfection should occur in a designated clean area that is separate from the decontamination area.
 * Separating the clean area from the area where devices are cleaned and prepared for high-level disinfection reduces the risk of device contamination that might occur when both clean and contaminated processing activities are performed in a single area.
- Recommendation VI.c.1.
 * A test strip or other Food and Drug Administration-cleared testing device specific to the disinfectant and the active ingredient in the disinfectant should be used before each use of the HLD solution.
- Recommendation VI.d.1.
 * The temperature of the HLD solution should be verified before each use with a thermometer calibrated within the applicable range.
- Recommendation IX:
 * Documentation should be completed to enable the identification of trends and demonstrate compliance with regulatory and accrediting agency requirements.
- Recommendation IX.a.
 * Records related to manual chemical high-level disinfection should include:
 The date and time of high-level disinfection;
 HLD solution lot number;
 HLD solution shelf-life date;
 HLD solution activation date;
 HLD solution reuse-life date;
 Results of solution test strip testing;
 Results of MRC or MEC testing, if applicable;
 HLD solution temperature;
 HLD solution exposure time;
 Quantity and description of the device or item;

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and
Identity of the person performing high-level disinfection.

10. Review of the facility's policy titled, "Cleaning, Disinfection, and Sterilization," dated 07/09/18, showed to ensure integrity, visually inspect previously used solution before use, test and record results in appropriate testing log daily.

11. Review of the manufacturer's IFU for Cidex OPA showed:
- Reuse for Disinfection:
 * The concentration of Cidex OPA Solution during its use-life (time between activation of the solution and last date to be used) must be verified by the test strips prior to each use.
 * This is to ensure the minimum effective concentration is present.
 * Cidex OPA Solution may be used for up to a maximum of 14 days provided the required conditions of concentration and temperature exist.

12. Review of the facility's documents titled, "Cidex OPA Solution MEC test log showed:
- The document was used to record the following information:
 * Date the solution was poured into the secondary container (a soaking pan);
 * Staff initials;
 * MEC test strip results; and
 * Comments/resolution.
- Review of the monthly logs showed:
 * 11/18 - entries on three days;
 * 12/18 - entries on three days;
 * 01/19 - entries on four days;
 * 02/19 - entries on seven days; and
 * 03/01/19 - 03/11/19 - entries on four days:
 * Staff documented that the solution was

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L1131	Continued From page 22 changed four times in 19 weeks. - Staff failed to document: * The date and time of high-level disinfection; * HLD solution lot number; * HLD solution reuse-life date; * HLD solution exposure time; and * Quantity and description of the devices or items disinfected. 13. During an interview on 03/13/19 at 8:35 AM, Staff F stated that: - Staff checked the Cidex daily; - They only checked the Cidex on days they had procedures that required HLD. - The Cidex expired 14 days after it was mixed regardless of the MEC. - The number of HLD loads disinfected averaged between 12 and 15 HLD loads per day on procedure days. - She did not check the Cidex MEC prior to disinfection of each load. 14. During an interview on 03/13/19 at 9:30 AM, Staff A stated that: - She did not know the Cidex MEC should be validated prior to each HLD load of instruments; and - She was not aware the time of high-level disinfection, solution lot number, reuse-life date, exposure time, quantity, and description of the device or item disinfected should be documented. 15. Review of the ANSI/ AAMI document titled, "ANSI/AAMI ST79:2017, Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities," dated 2018, showed: - 13.3.3 Sterilizer records * The process critical parameters (time and temperature) provided on the recording chart,	L1131		

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printer, or tape should be reviewed, signed, and dated by the operator to indicate an acceptable cycle.
* For each sterilization cycle, the following information should be recorded:
(a) The load number;
(b) The specific contents of the lot or load, including quantity, department, and a specific description of the items(e.g., towel packs, type/name of instrument sets);
(c) The exposure time and temperature, if not provided on the sterilizer recording chart; and
(d) Operator identification.

16. Review of the facility's policy titled, "Cleaning, Disinfection, and Sterilization," dated 07/09/18, showed:
- Information that should be recorded and maintained for each sterilization cycle includes guidance from Consolidated Test of American National Standard/Advancing Safety in Medical Technology:
* Specific contents of the lot or load, including quantity, department, and specific description of the items (e.g. towels, type/name of instrument sets);
* Exposure time and temperature, if not provided on the sterilizer recording chart;
* Name or initials of operator; and
* Results of biological testing, if applicable.

17. During an interview on 03/12/19 at 9:15 AM in the sterile processing room, Staff D, ST, stated that:
- They did not maintain a sterilization log.
- She never had any training on the sterilization process; she just continued to do what she had seen was done in the past.
- She only logged sterilizer cleaning and results of the biologicals.

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L1131	Continued From page 24 - Each instrument package and set should be labeled with a load number and autoclave number. - She did not know they should keep a record of the content, time and temperature for each sterilizer load. 18. During an interview on 03/12/19 at 9:30 AM in the sterile processing room, Staff A stated that: - They tested the Cidex OPA solution daily. - She did not know they were supposed to test the Cidex OPA solution before every load of instruments processed. - They did not have a log to document load content, time, and temperature for the Cidex OPA solution or the steam sterilizers. 19. Review of the ANSI/AAMI document titled, "ANSI/AAMI ST79:2017, Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities," dated 2017, showed: - 13.3.1 General considerations * Each item or package intended for use as a sterile product should be labeled with a lot control identifier to allow full traceability of that item to the patient. * Each load should have a load control record that includes a detailed content list, including specific identification of sets and the contents of sealable pouches. - 13.3.2 Package labeling * Each item or package intended for use as a sterile product should be labeled with a lot control identifier prior to sterilization. The lot control identifier should identify: a) The sterilizer identification number or code; b) A detailed list of the contents (e.g., identification of multiple sets and the contents of paper-plastic pouches); c) The person who assembled the package;	L1131		

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L1131	Continued From page 25 d) The date of sterilization; e) The cycle number (cycle run of the sterilizer); and f) The patient, if applicable. - Rationale: Labeling items with a lot control number and an expiration statement or (when applicable) expiration date is necessary for proper stock rotation. Lot identification enables personnel to retrieve items in the event of a recall and to trace problems (e.g., wet packs) to the source. Pre-sterilization labeling can be done after sterilizer and cycle assignment is determined and as the cart is loaded. Accountability to the patient and surgeon for the sterility of a reprocessed device requires documentation that can be traced to the patient. Traceability is especially important as the consequences of infection can result in increased morbidity and mortality. 20. Review of the facility's policy titled, "Cleaning, Disinfection and Sterilization," dated 07/09/18, showed: - Documentation establishes accountability by documenting what instruments have been processed and provides evidence of monitoring controls for those items. * In the event of a sterilization process failure, good records will help the staff trace each package back to the event itself. * Each item or pack should be labeled with a lot identifier that designates the sterilizer identification number or code, the date of sterilization, and the cycle number (cycle run of the sterilizer). *Lot identification enables retrieval of items in the event of a recall, tracing problems to their source and facilitates proper stock rotation. 21. Observation on 03/11/19 at 3:00 PM in the	L1131		

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sterile processing room showed 13 of 26 sterile instrument packages observed did not have a sterilizer or load number identified on the package.

During an interview upon the observation, Staff O, Clinical Manager, stated that she did not know the sterilizer and load number should have been identified on the packages of sterilized instruments. Staff F stated that she did not know she was supposed to label every instrument package with the sterilizer number and load number.

22. Observation on 03/11/19 at 1:30 PM in the sterile supply storage room showed:
- A box of 50 infusion sets (small tubing with needle inserted into a vein for administering medication and fluid) that had expired 08/18.
- Staff A removed the box of expired supplies.

During an interview upon the observation, Staff A stated that Staff H, Patient Flow Coordinator and Staff T, Shipping and Receiving Coordinator, were responsible for checking for expired supplies at least monthly.

23. Observation on 03/11/19 from 1:50 PM through 2:45 PM during tour of the patient care areas, showed seven expired cans of alcohol-based hand sanitizer with expiration dates ranging from 08/18 through 12/18.

24. During an interview on 03/13/19 at 11:02 AM, Staff O stated that she did not know who was responsible to monitor the expiration dates of the alcohol-based hand sanitizer.

25. During an interview on 03/13/19 at 11:10 AM, Staff H stated that she did not know who was

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L1131	Continued From page 27 responsible to monitor the expiration dates of the alcohol-based hand sanitizer.	L1131		
L1146	19 CSR 30-30.060(5)(F) The facility shall follow all applicable laws The facility shall follow all applicable laws and regulations pertaining to controlled substances. This regulation is not met as evidenced by: Based on state statute, policy review, record review, and interview, the facility failed to: - Ensure controlled substance logs were maintained to include the addresses of patients who received controlled substances; and - Ensure controlled substance logs were maintained to include the reason for the destruction or wastage of controlled substances not administered. The Abortion Facility does an average of 216 cases per month. On the first day of the survey, there were 21 cases. Findings included: 1. Review of Missouri's 19 Code of State Regulations (CSR) 30-1.048(1)(3), dated 04/30/17, showed: - Each individual practitioner, institutional practitioner, and pharmacy shall maintain records with the following information for each controlled substance received, maintained, dispensed, or disposed: * The name of the substance; * Each finished form (for example, ten milligram (10 mg) tablet or ten milligram (10 mg) concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container (for example, one	L1146		4/30/19

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hundred (100) tablet bottle or three milliliter (3 ml) vial);
* The number of commercial containers of each finished form received from other persons, including the date of and number of containers in each receipt and the name, address and registration number of the person from whom the containers were received;
* The number of units or volume of the finished form dispensed including the name and address of the person to whom it was dispensed, the date of dispensing, the number of units or volume dispensed, and the written or typewritten name or initials of the individual who dispensed or administered the substance; and
* The number of units or volume of the finished forms, commercial containers, or both, disposed of in any other manner by the registrant, including the date and manner of disposal and the quantity of the substance in finished form disposed.
- Individual practitioners shall maintain the records listed in subsections (1)(A)-(E) of this rule separately from patient medical records.

2. Review of Missouri's 19 CSR 30-1.078(5) showed the following shall be entered in the controlled substance administration record or a separate controlled substance destruction record when the controlled substance is destroyed in the patient care area: the date and hour of destruction, the drug name and strength, the amount destroyed, the reason for destruction and the patient's name and room number. The nurse, pharmacist or physician and the witnessing hospital employee shall sign the entry.

3. Review of the facility's policy titled, "Policy Statement & Work Practices for Management of Controlled Substances," dated 04/30/18, showed:
- The dispensing log must include the date

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dispensed, patient name, patient address, drug name, strength, dosage form and quantity dispensed, and the name/initials of the person performing the dispensing.
- The chief circumstances for disposal of unwanted controlled substances are:
* The drug has been contaminated by patient contact, left over injectable drugs in a syringe, or a tablet that has fallen out of a patient's hand or mouth. In these cases the drug may be destroyed by two employees. The drug must be destroyed beyond reclamation and documented as described below.
* When practitioners administer injectable controlled substances, there will be a small amount remaining in the hub of the syringe. These are considered insignificant in the course of normal practice. These amounts are not considered lost. They should be documented on the logs so they are accounted for and records balance.
(Note: The facility did not include documenting the reason for wastage in their list of required documentation.)

4. Review of the facility's documents titled, "Controlled Substance Dispensing Or Administration Log," dated 01/30/19 through 03/13/19, showed:
- Staff did not include the patients' addresses on the log; and
- Staff did not document the reason controlled substances were wasted.

5. During an interview on 03/12/19 at 9:00 AM, Staff B, Registered Nurse, stated that:
- They did not document the patient's address on the "Controlled Substance Dispensing Or Administration Log;" and
- Staff did not document the reason controlled

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L1146	Continued From page 30 substances were wasted unless the reason for wastage was something "weird."	L1146		

EXHIBIT B

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L 000	Initial Comments An on-site, unannounced state licensure survey was conducted from 03/11/19 to 03/13/19 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). See below for findings:	L 000		
L 069	19 CSR 30-30.020(1)(A)(6) A written plan shall provide A written plan shall provide for the evacuation of patients, visitors and personnel in the event of fire or other disaster within the facility and for an alarm system to notify personnel. Personnel are to be acquainted with the evacuation plan to properly perform their duties in the event of a fire or disaster. This regulation is not met as evidenced by: Based on policy review, record review, and interview, the facility failed to ensure that all employees participated in a fire drill at least annually. The Abortion Facility does an average of 216 cases per month. On the first day of the survey, there were 21 procedures. Findings included: 1. Review of the facility's policy titled, "Natural Disasters, Chemical Attacks, and Physical Actions," dated 04/18, showed that fire drills are performed at least annually. All staff should be involved. The drill is to familiarize staff with assigned emergency duties.	L 069		

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

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

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

2. **Required elements of an acceptable Plan of Correction**. **Each** deficiency shall be addressed separately by completing the applicable information for **all** elements below for **every** citation.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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	The list of medications prescribed include "Mifeprex 200mg PO administered to pt in clinic, 1 ordered, ordered by Attending Physician, MD [name redacted], transaction category: administered." In addition, Finding #6 observes that the Attending Physician "was in the room" during the procedure. The Attending Physician made an error in documentation by neglecting to sign off the medical record as the supervising provider. However, the Attending Physician did make an addendum at a later date, which states, in part, the following: "I supervised Fellow Physician [name redacted], throughout this clinical encounter, including with the provision of mifepristone for medication abortion as is reflected by my signature on medication documentation from that encounter." The facility will ensure that the Attending Physician will complete a supervisory note in all patient records for whom the Fellow Physician hands the patient the medications, including re-educating the Attending Physician of this requirement. Therefore, the facility is in				

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

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

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

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

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

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	- HLD solution exposure time - Quantity and description of the device or item - Identity of the person performing high-level disinfection. All Reproductive Health Services staff will be trained to document the required monitoring controls for HLD regarding the disinfection of instruments as directed in the manufacturer's instructions. . Each log shall include each disinfection use including the item(s) sterilized and the quantity. Temperature of the HLD solution shall be verified with a thermometer calibrated within the applicable range according to the manufacturer's instructions. Labeling of sterile instruments and packages. Log edited to include: -The sterilizer identification number (machine 1 or machine 2) -A detailed list of contents (i.e. 2 LAM Packs, 4 two pack dilators) -The person who assembled the package -The date of sterilization -The cycle number All staff shall be trained to follow the acceptable sterilization standards and facility			expired. Staff shall be trained to keep the proper window and doors closed in the decontamination area in order to prevent cross-contamination and to adhere to best practices. Director of Surgical Services shall review with the Quality Assessment and Performance Improvement (QAPI) program Infection Control standards in accordance with 19 CSR 30-30.060(4)(A) changes until compliance is achieved.	

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	policy for labeling of sterile instruments and packages. Expired wall hand sanitizers were removed and disposed of. New and non-expired hand sanitizers were placed in the wall holders, and the date of expiration was marked on the side of the canister in bold lettering. Reproductive Health Services currently has a physical separation of decontamination area from areas where clean items are handled to minimize the risk of cross-contamination. A smaller autoclave has been ordered to reorganize the sterilization room to be able to close the door properly. The current pass-through window shall remain closed except when passing clean/disinfected equipment from the decontamination area to the sterilization room. Both doors to the decontamination room and the sterilization room shall remain closed at all times				
L1146	Reproductive Health Services shall follow all applicable laws pertaining to controlled substances pursuant to 19 CSR 30-1.048(1)(3). The controlled substance logs shall be updated to include the addresses of patients who received controlled substances.	4/30/19	Clinical Manager, Quality Manager	Regular audits shall be performed of the updated controlled substance logs in order to ensure compliance to best practice standards and documentation by adding it to the monthly QM System Site Review checklist. The audit shall be incorporated in the Quality	Attachment Controlled Substance Administration & Disposal Log

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	The controlled substance logs, in accordance with subsection list (1)(A)-(E), shall be recorded separately from patient medical records. Reproductive Health Services, has updated the Missouri Department of Health & Senior Services Bureau of Narcotics and Dangerous Drugs Controlled Substance Dispensing or Administration Log to be in compliance with 19 CSR 30-1.048 & 19 CSR 30-1.78(5) including reason for wastage. Staff shall be trained on the updated log, including documenting the reason for wastage. Staff shall be trained in the practice of including patient addresses on the edited Controlled Substance Administration and Disposal Log			Assessment and Performance Improvement (QAPI) program until compliance is achieved.	

Condition	B	C
Patient factors		
▪ Unwilling to have an aspiration abortion	•	
▪ Cannot follow up to confirm the pregnancy was terminated	•	
▪ Does not have access to a telephone, emergency medical care (emergency treatment of incomplete abortion, blood transfusion or emergency resuscitation), and transportation	•	
Porphyria – inherited	•	
Renal failure	•	
Respiratory disease – chronic		•

1.1.3 Medical Screening and Evaluation

1.1.c. Table: Medical Screening and Evaluation – Medication Abortion

History	Physical Examination	Laboratory Testing and Diagnostic Imaging
Must include ▪ LMP ▪ Comprehensive medical history ▪ Screening to identify possible contraindications and/or special conditions	**Must** include ▪ BP ▪ Bimanual exam when indicated (e.g., vaginal bleeding or abdominal/pelvic pain, or as required by Missouri regulations) ▪ Additional examination as indicated by history or laboratory findings	**Must** include ▪ Hgb or hct ▪ Rh typing — unless patient reports Rh-negative status or written documentation of Rh status is available. ▪ GC/CT Testing per CDC STD Treatment Guidelines ✓ CDC STD Treatment Guidelines ▪ Ultrasound confirmation of gestational age* ▪ Other tests as indicated

* *PER Missouri 1 CSR 30-30 E, Ultrasounds at abortion facility to confirm gestational age and for other imaging purposes such as ultrasounds per 188.027(4) shall be performed by a physician or person who holds a current certification by the American Registry for Diagnostic Medical Sonography (ARDMS).*

1.1.14 Medical Screening and Evaluation

1.2.c. Table: Medical Screening and Evaluation – Surgical Abortion

History	Physical Examination	Laboratory Testing and Diagnostic Imaging
Must include ▪ LMP ▪ Comprehensive medical history ▪ Screening to identify possible contraindications and/or special conditions ▪ Allergies to medications, antiseptic solutions, and latex For digoxin use ▪ Assessment of family history for sudden cardiac death in young healthy family member or strong family history of cardiac arrhythmias	**Must** include ▪ Temperature, if symptomatic of infection ▪ BP ▪ Visual exam of the vulva, vagina, and cervix ▪ Bimanual exam, including estimation of uterine size and position and palpation of the adnexa ▪ Abdominal palpation (not required when ultrasound and bimanual exam are consistent with gestational age) ▪ Additional examination as indicated by history or laboratory findings For digoxin use ▪ Cardiac auscultation	**Must** include ▪ Urine or blood pregnancy test performed at affiliate within 7 days, unless ultrasound documented an intrauterine pregnancy ▪ Hgb or Hct ▪ Rh typing — unless patient reports Rh-negative status or written documentation of Rh status is available. ▪ GC/CT testing per CDC STD Treatment Guidelines ✓ CDC STD Treatment Guidelines ▪ Ultrasound, if indicated* ▪ Other tests as indicated ✓ FYI - Bacterial Vaginosis and Abortion

* *PER Missouri 1 CSR 30-30 E, Ultrasounds at abortion facility to confirm gestational age and for other imaging purposes such as ultrasounds per 188.027(4) shall be performed by a physician or person who holds a current certification by the American Registry for Diagnostic Medical Sonography (ARDMS).*

Reproductive Health Services of Planned Parenthood of the St. Louis Region
4251 Forest Park Avenue, 63108 314-531-7526

QM Monthly Site System Review **Month**_____/_____

To be completed monthly by Director of Surgical Services/Delegate

Site_____ **Auditor**_____

Date	System Reviewed *(During Clinical Operations Including Patient Care/Interactions)*	Guidelines Met	Guidelines Not Met
	Exit and pathways in the surgical center are clear		
	Ceiling vents clear of dust and debris		
	Computer passwords are secured and not visible		
	Universal Precautions used by all staff (Including before & after pt contact) {Initials of staff observed} — Compliant — Non-Compliant Lab staff { } { } { } Sono staff { } { } { } Procedure Room staff { } { } { } Decontamination staff { } { } { } Sterilization staff { } { } { } Environmental Services staff { } { } { }		
	Personal Protective Equipment available & appropriately used (i.e. masks, lab coats, gloves in various sizes, face shield, vinyl gloves, utility gloves) as appropriate for job duty {Initials of staff observed} — Compliant — Non-Compliant Lab staff { } { } { } Sono staff { } { } { } Procedure Room staff { } { } { } Decontamination staff { } { } { } Sterilization staff { } { } { } Environmental Services staff { } { } { }		
	Steps to follow when an accident occurs involving workers compensation is posted and forms readily available for staff		
	Emergency equipment ***audited by designee (_____) (initials)*** Resuscitative equipment First Aid Kit Spill Kit/Supplies Flashlights and back up lighting operable Ammonia Capsules Defibrillator Exit lighting operable Verify Emergency Inventory Checklist for each Procedure Rm & Recovery completed		
	Fire Extinguishers easily accessible, charged, inspection current for monthly and annually		
	MSDS Log current with supplies that are used in the health center: randomly checked the following area & supplies for MSDS sheets **Area** — **Supply Name** — **MSDS—yes/no** **Lab** **Sono** **Procedure** **Decon/Steriliz** **Enviro Services**		

<table>
<tr><th>Date</th><th>System Reviewed
(During Clinical Operations Including Patient Care/Interactions)</th><th>Guidelines Met</th><th>Guidelines Not Met</th></tr>
<tr><td></td><td>Environmental Care: Rooms & Equipment Clean, free from dust & debris
-Overall cleanliness of area (floors, counters, shelving, drawers, cabinets)
-Smooth cleanable surfaces
-Regular and biohazard trash not over flowing containers
-Disinfectant solution available
-Surface decontamination performed per infection control protocol
-Equipment clean
-Carts clean
-Segregation of clean/sterile items
-Shelving for sterile instruments clean and dry with protective barrier on bottom shelf
-Functional work areas physically separated by wall/closed sliding door during instrument reprocessing area (in decontamination area)
-Corrugated boxes not in clinical care/storage areas
<table><tr><th></th><th>Compliant</th><th>Non-Compliant</th></tr><tr><td>Lab Area</td><td></td><td></td></tr><tr><td>Sono rooms</td><td></td><td></td></tr><tr><td>Procedure rooms</td><td></td><td></td></tr><tr><td>Recovery room</td><td></td><td></td></tr><tr><td>Decontamination room</td><td></td><td></td></tr><tr><td>Sterilization room</td><td></td><td></td></tr><tr><td>Storage rooms</td><td></td><td></td></tr><tr><td>Work stations</td><td></td><td></td></tr><tr><td>Education/Interview rooms</td><td></td><td></td></tr></table></td><td></td><td></td></tr>
<tr><td></td><td>Staff use protective equipment for patient interactions, cleaning of rooms and equipment management as necessary</td><td></td><td></td></tr>
<tr><td></td><td>All specimens labeled, handled appropriately and staff follows general packaging requirements</td><td></td><td></td></tr>
<tr><td></td><td>Disposed specimen containers with PHI de-identified before disposal</td><td></td><td></td></tr>
<tr><td></td><td>Single use suction tubing discarded after each procedure</td><td></td><td></td></tr>
<tr><td></td><td>Decontamination receiving and clean/sterilized items separated</td><td></td><td></td></tr>
<tr><td></td><td>Checklist completed by assigned staff
-Daily lab refrig temp & cleaning documented -Decontamination & Sterilization Procedures documented -Sterilizer indicator with each autoclave batch -Weekly & Monthly autoclave cleaning -Daily Spore Testing with each load documented for each autoclave machine-Weekly air jet & Monthly safety valve check</td><td></td><td></td></tr>
<tr><td></td><td>Inventory & Control Logs current and completed</td><td></td><td></td></tr>
<tr><td></td><td>No expired medication/supplies/merchandise on shelves or in clinical area
<table><tr><th></th><th>Compliant</th><th>Non-Compliant</th></tr><tr><td>Lab</td><td></td><td></td></tr><tr><td>Sono rooms</td><td></td><td></td></tr><tr><td>Procedure rooms</td><td></td><td></td></tr><tr><td>Recovery room</td><td></td><td></td></tr><tr><td>Decontamination room</td><td></td><td></td></tr><tr><td>Sterilization room</td><td></td><td></td></tr><tr><td>Storage areas</td><td></td><td></td></tr><tr><td>Wall hung hand sanitizer</td><td></td><td></td></tr></table></td><td></td><td></td></tr>
<tr><td></td><td>Multi-dose vials dated when opened: documentation of date/time opened & staff initials & discarded within 28 days</td><td></td><td></td></tr>
<tr><td></td><td>Multi-dose vials restricted to centralized area of designated nurses station
-Prepared medication syringes in drawer labeled "injectable" medicine at Nurses' Medication Prep Station in recovery area</td><td></td><td></td></tr>
<tr><td></td><td>Controlled substance log has appropriate documentation completed when applicable</td><td></td><td></td></tr>
</table>

<table>
<tr><th>Date</th><th>System Reviewed</th><th>Guidelines Met</th><th>Guidelines Not Met</th></tr>
<tr><td></td><td>Sharp Collectors placed on shelves or in wall brackets
<table>
<tr><th></th><th>Compliant</th><th>Non-Compliant</th></tr>
<tr><td>Lab area</td><td></td><td></td></tr>
<tr><td>Sono room</td><td></td><td></td></tr>
<tr><td>Procedure room</td><td></td><td></td></tr>
<tr><td>Recovery room</td><td></td><td></td></tr>
<tr><td>Decontamination room</td><td></td><td></td></tr>
<tr><td>Sterilization room</td><td></td><td></td></tr>
</table></td><td></td><td></td></tr>
<tr><td></td><td>Potentially infectious waste(i.e. blood soaked products, IV tubing with blood, tissue, POC) in appropriate containers</td><td></td><td></td></tr>
<tr><td></td><td>Disposal of sharps (i.e. needles, lancets, capillary tubes syringes with needles, used microscopic slides & cover slips, etc.) in appropriate sharp containers</td><td></td><td></td></tr>
<tr><td></td><td>Unexpired cleaning supplies & equipment accessible to staff</td><td></td><td></td></tr>
<tr><td></td><td>Clinic Procedure and Laboratory Practices Manual available to staff
Staff can identify how to access</td><td></td><td></td></tr>
<tr><td></td><td>Manufacturer's equipment guidelines for operational usage on site for:
▪ Laboratory Equipment
▪ Decontamination & Sterilization Equipment</td><td></td><td></td></tr>
<tr><td></td><td>Proficiency Log in place for all staff, including staff whose job duties began in current month</td><td></td><td></td></tr>
<tr><td></td><td>Workstations free of hazards</td><td></td><td></td></tr>
</table>

Comments/Corrective Actions:

Manger of Surgical Services/Delegate Review Signature:

Name _____ **Title** _____ **Date**_____

At completion of audit and review by Manger of Surgical Services, form submitted to Director of Quality and Training

Emergency Box: Medications and Supplies for Surgical Services and Reproductive Health Services

Supplies

3cc -5cc Syringes

21g or 22g Needles

Alcohol preps

Tape, Plastic/paper

Nasal cannula

O2 mask

Oxygen tank with liter meter

Angiocath: 18g - 20g (IV)

Sterile 4 x 4 gauze

Exam gloves (non-latex)

Tourniquet

IV start kit

IV tubing

Ringers Lactate (LR) +/or Normal Saline (NS)

Endotracheal equipment:
- Laryngeal mask airway (LMA)
- Ambu bag

IV Bag
30 ml foley catheter
Packing material

Suture kit

Yankauer

Saline flush

Medications

Diphenhydramine hydrochloride (Benadryl)

Epinephrine or EpiPen

Naloxone (Narcan) vial

Flumazenil (Romazicon)

Atropine Sulfate

Pitressin (Vasopressin) 20units/ml vial

Ammonia Capsules

Albuterol inhaler

Misoprostol

1.1.20 Contraception After Surgical Abortion

I. Information regarding all methods of contraception should be offered, and, if requested, a method **must** be provided or referrals given for that method.

II. Providers are encouraged to provide contraception on day of procedure according to the following
   A. CHC
   B. DMPA
   C. Implant
   D. IUC
   E. POPs
   F. Prescription barriers
   G. Non-prescription Methods

✓ See Chapter 6 Contraception — Reversible

III. EC, a prescription for EC, and/or information describing how EC can be obtained should be given to each patient.

1.3 MANAGEMENT OF ABORTION COMPLICATIONS

✓ Refer to ARMS Emergency Manual for management of acute emergencies.

Important Information — When a Surgical Abortion Procedure Must be Completed on the Same Day

A procedure **must** be completed, either at the health center or by transfer to a hospital, under the following circumstances:

- Patient unstable
- Known retained fetal parts when gestational age > to 13 weeks, and onsite resources have been unsuccessful (e.g. misoprostol, oxytocin, consultation with a more experienced provider, etc.)
- Suspected complicated uterine perforation (e.g. second trimester, lateral perforation, evidence of visceral injury)
- Patient unable to return for additional care
- Patient preference

Under any other circumstances, the procedure may be stopped and the patient sent home to return on another day and/or to see another provider.

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Planned Parenthood of the St. Louis Region and Southwest Missouri
4251 Forest Park avenue, Saint Louis, MO 63108 (314)531-7526

Patient Services Orientation Checklist

Name_____Title _____ Date hired ____/____/____

Safety/Security	**Reviewed by**	**Date**	**Employee Initials**
1. Fire Procedures			
2. Evacuation Procedures			
3. Handling Threats via Phones & in Person			
4. Emergency-Numbers & Important Contacts			
5. Panic Button			
6. Emergency Exit			
7. Signature Log			
8. Workers Comp Procedures			
*to be done first day in center and then reviewed during next drill			
9. Staff sign in log			
10. Voluntary Participation Policy signed			

Medical Emergencies	**Reviewed by**	**Date**	**Employee Initials**
1. Personnel Responsibilities			
2. Communicating Emergencies (SBAR)			
3. Contacting Outside Resources (i.e. 911)			
4. CPR Certification			
5. Location & Use of Emergencies Equipment/Supplies			
6. MSDS Sheets			
7. SAB Sites Only-Crash Cart			
*to be done first day in center and then reviewed during next drill			

Infection Control	**Reviewed by**	**Date**	**Employee Initials**
1. Location/Review of OSHA Manual			
2. Review of Infection Control Policy			
3. Personal Protective Equipment & Eyewash Station			
4. Cleaning of Lab, Exam Rooms, U/S equipment, etc			

Emergency Inventory Log

Month: **2019**

PROCEDURE ROOM # ☐ 1 ☐ 2 ☐ 3

(1) Each Unless Otherwise Indicated	Expiration Date	Date	Date	Date	Date	Date
Inspector (initials)*:						
Shelf # 1: Emergency Med. Kit, Saline Flush, Non-Sterile Gloves, Red Folder						
EMERGENCY MEDICATION KIT CONTENTS:						
Atropine 0.1mg/ml						
Diphenhydramine 50mg/ml						
Pitressin (Vasopressin) 20units/ml						
Naloxone 0.4mg/ml						
Flumazenil 1mg/10 ml						
Epi Pen 0.3mg						
Misoprostol 200mcg 4/btl						
50% Dextrose 25g/50mL						
(2) Normal Saline Flush						
3cc syringe w/ needle 21 x 1 (x3)						
Vaginal packing Guaze roll x 6						
Shelf #2: Foley Catheter, Drainage Bag, Catheterization Kit, IV Fluids, IV						
(2) Each Unless Otherwise Indicated	**Expiration Date**	**Date**	**Date**	**Date**	**Date**	**Date**
Inspector (initials)*:						
IV Admin. Set						
IVF Type: LR						
Size: ☐ 500 ml x2 **OR** ☐ 1L						
Drainage Bag						
-Continued-						
(2) Each Unless	**Expiration**	**Date**	**Date**	**Date**	**Date**	**Date**

Emergency Inventory Log

Month: **2019**

PROCEDURE ROOM # ☐ 1 ☐ 2 ☐ 3

Otherwise Indicated	**Date**					
Inspector (initials)*:						
22f/30ml Foley Catheter x 2						
30ml Prefilled Catheterization Kit x 2						
16f/30ml Urethral Catheter x 2						
10f/30ml All Purpose Urethral Catheter x 2						
Vicryl 2.0 stitch x 2						
Foley Drainage bag x 2						
Shelf #3: Oxygen Nasal Cannula, Oxygen Mask, Oral Airway						
Oxygen Nasal Cannula (2)	N/A					
Oxygen Mask (2)	N/A					
Ambu Bag (1)	N/A					
Suction Tubing	N/A					
Yankauer	N/A					

All shelves and items must be clean, dust, dirt and clutter free at all times. Do not store unauthorized items on cart or inside Emergency Kit. IMMEDIATELY report all expired medications to direct supervisor for replacement.

Print Name	Initials	Signature

*Initialing this audit tool indicates an audit was performed; all items were visualized and inspected. Each item is present, quantity and quality ensured at the time of inspection. Immediately report any issues to a clinic supervisor. _____ (sig)

Emergency Inventory Log MONTH: 2019

RECOVERY ROOM

(1) Each Unless Otherwise Indicated	Expiration Date *Grey fill indicates exp. date within 6 months	Date	Date	Date	Date	Date
Inspector (initials)*:						
Atropine 0.1mg/ml						
Diphenhydramine 50mg/ml						
Pitressin (Vasopressin) 20units/ml						
Naloxone 0.4mg/ml						
Flumazenil 1mg/10 ml						
Albuterol Inhaler (2)						
Epi Pen 0.3mg						
IVF 1000ml **OR** 500ml X2 ***indicate type***						
Dextrose 50% 0.5g/ml						
(3) Ammonia Inhalant						
0.9 Sodium Chloride 30ml						
(2) 20g IV Catheter						
(2) 18g IV Catheter						
(3) 21g Needle						
(3) 21g Safety Needle						
(3) 3cc Syringe w/needle						
(3) 5cc Syringe w/needle						
(3) 10cc Syringe w/o needle						

Emergency Inventory Log MONTH: 2019

(1) Each Unless Otherwise Indicated	*Expiration Date* *Grey fill indicates exp. date within 6 months	Date	Date	Date	Date	Date
Inspector (initial)*:						
(3) Normal Saline Flush						
(2) IVF Admin. Set						
(3) IV Heplock						
(3) 23g Blood Collection						
Alcohol Prep Pads	N/A					
(3) Vacutainer	N/A					
(2) Tourniquet (Latex Free)	N/A					
Medical Tape	N/A					
Oxygen Mask	N/A					
Oxygen Nasal Cannula	N/A					
Non-Sterile Exam Gloves	N/A					
Yankauer						
Suction Tubing						
Suction Machine	N/A					
LMA						

Misc. Storage Section Items: Chucks, Emesis Bags, Drape Sheets, Arms Emergency Procedure Ref. Guide

Print Name	Initials	Signature

Emergency Inventory Log MONTH: 2019

*Initialing this audit tool indicates an audit was performed; all items were visualized and inspected. Each item is present, quantity and quality ensured at the time of inspection. Immediately report any issues to a clinic supervisor.

Planned Parenthood
Care. No matter what

Reproductive Health Services of Planned Parenthood of the St. Louis Region

CONTROLLED SUBSTANCE ADMINSTRATION & DISPOSAL LOG

Patient Rm Number: Recovery Room

DRUG NAME & STRENGTH	Page #	BALANCE ON HAND	YEAR

DATE MRN PATIENT NAME PATIENT ADDRESS	AMT DISPENSED (vial)	AMT REC'D (ml)	AMT WASTED (ml)	REASON FOR WASTE: Full vial not given	REASON FOR WASTE: Other	Hour of disposal	BALANCE BROUGHT FORWAD	DISPENSER INITIALS	WITNESS INITIALS	PHYSICIAN NAME

RHS\L:\Templates\Controlled Substance Dispensing Log 040419
BNDD 19 CSR 30-1.078.3.A.5

DRUG NAME & STRENGTH	Page #	BALANCE ON HAND	YEAR

DATE MRN PATIENT NAME PATIENT ADDRESS	AMT DISPENSED (vial)	AMT REC'D (ml)	AMT WASTED (ml)	REASON FOR WASTE: Full vial not given	REASON FOR WASTE: Other	Hour of disposal	BALANCE BROUGHT FORWAD	DISPENSER INITIALS	WITNESS INITIALS	PHYSICIAN NAME

RHS\L:\Templates\Controlled Substance Dispensing Log 040419
BNDD 19 CSR 30-1.078.3.A.5

EXHIBIT C

[redacted]

From: Koebel, William
Sent: Thursday, April 11, 2019 9:51 AM
To: 'kawanna.shannon@ppslr.org' <kawanna.shannon@ppslr.org>; 'Williams, Cathy' <Cathy.Williams@ppslr.org>
Cc: Lanigan, David <David.Lanigan@health.mo.gov>
Subject: Interview Request

Ms. Shannon and Ms. Williams –

As you are aware, DHSS is conducting a complaint investigation and as a result, will need to conduct in-person interviews with the below listed practitioners:

Dr. [redacted]
Dr. Coleen McNicholas
Dr. [redacted]
Dr. [redacted] (I understand that this interview will be telephonic, if Dr. [redacted] is not in the state of MO)
Dr. [redacted]
Dr. [redacted]
[redacted]
Dr. David Eisenberg

Please contact me no later than the close of business **April 16, 2019**, with the interview availability for the above listed practitioners. To protect the integrity of our investigation, It is important to conduct an interview with Dr. [redacted] first, immediately followed by Dr. McNicholas. Please provide the availability for them as well as the remaining practitioners. My intent is to complete these

interviews prior to April 30, 2019, to allow for sufficient time for your agency to address deficient practices identified as a result of the investigation, if any, prior to the expiration of the facility license on May 31, 2019. I look forward to hearing from you. Thanks.

William Koebel, Administrator
Section for Health Standards and Licensure
P.O. Box 570
Jefferson City, MO 65102-0570

EXHIBIT D

STINSON
LEONARD
STREET

Charles W. Hatfield
573.636.6827 **DIRECT**
573.556.3632 **DIRECT FAX**
chuck.hatfield@stinson.com

April 16, 2019

William Koebel
Administrator, Section for Health Standards and Licensure
Missouri Department of Health and Senior Services
P.O. Box 570
Jefferson City, MO 65102-0570

Re: Interview Requests to Reproductive Health Services

Dear Mr. Koebel:

As I have previously communicated to Mr. Wille at your Department, my firm represents abortion facility licensee Reproductive Health Services of Planned Parenthood of the St. Louis Region (RHS). RHS understands that you are conducting an investigation of a patient complaint or complaints, and RHS has previously provided you documents you requested for that investigation, as well as allowing staff to answer your questions about those records and other matters. My understanding is that you previously requested to interview 2 doctors associated with RHS and now, by way of an email dated April 11, 2019, are requesting to interview 7 doctors and a nurse associated with RHS. Your email requested that RHS provide you with the interview availability for these practitioners by close of business today.

RHS has and will continue to cooperate with your investigation, as we take patient complaints very seriously, but at this time RHS is unable to provide the information requested. While these practitioners provide health care services at RHS most, including the practitioner you requested to interview first, have separate counsel. As a result, we have been actively working to reach their counsel and discuss this matter and their willingness to present for these interviews. **We have not completed that process and therefore request an additional two business days to complete the process and provide you with a response.**

Notably, we can find nothing in the law that obligates licensees, as part of their licensure requirements, to interrupt patient care and make these personnel available to be interviewed without some notice of topic or consequences for declining your request. Mr. Wille indicated that, if RHS fails to make these doctors available for unrestricted interviews, the Department "might" consider such failure grounds for discipline. Similarly, your email suggests renewal of RHS's license may be contingent on acceding to your interview request. I can find no basis in the law for that position.

The Department may of course take action against a license when it "finds that there has been a substantial failure to comply with the requirements of sections 197.200 to 197.240." § 197.220, RSMo. But nothing in sections 197.200 to 197.240, RSMo requires personnel to be made available for interviews or even requires the cooperation RHS has already been giving. Nor is declining to have personnel available to speak with inspectors a "substantial failure to comply"

with the licensure statutes. Section 197.230, RSMo governs inspections and investigations of abortion facilities. Conspicuously absent from any of the statutory requirements, including §197.230, RSMo, is an obligation on licensees to cooperate with inspections by making their staff and independent contractors available for interviews. Additionally, the regulations do not require it. Although the regulations allow the Department to investigate patient complaints, the regulations do not require the facility to make personnel available for interviews. Nor does the statute or regulations confer authority on the Department to discipline licensed medical providers.

The fact that the statutes and regulations do not contain any requirement to produce personnel for free-ranging interviews is significant. Other licensure statutes do impose discipline for failure to cooperate with an investigation. *See* §§334.100, 335.066, and 340.264, RSMo. The legislature conferred no similar authority on the Department with respect to ambulatory surgical centers and abortion facilities. *See Wolff Shoe Co. v. Dir. of Revenue*, 762 S.W.2d 29, 32 (Mo. 1988); *see also State v. Reproductive Health Services*, 97 S.W.3d 54, 61 (Mo. 2002).

In addition to the lack of any statutory authority to compel these open-ended interviews, basic due process requires the Department to provide meaningful notice of the patient allegation, including its substance, and any possible sanctions for failure to comply. *See Jamison v. State, Dep't of Soc. Servs., Div. of Family Servs.*, 218 S.W.3d 399, 408–09 (Mo. 2007) (holding investigation "plainly insufficient" to warrant sanction because nurses "were not afforded specific notice of the allegation being investigated" and thus were not afforded "an opportunity to be heard at a meaningful time or in a 'meaningful manner'"); *see also Lewellen v. Franklin*, 441 S.W.3d 136, 146 (Mo. 2014) (due process requires notice of the "severity of the penalty that a State may impose" (internal quotation marks omitted)).

Separate from the question of legal authority, RHS has fully cooperated with your investigation to date and continues to desire this matter be resolved quickly so that it can continue to care for the women of Missouri without further interruption. To that end, RHS is willing to consider various options in order to provide investigators with the information they need including:

- RHS answering written questions posed by the Department;
- Recommending individual attending/supervising physicians answer written questions provided by the Department;
- Recommending individual attending/supervising physicians make themselves available for interviews after the Department provides a list of topics and agrees to reasonable limits.

As we continue to attempt to reach the providers and their counsel, RHS requests that the Department seriously consider the above alternatives. RHS is open to any other suggestions you have on how to get the Department the information it needs without requiring its clinicians to participate in unlimited interviews. **In the interim, RHS requests that the Department provide us in writing with the basis for its authority to proceed with these interviews and the penalty for noncompliance.**

I look forward to hearing from you.

Sincerely,

Stinson Leonard Street LLP

Charles W. Hatfield

CWH:ASC

EXHIBIT E

Wille, Josh

From: Wille, Josh
Sent: Monday, April 22, 2019 11:38 AM
To: 'Hatfield, Charles'
Cc: Moore, Richard; Koebel, William
Subject: FW: LTR to DHSS from Hatfield re RHS Investigation.DOCX

Hi, Chuck. In your April 16 letter you requested that the Department provide the basis for its authority to proceed with the interviews and the penalty for noncompliance. I needed to be out of the office on short notice later last week and didn't get a chance to provide this information to you before I needed to leave. I also note your email from today requesting this information again.

The basis for the authority to proceed with the interviews is the Department's general authority under section 197.230.1 RSMo, which obligates the Department to "make, or cause to be made, such inspections and investigations as it deems necessary." The Department's position is that such inspections and investigations would include witness interviews deemed necessary by the Department to determine whether statutory and regulatory requirements applicable to abortion facilities were being met. In addition to this general authority, 19 CSR 30-30.060(7)(C) obligates the Department to investigate complaints regarding abortion facilities.

The consequences for noncompliance with the laws applicable to abortion facilities are provided in sections 197.220 and 197.293 RSMo, and 19 CSR 30-30.050(2)(I). Under section 197.220 RSMo, the Department may deny, suspend or revoke a license in any case in which the Department finds that there has been a substantial failure to comply with the requirements of sections 197.200 to 197.240, or where the Department finds that the licensure status or record of the applicant indicates that granting a license to the applicant would be detrimental to the interests of the public. In addition to section 197.220 RSMo's powers, section 197.293 RSMo obligates the Department generally to use standards of progressive discipline (generally beginning with a plan of correction) when a deficiency in meeting regulatory standards is found. And under 19 CSR 30-30.050(2)(I), the Department is prohibited from issuing or renewing a license until the Department has inspected the facility and determined that the facility is in compliance with all statutory and regulatory requirements.

Joshua A. Wille
Legal Counsel
Missouri Department of Health and Senior Services
912 Wildwood Drive
Jefferson City, MO 65102
Phone: (573)526-5619
Fax: (573)751-0247

communicating to you via e-mail because you have consented to receive communications via this medium. If you change your mind and want future communication to be sent in a different fashion, please advise our office at once.

From: Wille, Josh
Sent: Wednesday, April 17, 2019 11:48 AM
To: 'Hatfield, Charles' ; Koebel, William
Cc: Moore, Richard
Subject: RE: LTR to DHSS from Hatfield re RHS Investigation.DOCX

Hi, Chuck. We're fine with the request in the letter for the two-day extension. Also, I've copied Richard Moore from my office on this email. Please include him and Bill on any response. Thanks.

Joshua A. Wille
Legal Counsel
Missouri Department of Health and Senior Services
912 Wildwood Drive
Jefferson City, MO 65102
Phone: (573)526-5619
Fax: (573)751-0247

From: Hatfield, Charles <chuck.hatfield@stinson.com>
Sent: Tuesday, April 16, 2019 4:17 PM
To: Koebel, William <William.Koebel@health.mo.gov>; Wille, Josh <Josh.Wille@health.mo.gov>
Cc: Williams, Cathy <Cathy.Williams@ppslr.org>; 'kawanna.shannon@ppslr.org' <kawanna.shannon@ppslr.org>
Subject: LTR to DHSS from Hatfield re RHS Investigation.DOCX

Mr. Koebel and Mr. Wille,

Please see attached letter responding to Mr. Koebel's email to Ms. Shannon and Ms. Williams (April 11, 2019). Happy to discuss at your convenience and see if we can resolve this.

Charles W. Hatfield | Partner | Stinson Leonard Street LLP
230 W. McCarty Street | Jefferson City, MO 65101-1553
T: 573.636.6827 | M: 573.230.2610 | F: 573.556.3632

chuck.hatfield@stinson.com | www.stinson.com
Legal Administrative Assistant: Bethany Cox | 573.556.3604 | bethany.cox@stinson.com

EXHIBIT F

[redacted]

From: Feldhaus, Mark R. <mfeldhaus@lashlybaer.com>
Sent: Tuesday, May 07, 2019 8:46 AM
To: Koebel, William <William.Koebel@health.mo.gov>
Cc: Lanigan, David <David.Lanigan@health.mo.gov>; Voss, Kathy <kvoss@lashlybaer.com>
Subject: RE: Dr. [redacted]

Mr. Koebel,

Thank you for speaking with me this morning. As we discussed, Dr. [redacted] is going to decline your invitation for an interview. Please let me know if you would like to discuss further.

Best regards,

MARK R. FELDHAUS
Attorney at Law
DIRECT: 314 436.8318
mfeldhaus@lashlybaer.com
Licensed in Missouri and Illinois

LASHLY & BAER, P.C.
Attorneys at Law
714 Locust Street St. Louis, MO 63101-1699 TEL: 314 621.2939
20 East Main Street Belleville, IL 62220-1602 TEL: 618 233.5587
FAX: 314 621.6844 www.lashlybaer.com

From: Koebel, William <William.Koebel@health.mo.gov>
Sent: Wednesday, April 24, 2019 2:48 PM
To: Feldhaus, Mark R. <mfeldhaus@lashlybaer.com>
Cc: Lanigan, David <David.Lanigan@health.mo.gov>; Voss, Kathy <kvoss@lashlybaer.com>
Subject: RE: Dr. [redacted]

Mr. Feldhaus:

Thanks for getting back to me. The Department of Health and Senior Services is conducting an investigation regarding Reproductive Health Services (Planned Parenthood- STL). Myself and David Lanigan, Deputy Section Administrator would like to schedule an interview with your client in regard to his work at RHS. Please let me know when this may be possible. Thanks again.

William Koebel, Administrator
Section for Health Standards and Licensure
P.O. Box 570
Jefferson City, MO 65102-0570

From: Feldhaus, Mark R. <mfeldhaus@lashlybaer.com>
Sent: Wednesday, April 24, 2019 8:59 AM
To: Koebel, William <William.Koebel@health.mo.gov>
Cc: Lanigan, David <David.Lanigan@health.mo.gov>; Voss, Kathy <kvoss@lashlybaer.com>
Subject: RE: Dr. [redacted]

Mr. Koebel,

I just returned from an out-of-state deposition, so I apologize for not responding yesterday. I represent Dr. [redacted] a discrete matter. As an initial matter, can you let me know the interview topics in which you are interested so that I may convey the same to Dr. [redacted] Who, specifically, will be interviewing him? I am also in the office today if you wish to speak by telephone.

Best regards,

MARK R. FELDHAUS
Attorney at Law
DIRECT: 314 436.8318
mfeldhaus@lashlybaer.com
Licensed in Missouri and Illinois

LASHLY & BAER, P.C.
Attorneys at Law
714 Locust Street St. Louis, MO 63101-1699 TEL: 314 621.2939
20 East Main Street Belleville, IL 62220-1602 TEL: 618 233.5587
FAX: 314 621.6844 www.lashlybaer.com

From: Koebel, William <William.Koebel@health.mo.gov>
Sent: Monday, April 22, 2019 1:34 PM
To: Feldhaus, Mark R. <mfeldhaus@lashlybaer.com>
Cc: Lanigan, David <David.Lanigan@health.mo.gov>
Subject: Dr. [redacted]

Mr. Feldhaus:

I have been informed that you represent Dr. [redacted] The Missouri Department of Health is conducting an investigation regarding a licensee – Reproductive Health Services, Planned Parenthood in St. Louis, MO. In the course of the investigation, an interview will be required with Dr. [redacted]h and I am contacting you in the interest of arranging an interview. I am aware that Dr. [redacted] does not reside in the state of Missouri and the interview may have to be telephonic. Any assistance you can provide would be helpful. I'll look forward to hearing from you. I can be reached directly at 573-751-6310. Thanks again for your time.

William Koebel, Administrator
Section for Health Standards and Licensure
P.O. Box 570
Jefferson City, MO 65102-0570

calling 573-526-1864. Thank you.

Disclaimer

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EXHIBIT G

[redacted]

From: Russell Makepeace <rmakepeace@sandbergphoenix.com>
Sent: Tuesday, May 21, 2019 4:58 PM
To: Koebel, William <William.Koebel@health.mo.gov>
Subject: RE: Interview requests [SPVG-LIB1.FID1716007]

Thanks, Mr. Koebel. I understand this is time-sensitive, but it's a matter of stress and concern for these young doctors, who are still in training, to sit for interviews with a government agency on topics you won't reveal. I'm sure you understand that. If you remain committed to interrogating the most junior doctors first, without providing any information about the nature of your inquiry or their involvement, I can't recommend that they speak with you. If your position changes, please let me know. Thanks.

Russell

SANDBERG PHOENIX
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Russell Makepeace
Shareholder
600 Washington Ave., 15th Floor
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rmakepeace@sandbergphoenix.com
Tel: 314-231-3332 | Direct: 314-446-4267 | Fax: 314-241-7604
http://www.sandbergphoenix.com

231-3332 or by reply e-mail, and delete this e-mail message and any attachment(s) from your system.

From: Koebel, William [mailto:William.Koebel@health.mo.gov]
Sent: Tuesday, May 21, 2019 9:09 AM
To: Russell Makepeace
Subject: RE: Interview requests [SPVG-LIB1.FID1716007]

Mr. Makepeace –

It's not premature. Unfortunately, I learned from Bob Harr last week that Dr. [redacted] has declined my request for interview, as well as Dr. [redacted]. It was my intent to speak with Dr. [redacted], immediately followed by her supervising physician, Dr. McNicholas. Since that is no longer possible, I'm ready to speak with Dr. [redacted] and will follow her interview by Dr. McNicholas, if available and willing. Since Dr. [redacted] supervising physician has already declined an interview, I can interview Dr. [redacted] on the same day as Dr. [redacted], if that is more convenient for you and them. Please let me know as soon as possible when they are available for interview. As I'm sure you are aware, this is a time sensitive issue. Thanks again.

William Koebel, Administrator
Section for Health Standards and Licensure
P.O. Box 570
Jefferson City, MO 65102-0570

From: Russell Makepeace <rmakepeace@sandbergphoenix.com>
Sent: Monday, May 20, 2019 3:09 PM
To: Koebel, William <William.Koebel@health.mo.gov>
Subject: RE: Interview requests [SPVG-LIB1.FID1716007]

If you're insisting on that order and requesting interviews with [redacted] am I to understand you have interviews set with Dr. [redacted] and Dr. McNicholas already? If not, is this conversation premature?

SANDBERG PHOENIX
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Russell Makepeace
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rmakepeace@sandbergphoenix.com
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http://www.sandbergphoenix.com

From: Koebel, William [mailto:William.Koebel@health.mo.gov]
Sent: Monday, May 20, 2019 1:37 PM
To: Russell Makepeace
Subject: RE: Interview requests [SPVG-LIB1.FID1716007]

Mr. Makepeace-

I have not withdrawn my request to interview the residents you represent. Please let me know when you are able to make [redacted] available for interview, as they provided some of the care in question at RHS. In order to complete our investigation, interviews with practitioners will need to be conducted in the following order: [redacted], Dr. Colleen McNicholas, [redacted] and Dr. David Eisenberg. Please let me know if/when this will be possible. Thanks again.

William Koebel, Administrator
Section for Health Standards and Licensure
P.O. Box 570
Jefferson City, MO 65102-0570

From: Russell Makepeace <rmakepeace@sandbergphoenix.com>
Sent: Monday, May 20, 2019 12:10 PM
To: Koebel, William <William.Koebel@health.mo.gov>
Subject: RE: Interview requests [SPVG-LIB1.FID1716007]

Mr. Koebel,

When last we spoke, I understood you were following up with The Washington University regarding your request for physician interviews. I had anticipated that you would complete the interviews of the WU attendings, as the most knowledgeable physicians involved in the care, then re-evaluate your

needs for additional interviews, including those of the BJH residents I represent. It now sounds like you are withdrawing your requests if the interviews of all seven physicians cannot be scheduled in a particular order. Can you please confirm so that I can update my residents? Thanks.

Russell

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& VON GONTARD P.C.

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http://www.sandbergphoenix.com

From: Koebel, William [mailto:William.Koebel@health.mo.gov]
Sent: Friday, April 26, 2019 12:34 PM
To: Russell Makepeace
Subject: RE: Interview requests [SPVG-LIB1.FID1551280]

I understand your position and I'll let you know what I can in order to assist in your effort to represent your clients. I'll look forward to speaking with you at around 1:00 p.m. Thanks.

William Koebel, Administrator
Section for Health Standards and Licensure
P.O. Box 570
Jefferson City, MO 65102-0570

From: Russell Makepeace <rmakepeace@sandbergphoenix.com>
Sent: Friday, April 26, 2019 10:26 AM
To: Koebel, William <William.Koebel@health.mo.gov>
Subject: RE: Interview requests [SPVG-LIB1.FID1551280]

Mr. Koebel,

Thank you for agreeing to speak with me. I'll try to call you this afternoon, starting at 1 pm. We are of course willing to assist your investigation, but I am not yet able to advise [redacted] regarding your request that they submit for interviews. I'm sure you can appreciate how daunting this request could appear to new physicians. They clearly have a right to counsel, and I can't effectively advise them without knowing the nature of the inquiry and whether they are being accused of wrongdoing. Given that some of the Missouri laws related to abortion can carry criminal and licensure penalties for violation, I need to understand, among other things, how to advise them on their privilege against self-incrimination. Although I would not encourage it, [redacted] need to make an informed decision about whether they want private counsel to advise them on the precise scope, the nuances, and the boundaries of the Fifth Amendment (*Maness v. Meyers*, 419 U.S. 449 (1975)) and its corollary under the Missouri Constitution at Article 1, section 19 (*State ex rel. Munn v. McKelvey*, 733 S.W.2d 765 (Mo. banc 1987)). I recognize your need to protect the integrity of your investigation, but hopefully we can agree on a way forward.

Thanks.

Russell

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rmakepeace@sandbergphoenix.com
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http://www.sandbergphoenix.com

From: Koebel, William [mailto:William.Koebel@health.mo.gov]
Sent: Thursday, April 25, 2019 4:21 PM
To: Russell Makepeace
Cc: Lanigan, David; 'Hannah Nelson'; Anne Justice
Subject: RE: Interview requests

Absolutely. I'll be in the office all day Friday and can be reached directly at 573-751-6310 or 573-526-1864. If I'm not available for some reason when you are able to call, leave a number and I'll get right back with you. Thanks.

William Koebel, Administrator
Section for Health Standards and Licensure

P.O. Box 570
Jefferson City, MO 65102-0570

From: Russell Makepeace <rmakepeace@sandbergphoenix.com>
Sent: Thursday, April 25, 2019 12:21 AM
To: Koebel, William <William.Koebel@health.mo.gov>
Subject: Fwd: Interview requests

Mr. Koebel,
I have been asked to assist Hannah Nelson and Anne Justice with your request regarding interviews of BJH residents. Would you have any availability on Friday to discuss the nature of these interviews? I'm fairly flexible on times.
Thanks.
-Russell Makepeace

From: Hannah Nelson
Sent: Tuesday, April 23, 2019 9:51 AM
To: Koebel, William <William.Koebel@health.mo.gov>
Cc: Anne Justice <anne.justice@bjc.org>
Subject: RE: Interview requests

Mr. Koebel:
Thank you for reaching out. I'm hoping we will have more of an update soon for you. I am going out of the office and my colleague Anne Justice will be on point for this.
Thanks.
Hannah

Hannah Nelson
BJC HealthCare
Senior Counsel
4901 Forest Park Avenue
Suite 1140, Mailstop: 90-75-573
St. Louis, MO 63108
Office Phone: 314-286-0683
Hannah.Nelson@bjc.org

From: Koebel, William [mailto:William.Koebel@health.mo.gov]
Sent: Monday, April 22, 2019 1:23 PM

To: Hannah Nelson <hannah.nelson@bjc.org>
Subject: RE: Interview requests

Ms. Nelson --

I just wanted to follow-up with you regarding our discussion on Friday and ask if you had made a determination as to when/if your clients would be made available for an interview? Thanks.

William Koebel, Administrator
Section for Health Standards and Licensure
P.O. Box 570
Jefferson City, MO 65102-0570

From: Hannah Nelson <hannah.nelson@bjc.org>
Sent: Wednesday, April 17, 2019 5:24 PM
To: Koebel, William <William.Koebel@health.mo.gov>
Subject: Interview requests

Mr. Koebel:
It is my understand DHSS has requested interviews of two Barnes Jewish Hospital residents as part of an investigation at Planned Parenthood. The names I have are [redacted]. Would I be able to discuss this with you or DHSS counsel at your convenience?
Thanks,
Hannah

Hannah Nelson
BJC HealthCare
Senior Counsel
4901 Forest Park Avenue
Suite 1140, Mailstop: 90-75-573
St. Louis, MO 63108
Office Phone: 314-286-0683
Hannah.Nelson@bjc.org

EXHIBIT H

STINSON

Charles W. Hatfield
PARTNER
DIRECT: 573.636.6827
OFFICE: 573.636.6263
chuck.hatfield@stinson.com

May 3, 2019

Joshua A. Wille
Deputy General Counsel
Missouri Department of Health and Senior Services
912 Wildwood Drive
PO Box 570
Jefferson City, MO 65102-0570

Re: Reproductive Health Services of Planned Parenthood of the St Louis Region

Dear Mr. Wille:

I am writing to follow-up regarding the annual inspection and the patient complaint investigation. Reproductive Health Services (RHS) intends to continue to cooperate with the complaint investigation. As you are aware, RHS provided copies of the six requested records, and the Department interviewed RHS's employee on April 24. RHS has also previously offered to answer written questions, and that offer remains. RHS would like to ensure that its licensure renewal is not delayed because of this investigation. RHS hopes either the complaint investigation will be resolved prior to the expiration of RHS's license on May 31, 2019, or the process for licensure renewal will continue promptly and unencumbered by the ongoing complaint investigation.

I am aware that the Department has not interviewed the physicians you requested to interview. As RHS has informed you, the physicians who the Department has requested to interview are not RHS employees and are represented by their own counsel. RHS provided the Department with the names of those counsel, and it is my understanding the Department contacted those lawyers to schedule the remaining interviews. RHS continues to be in contact with those attorneys as well. As such, we hope the Department can move forward on RHS's licensure renewal even if these interviews are not completed by May 31. As we have previously communicated, it would facilitate the process greatly if the Department would identify the scope of topics about which the Department wishes to conduct interviews. As you and I discussed, any lawyer would be understandably cautious about producing a client for an interview with the government without knowing the topics to be covered, particularly when there is no clear authority requiring participation in interviews.

Separate from the patient complaint investigation with which we intend to continue to cooperate, the Department conducted its annual onsite licensure survey of RHS on March 11, 12, and 13, 2019. During that survey, Department inspectors interviewed several physicians and staff. The Department then submitted written follow-up questions by email on March 20, to which RHS answered in writing on March 25. The Department sent RHS a statement of deficiency on March 27, and RHS submitted a plan of correction by the extended deadline on April 9. Because the Department's licensure inspection is complete, we respectfully request that the Department respond to the plan of correction we submitted more than three weeks ago so RHS's license can be

reissued without delay and by the current license's expiration date of May 31, 2019, to ensure that Missouri women's sole access to abortion services remains uninterrupted.
Principles of due process and section 197.293, RSMo., require the Department to provide notice of any deficiency and allow RHS sufficient time to develop and implement a plan of correction before it may take any licensure action. In order to avoid any interruption in services, we expect the Department shortly to make a determination on RHS's April 9 plan of correction, so that if any revised plan is necessary, it can be submitted, reviewed, and approved by May 31. Separately, we expect that if the Department finds any deficiency as a result of its patient complaint investigation, it promptly provide RHS with notice of such deficiency and a reasonable opportunity to respond and implement a plan of correction *before* any action is taken on RHS's license.

Accordingly, please confirm by May 7 when RHS can expect a determination on its plan of correction.

Finally, as you are aware, yesterday I received a notification that the Department intends to "collect additional records" from RHS. The Department has expressed its position that subsection 197.230.2 prohibits the Department from providing notice of the date and time when Department inspectors will return to RHS to collect patient records, but that provision states only that the Department must make or cause at least one unannounced inspection per year. It does not say not that every inspection the Department conducts of abortion facilities be unannounced. Further, the Department cited no authority allowing its employees to "collect" protected patient records and remove them from RHS's facility (rather than just "inspecting" them onsite). As you are aware, patient medical records are of the utmost 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's facility.

Sincerely,

Stinson LLP

Charles W. Hatfield

CWH:krp

EXHIBIT I

Wille, Josh

From: Wille, Josh
Sent: Monday, May 6, 2019 4:58 PM
To: 'Hatfield, Charles'
Cc: 'Muniz, Richard'; Moore, Richard
Subject: RE: 2019.05.03 LTR to Wille from Hatfield re RHS.PDF

Chuck, this is regarding the last part of your letter about the Department's upcoming visit and patient records. I agree that section 197.230.2 RSMo doesn't require that the return visit to RHS to collect additional records be unannounced. Mr. Koebel and Mr. Lanigan plan to arrive at RHS on May 8, 2019, at approximately 10:00 AM.

As for the authority to remove records from RHS's facility, it should be clarified that the Department would seek only to remove *copies* of records from RHS, not the records themselves. The authority to do that here—for an investigation the Department has deemed necessary to assure compliance with statutory and regulatory requirements—is part of the Department's duty to "make, or cause to be made, such inspections and investigations as it deems necessary." § 197.230.1 RSMo. At least one court has recognized that "lawful statutory authority to search . . . 'carries with it the right to examine and photocopy' the records inspected." *United States v. Goff*, 677 F. Supp. 1526, 1538 (D. Utah 1987), *on reconsideration*, 736 F. Supp. 1087 (D. Utah 1990).

Copying of records occurs routinely with all provider types inspected and investigated by the Department. The review of records necessary to determine compliance is not always able to be completed during the limited time surveyors are onsite. Records are also copied as necessary to support findings of noncompliance. Collecting information during a statutorily authorized inspection or evaluation of an abortion facility (as well as other health facilities and agencies) is also expressly contemplated by section 197.477 RSMo, which governs such information and requires that it be kept confidential (except for certain reports).

I agree that patient medical records, while necessary for the investigation, contain very sensitive information. These records are protected statutorily by the confidentiality required by section 197.477 RSMo. In addition, within the Department, such records are securely kept in offices with restricted access and are permitted to be reviewed only by those limited employees who need the information for their duties.

Joshua A. Wille
Legal Counsel
Missouri Department of Health and Senior Services
912 Wildwood Drive
Jefferson City, MO 65102
Phone: (573)526-5619
Fax: (573)751-0247

firm's computers or even some computer unconnected to either of us which the e-mail passes through. This office is communicating to you via e-mail because you have consented to receive communications via this medium. If you change your mind and want future communication to be sent in a different fashion, please advise our office at once.

From: Hatfield, Charles <chuck.hatfield@stinson.com>
Sent: Friday, May 3, 2019 4:05 PM
To: Wille, Josh <Josh.Wille@health.mo.gov>
Cc: 'Muniz, Richard' <richard.muniz@ppfa.org>
Subject: FW: 2019.05.03 LTR to Wille from Hatfield re RHS.PDF

Josh, see attached letter regarding the RHS inspection and the RHS investigation.

Charles W. Hatfield
Partner

STINSON LLP
230 W. McCarty Street
Jefferson City, MO 65101-1553
Direct: 573.636.6827 \ Mobile: 573.230.2610

Assistant: Bethany Cox \ 573.556.3604 \ bethany.cox@stinson.com

STINSON.COM
Our name has changed to Stinson LLP. Please update your records.

From: Page, Kristina R. <kristina.page@stinson.com>
Sent: Friday, May 03, 2019 3:59 PM
To: Hatfield, Charles <chuck.hatfield@stinson.com>
Subject: 2019.05.03 LTR to Wille from Hatfield re RHS.PDF

Kristina R. Page
Legal Administrative Assistant
Jefferson City
573.556.3614
x63614

Wille, Josh

From: Wille, Josh
Sent: Tuesday, May 7, 2019 5:28 PM
To: 'Hatfield, Charles'
Cc: 'Muniz, Richard'; Moore, Richard
Subject: RE: 2019.05.03 LTR to Wille from Hatfield re RHS.PDF

Chuck, this is in regard to the request that the Department confirm when RHS can expect a determination on its Plan of Correction. As has been communicated to RHS, the Department became aware of additional issues regarding RHS's compliance with the statutory and regulatory requirements of abortion facilities after the annual inspection. The Department is investigating those issues, which includes attempting to interview the physicians noted in your letter as well as collecting relevant records (with a visit planned to occur tomorrow, May 8, 2019). Because there is no date established for when the Department will be able to interview the physicians, and because RHS has not yet confirmed whether the Department will be able to collect records, the Department cannot yet confirm a date when when RHS can expect a determination on its Plan of Correction.

Joshua A. Wille
Legal Counsel
Missouri Department of Health and Senior Services
912 Wildwood Drive
Jefferson City, MO 65102
Phone: (573)526-5619
Fax: (573)751-0247

From: Hatfield, Charles <chuck.hatfield@stinson.com>
Sent: Friday, May 3, 2019 4:05 PM
To: Wille, Josh <Josh.Wille@health.mo.gov>
Cc: 'Muniz, Richard' <richard.muniz@ppfa.org>
Subject: FW: 2019.05.03 LTR to Wille from Hatfield re RHS.PDF

Josh, see attached letter regarding the RHS inspection and the RHS investigation.

Charles W. Hatfield
Partner

STINSON LLP
230 W. McCarty Street
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Direct: 573.636.6827 \ Mobile: 573.230.2610

Assistant: Bethany Cox \ 573.556.3604 \ bethany.cox@stinson.com

STINSON.COM
Our name has changed to Stinson LLP. Please update your records.

From: Page, Kristina R. <kristina.page@stinson.com>
Sent: Friday, May 03, 2019 3:59 PM
To: Hatfield, Charles <chuck.hatfield@stinson.com>
Subject: 2019.05.03 LTR to Wille from Hatfield re RHS.PDF

Kristina R. Page
Legal Administrative Assistant
Jefferson City
573.556.3614
x63614

EXHIBIT J

Wille, Josh

From: Muniz, Richard <richard.muniz@ppfa.org>
Sent: Thursday, May 16, 2019 4:38 PM
To: Wille, Josh
Cc: Hatfield, Charles; Moore, Richard
Subject: Re: FW: Collection of records and physician interviews needed - RHS

Josh --

I am writing with an update and to inquire again about RHS's licensure status. As you know, the Department recently requested copies of: (1) a patient roster for September 5, 2018; (2) records for the 17 patients seen on September 5, 2018; (3) the supervisory note for a patient seen on September 5, 2018; (4) the April 16, 2019 record for a patient; and (5) chapters of RHS's Policy and Procedures Manual. After receiving an assurance from you that the documents the Department sought would be held confidential under section 197.477, RSMo. because they are part of an inspection or evaluation, RHS provided those documents on May 11—with the exception of the fourth request regarding the April 16 clinic record of a patient, because RHS did not have an encounter with that patient on that date. You then clarified which records from that patient you were seeking, which we then provided on May 13. On May 14, the Department requested a copy of RHS's policy for physician credentialing, which I provided today.

Then, on May 15, the Department requested (1) the dates of QAPI meetings held in 2018, (2) the identity and position of personnel in attendance, and (3) documentation of what actions were taken to address identified problems during that time period. RHS is processing those requests.

With respect to the interviews of the physicians requested by the Department, it is my understanding that counsel for Washington University made the Department aware that Dr. Eisenberg would sit for an interview Friday, May 17, and Dr. McNicholas some time next week. Despite that these physicians are the ones responsible for the care provided at RHS when they are the attending physician, the Department rejected those offers because: "As I have previously made known to RHS, in order to complete our investigation, interviews with practitioners will need to be conducted in the following order: Dr. Amy Addante, Dr. Colleen McNicholas, Dr. Ann Bruno, Dr. Kelsey Oelrich, Dr. Gillian Schivone, Dr. Justin Diedrich and Dr. David Eisenberg."

As an initial matter, I note that this order actually differs somewhat from what you provided to RHS on April 11; the Department then listed the providers in the following order: Dr. Amy Addante; Dr. Colleen McNicholas; Dr. Ann Bruno; Dr. Justin Diedrich; Dr. Kelsey Olerich; Dr. Gillian Schivone; Wendy Ann Stamilio, RN; and, Dr. David Eisenberg. While the Department did request to "conduct an interview with Dr. Addante first, immediately followed by Dr. McNicholas," it was far from clear that this was a mandatory order because, as you know, on April 24, the Department interviewed RHS's employee, nurse Wendy Stamilio, although she was listed seventh on the initial list of eight.

We are unable to understand why the Department would request but then refuse to interview Drs. McNicholas and Eisenberg. Drs. Eisenberg and McNicholas (along with Dr. Madden, who you've not requested to interview) supervise all care provided by trainees at RHS, and thus any questions you may have about the care provided by attending physicians or their trainees could have been explored in interviews with them. Your demand to interview the Barnes Jewish Hospital residents is even more unreasonable, as those residents have not provided care at RHS since September 2018, when their clinical rotation at RHS ended, and there is no plan to have them return to RHS.

Finally, as you know, the physicians are not RHS employees, and therefore, we are unable to compel them to sit for an interview—particularly a free-ranging interview and under circumstances in which the Department has indicated it could make criminal or board of healing arts referrals.

We have previously raised that RHS's current license expires on May 31 and specifically requested that the licensure renewal process be completed so that there is no lapse in service. It has now been over one month since RHS timely submitted its plan of correction—on April 9—in response to the Department's March 25 statement of deficiency. Despite ample time for the Department to process and respond to the plan of correction, you've indicated that "the Department became aware of additional issues regarding RHS's compliance with the statutory and regulatory requirements of abortion facilities after the annual inspection" that the Department was investigating, though you have not indicated what those issues are or otherwise provided notice of any additional deficiencies to RHS, as required by section 197.293, RSMo. You also stated that "[b]ecause there is no date established for when the Department will be able to interview the physicians, and because RHS has not yet confirmed whether the Department will be able to collect records, the Department cannot yet confirm a date when when [*sic*] RHS can expect a determination on its Plan of Correction." As I noted above, RHS has provided the additional records that you referenced (as well as other documents since), and the two attending physicians responsible for the care provided by trainees at RHS that you asked to interview have offered to do so.

As you are well aware, RHS has been licensed by the Department to provide health care services to Missouri women for many years, and it is now the only available abortion provider in the state of Missouri. Its license expiration is only two weeks away. Given RHS's compliance with all the Department's demands over the past two months, including but not limited to on-site inspections, review of medical and other records, RHS's provision of records to the Department, interviews of employees, as well as the offer to interview non-employees, we expect a response to our plan of correction to allow RHS and the Department sufficient time to resolve any outstanding issues so that its the license can be renewed so that Missouri women are able to continue to exercise their constitutional right to choose. We, therefore, request that you respond to **our plan of correction by Noon CT on Monday, May 20, 2019. If you do not, we will assume you have denied our license renewal application.**

Although the Department has not shared with RHS information about the patient complaint that is the subject of its investigation, it appears possible that the Department may have concerns with how RHS complies with sections 188.027.6 and 188.047, RSMo., which relate to informed content and tissue examinations, respectively. Historically, when the Department has concerns about an interpretation of a statute or regulation on abortion, the Department has advised us of its interpretation, and RHS, through the plan-of-correction process, has adjusted its practices to meet the Department's interpretation going forward. It appears, however, the Department has no interest in working with RHS to develop and implement a plan of correction that would address any issues the Department may have. This is unfortunate; we remain committed to working with the Department on these and any other issues so that the license can be renewed without any disruption of service.

Best,
Richard

On Mon, May 13, 2019 at 11:50 AM Muniz, Richard <richard.muniz@ppfa.org> wrote:
Josh -- Bill Koebel can access those outside records from 4/16/2019 for that patient here.

On Sat, May 11, 2019 at 3:51 PM Wille, Josh <Josh.Wille@health.mo.gov> wrote:
Thanks, Richard. For Patient 15884, I believe the record would be an outpatient clinic note from a clinic outside of RHS where the patient was seen on 4/16/19. If RHS has that record, that's what we are seeking.

From: Muniz, Richard <richard.muniz@ppfa.org>
Sent: Saturday, May 11, 2019 11:59:58 AM
To: Wille, Josh
Cc: Hatfield, Charles; Moore, Richard
Subject: Re: FW: Collection of records and physician interviews needed - RHS

Josh -- Thank you for your assurance that the documents the Department seeks would be during an inspection or evaluation and thus must be held confidential under section 197.477, RSMo., including patient records, patient roster from 9/5/2018, and chapters 1.1, 1.2, and 1.3 of RHS's confidential and proprietary Manual of Medical Standards and Guidelines. With this assurance, and given RHS's commitment to cooperate with the investigation so that this matter can be resolved promptly without any interruption of services, RHS will provide the information requested—with redactions of any PII excepting patient numbers. With regard to the record of patient 158884 on April 16, 2019, I have been advised that there was no encounter with that patient at RHS on that date. Mr. Koebel can download these documents here.

On Fri, May 10, 2019 at 11:54 AM Wille, Josh <Josh.Wille@health.mo.gov> wrote:

Richard, I should have also asked, is RHS agreeing to provide Chapters 1.1, 1.2, and 1.3 of their Policy and Procedures Manual? If so, we would like to receive a copy of that today. It can be emailed to William.Koebel@health.mo.gov, or we can come pick it up if RHS prefers.

Joshua A. Wille

Legal Counsel

Missouri Department of Health and Senior Services

912 Wildwood Drive

Jefferson City, MO 65102

Phone: (573)526-5619

Fax: (573)751-0247

From: Wille, Josh
Sent: Friday, May 10, 2019 8:27 AM
To: 'Muniz, Richard' <richard.muniz@ppfa.org>
Cc: Hatfield, Charles <chuck.hatfield@stinson.com>; Moore, Richard <Richard.Moore@health.mo.gov>
Subject: RE: Collection of records and physician interviews needed - RHS

Richard, a person who submits a Sunshine request for abortion-facility-investigation records can receive the reports disclosable under section 197.477 RSMo, but "[a]ll other information whatsoever . . . collected during such inspections or evaluations or information which is derived as a result of such inspections or evaluations shall be confidential . . . ." I don't think a Missouri court would be persuaded by an argument that an investigation pursuant to one of the statutes referenced in section 197.477 RSMo doesn't constitute an "inspection or evaluation" under section 197.477 RSMo; the investigation at the very least would entail an "evaluation" of the information collected.

The patient records we are seeking would be collected during an inspection or evaluation under section 197.230.1 RSMo, so section 197.477 RSMo applies. They aren't reports that are disclosable under section 197.477 RSMo, so they shall be confidential under that statute. Because they shall be confidential, they would be "protected from disclosure by law" under section 610.021(14) RSMo. This sort of reasoning has supported my decision to close abortion-facility-investigation records in response to Sunshine requests up to this point, and I can think of no plausible reason why it should or would not be applied going forward.

Joshua A. Wille

Legal Counsel

Missouri Department of Health and Senior Services

912 Wildwood Drive

Jefferson City, MO 65102

Phone: (573)526-5619

Fax: (573)751-0247

From: Muniz, Richard <richard.muniz@ppfa.org>
Sent: Thursday, May 9, 2019 5:19 PM
To: Wille, Josh <Josh.Wille@health.mo.gov>
Cc: Hatfield, Charles <chuck.hatfield@stinson.com>; Moore, Richard <Richard.Moore@health.mo.gov>
Subject: Re: Collection of records and physician interviews needed - RHS

Josh --

In your May 6 email to Chuck and me, you referenced the confidentiality requirement in section 197.477, RSMo. That statute, by its terms, applies only to "inspection[s] or evalution[s]" of licensed health-care facilities. As you have previously stated, the Department has invoked 197.230.1, RSMo., as its authority to conduct the ongoing complaint "investigation," and it is pursuant to that authority that the Department seeks copies of additional patient records. It appears, then, section 197.477 does not offer the protection you say it provides for patient records provided to the Department as part of its investigation of RHS, and as a result, the Department may be obligated to disclose the records under the Sunshine Law.
As you well know, the Fourteenth Amendment protects an individual interest in avoiding disclosure of personal matters, and in particular, medical information including an individual's decision to obtain an abortion. *See Eagle v. Morgan*, 88 F.3d 620, 625 (8th Cir. 1996) (quoting *Whalen v. Roe*, 429 U.S. 589 (1977)). We appreciate the Department's willingness to accept records that have been redacted of patient-identifying information, but I know the Department agrees that even redacted information does not fully protect a patient's privacy. *See Nw. Mem'l Hosp. v. Ashcroft*, 362 F.3d 923, 924, 928-29 (7th Cir. 2004); 45 C.F.R. § 164.514.

Thus, to protect RHS's patients' constitutionally protected interest in avoiding disclosure of their health care and information, RHS will agree to provide Department employees with copies of patient records after they have been redacted of any patient identifying information (except for the patient numbers) and only after it receives written assurance that information obtained from the patient's medical record will be maintained confidential, including records previously provided or provided in the future as part of the investigation, because the Department agrees such information is protected from disclosure by law. *See* § 610.021(14), RSMo. (exempting "[r]ecords which are protected from disclosure by law").

As we've stated several times, RHS intends to cooperate so that this matter can be resolved quickly and RHS's license can be renewed by June 1.

Best,
Richard

On Thu, May 9, 2019 at 5:36 PM Wille, Josh <Josh.Wille@health.mo.gov> wrote:

They need copies of documents they've already inspected because all that they have now from yesterday are their notes of what the documents show, rather than copies of the documents themselves. Copies of the documents themselves are better representations of what the documents show than notes of what those documents show. They also need copies of the documents to support deficiencies being cited related to those records.

Patient records without patient-identifying information would work well for us, so long as the patient numbers are shown or we are provided them for each patient. Here's what we're seeking in that regard:

- A patient roster for September 5, 2018;
- Medical-record and informed-consent records for each patient seen on September 5, 2018;
- The supervisory note for Dr. [redacted] on September 5, 2018, related to Patient #110940; and
- The clinic record for Patient #158884 from April 16, 2019.

We're also seeking copies of Chapters 1.1, 1.2, and 1.3 of RHS's Policy and Procedures Manual. The requested records can be sent to Bill Koebel at William.Koebel@health.mo.gov. Thanks.

Joshua A. Wille

Legal Counsel

Missouri Department of Health and Senior Services

912 Wildwood Drive

Jefferson City, MO 65102

Phone: (573)526-5619

Fax: (573)751-0247

From: Hatfield, Charles <chuck.hatfield@stinson.com>
Sent: Thursday, May 9, 2019 8:45 AM
To: Wille, Josh <Josh.Wille@health.mo.gov>
Cc: Moore, Richard <Richard.Moore@health.mo.gov>; 'Muniz, Richard' <richard.muniz@ppfa.org>
Subject: RE: Collection of records and physician interviews needed - RHS

Why would they need copies of documents they have already inspected?

I don't think we are opposed to providing copies without identifying patient information if you will send me a list of the documents you want. But I will need to review for client.

Charles W. Hatfield
Partner

STINSON LLP
230 W. McCarty Street
Jefferson City, MO 65101-1553
Direct: 573.636.6827 \ Mobile: 573.230.2610

Assistant: Bethany Cox \ 573.556.3604 \ bethany.cox@stinson.com

STINSON.COM

Our name has changed to Stinson LLP. Please update your records.

From: Wille, Josh <Josh.Wille@health.mo.gov>
Sent: Thursday, May 09, 2019 8:40 AM
To: Hatfield, Charles <chuck.hatfield@stinson.com>
Cc: Moore, Richard <Richard.Moore@health.mo.gov>
Subject: Collection of records and physician interviews needed - RHS

External Email – Use Caution

Chuck, I understand that Bill Koebel and David Lanigan from the Department were permitted to review but not copy and collect RHS's records—including RHS's policies which have no patient information—during their visit at RHS yesterday. Collecting records is a routine part of the Department's inspections and investigations for all provider types, and the Department had done so as part of its inspections and investigations of RHS with no apparent concerns until yesterday's visit. As with the physician interviews that the Department has unsuccessfully been attempting to conduct regarding issues stemming from the patient records collected from RHS on April 2 and 3, 2019, the collection of RHS's records is a necessary part of the Department's investigation that must occur for the Department to determine whether RHS is in compliance with statutory and regulatory requirements.

Joshua A. Wille

Legal Counsel

Missouri Department of Health and Senior Services

912 Wildwood Drive

Jefferson City, MO 65102

Phone: (573)526-5619

Fax: (573)751-0247

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--

Richard Muniz
Staff Attorney, Public Policy Litigation & Law
Planned Parenthood Federation of America
202-973-4997

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Staff Attorney, Public Policy Litigation & Law

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EXHIBIT K

[redacted]

From: Koebel, William
Sent: Wednesday, May 15, 2019 8:42 AM
To: 'Robert T. Haar' <roberthaar@haar-woods.com>
Subject: Physician Interviews

Mr. Harr-

In reference to our conversation yesterday afternoon: As I have previously made known to RHS, in order to complete our investigation, interviews with practitioners will need to be conducted in the following order: Dr. [redacted] Dr. Colleen McNicholas, Dr. [redacted], Dr. [redacted] and Dr. David Eisenberg. Please let me know if this will be possible. Thanks again.

William Koebel, Administrator
Section for Health Standards and Licensure
P.O. Box 570
Jefferson City, MO 65102-0570

calling 573-526-1864. Thank you.

EXHIBIT L

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired and Voice dial: 711

Randall W. Williams, MD, FACOG
Director

Michael L. Parson
Governor

May 20, 2019

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

Re: POC Rejection / Incomplete Investigation

Dear Ms. Williams:

On April 9, 2019, our Bureau of Ambulatory Care received your Plan of Correction as a result of a Licensure inspection conducted on March 13, 2019. Your Plan of Correction is not acceptable as submitted. The following issues need additional clarification and/or information in order for the Plan of Correction to be acceptable, and we recommend that you submit an amended Plan of Correction that addresses these issues promptly. These areas are as follows:

In reference to the deficiency identified in ***L-1076***- Regarding patient #10, the Statement of Deficiencies (SOD) misidentified Staff AA as the physician who induced the medication abortion and will be updated to reflect the removal of that statement (revised SOD attached). Second, in accordance with section 188.027.6 RSMo, the physician performing the physician portion of the informed consent must be the same physician who performs or induces the abortion. A supervising physician who is merely present in the building without taking any active role in performing or inducing the abortion—while a resident or fellow actually performs or induces the abortion—does not "perform or induce" the abortion under the statute. Your proposed Plan of Correction states that, in the two specific instances cited in the SOD, the supervising physician who carried out the physician portion of the informed consent actively participated in inducing the abortion. But our investigation commenced on April 3, 2019, has identified additional instances in which medical records indicate that the physician who carried out the physician portion of the informed consent differed from the physician who performed or induced the abortion. We have been unable to verify the fact or extent of your compliance with this requirement because several physicians identified in those records have refused to participate in interviews. The Plan of Correction fails to provide adequate assurance of compliance and fails to identify the systemic changes that will be implemented to ensure that the deficient practice will not recur. The description must be specific, realistic and complete.

In reference to the deficiency identified in ***L-1103***- A pelvic examination must be completed prior to every abortion for the purpose of "*determining the duration of gestation, identifying preexisting medical or other complications, and detecting factors which could influence the choice of the procedure, anesthesia, or preoperative and postoperative management*" in accordance with 19 CSR 30-30.060(2)(D) (emphasis added). Inspectors found that pelvic examinations were performed immediately prior to the actual abortion procedure in the case of surgical abortions, not meeting the purpose of the

requirement, which as noted above includes "detecting factors which could influence the choice of the procedure." Additionally, your policy indicates a pelvic examination is completed for medication abortions only "when indicated (e.g., vaginal bleeding or abdominal/pelvic pain, or as required by Missouri regulations)." This suggests that there may be times when a pelvic examination would not be required by Missouri regulations, which is not correct under 19 CSR 30-30.060(2)(D). The Plan of Correction fails to identify the systemic changes that will be implemented to ensure that the purpose of the rule is met and the deficient practice will not recur. The description must be specific, realistic and complete.

In reference to the deficiency identified in ***L-1131-*** Please provide more specific information regarding the frequency and type of audits that will be completed to ensure compliance is maintained.

Please submit a revised Plan of Correction with the above mentioned information as soon as possible via email to BAC@health.mo.gov or fax to (573) 751-6648 or mail to Missouri Department of Health and Senior Services, Bureau of Ambulatory Care, P.O. Box 570, Jefferson City, MO 65102-0570. I have attached a detailed instruction sheet for your reference.

On April 3, 2019, you were notified of a complaint investigation regarding Reproductive Health Services of Planned Parenthood of the St. Louis Region (RHS). As part of the investigation, interviews were requested with your physician abortion providers. To date, RHS has been unable to produce some physician abortion providers, as identified in the medical records, for interview with Department Inspectors. As a result of the investigation, more than thirty (30) potential deficient practices were identified, including but not limited to those discussed above. Please note that the Department cannot complete our investigation as required until we interview the physicians involved in the care provided in the potential deficient practices, noted above, at the facility. Historically, RHS has always provided physicians for interview. This is also the standard practice across all regulated provider types.

The Department is in receipt of your licensure renewal application, received on May 16, 2019. As I have informed RHS staff since April 3, 2019, the complaint investigation needs to be completed and any deficiencies resolved before the expiration of RHS's license on May 31, 2019. And on April 22, 2019, RHS was also notified in relation to the the requested physician interviews of the prohibition in 19 CSR 30-30.050(2)(I), which states: "No license shall be issued or renewed by the department until the department has inspected the facility and determined that it is in compliance with all requirements of applicable statutes and regulations." As indicated above, until the Department interviews the physicians, we cannot complete our investigation and determine compliance with all applicable statutes and regulations.

Sincerely,

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

EXHIBIT M

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 _____	03/13/2019

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 licensure survey was conducted from 03/11/19 to 03/13/19 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). See below for findings:	L 000		
L 069	19 CSR 30-30.020(1)(A)(6) A written plan shall provide A written plan shall provide for the evacuation of patients, visitors and personnel in the event of fire or other disaster within the facility and for an alarm system to notify personnel. Personnel are to be acquainted with the evacuation plan to properly perform their duties in the event of a fire or disaster. This regulation is not met as evidenced by: Based on policy review, record review, and interview, the facility failed to ensure that all employees participated in a fire drill at least annually. The Abortion Facility does an average of 216 cases per month. On the first day of the survey, there were 21 procedures. Findings included: 1. Review of the facility's policy titled, "Natural Disasters, Chemical Attacks, and Physical Actions," dated 04/18, showed that fire drills are performed at least annually. All staff should be involved. The drill is to familiarize staff with assigned emergency duties.	L 069		

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

Facility Name	Reproductive Health Services of Planned Parenthood	Survey Exit Date	3/13/19
Facility Address/ City/Zip	4251 Forest Park Avenue, St. Louis, MO 63108	Statement of Deficiencies (SOD): L-tags	L-1076, L-1103, L-1131

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

2. **Required elements of an acceptable Plan of Correction. Each** deficiency shall be addressed separately by completing the applicable information for **all** elements below for every citation.

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

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

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

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

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

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

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

A (TAG)	B (CORRECTIVE ACTION)	C (WHEN)	D (WHO)	E (EVIDENCE OF COMPLIANCE)	F
ID/tag number (L1128)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date	Title of Person Responsible for Correction. No names	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "D"	Evidence/ Exhibit Attachment Numbers or "N/A"
L-1076 & L-1103	On May 20, 2019, RHS received a letter responding to the Plan of Correction it timely submitted on April 9, 2019, in response to the Statement of Deficiencies issued by the Department on March 25, 2019. The Department's May 20 letter seeks additional clarification or information regarding RHS's Plan of Correction of three cited deficiencies. RHS appreciates this opportunity to provide additional clarification and/or information on these three deficiencies, and understands its Plan of Correction of all other deficiencies identified in the Statement of Deficiency to be acceptable to the Department. As the Department is aware, our license is scheduled to expire on May 31, 2019, and RHS has been endeavoring in good faith to resolve the issues raised by the Department, including by making multiple physicians available for interviews, providing patient records, and otherwise complying with the Department's investigation. RHS once again asks the Department to renew its license prior to the May 31 expiration date, and to respond to this amended Plan of Corrections by Friday, May 24. RHS takes our responsibility to provide the best possible care for our patients very seriously. We are committed to			See column B (CORRECTIVE ACTION)	N/A

A (TAG)	B (CORRECTIVE ACTION)	C (WHEN)	D (WHO)	E (EVIDENCE OF COMPLIANCE)	F
ID/tag number (L1128)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date	Title of Person Responsible for Correction. No names	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "D"	Evidence/ Exhibit Attachment Numbers or "N/A"
	the highest medical, legal, and ethical standards. The health and safety of our patients is our top priority. Ensuring the health and safety of our patients is central to our mission and fundamental to every person who works at RHS. RHS adheres to the highest standards, and we take swift action to correct any deficiency if we ever discover that these standards are not being met. As a high-quality health care provider, we constantly strive to improve, and we welcome all opportunities to do so. We always cooperate fully with all Department inspections and quickly address any issues that officials share with us. And we are committed to doing so in the future, because we are committed to our patients and providing them the best care. Under section 188.027.6 RSMo., "[t]he physician who is to perform or induce the abortion shall, at least seventy-two hours prior to such procedure, inform the woman orally and in person of" the information required in the statute. As RHS observed in the April Plan of Correction, with regard to the two patients identified (#7 and #10), the physician who consented the patient also provided the procedure to the patient. The Department's May 20 letter appears to acknowledge that there is no deficiency with				

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ID/tag number (L1128)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date	Title of Person Responsible for Correction. No names	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "D"	Evidence/ Exhibit Attachment Numbers or "N/A"
	regard to these two patients. Nevertheless, the Department references unspecified "additional instances" in which the physician providing the state-mandated information "differed" from the physician who provided the abortion. But in the very next sentence, the letter states that the Department has "been unable to verify the fact or extent of your compliance." Moreover, the Department expresses concern that a supervising physician who "is merely present in the building without taking any active role in perform or inducing the abortion" is not a physician who performs or induces an abortion within the meaning of section 188.027.6. As RHS noted in its Plan of Correction, the Department advised the Circuit Court of Jackson County in its legal filings that "[w]hen there are two or more physicians who are substantially involved in performing or inducing the abortion, any one of those physicians may satisfy section 188.027.6 by providing informed consent." Defendants' Suggestions in Opposition to Plaintiffs' Motion for Temporary Restraining Order at 22, Circuit Court of Jackson County, Missouri, Case No. 1716-CV24109 (Oct. 16, 2017). Additionally, as the circuit court found, under the Department's reading of the statute, "when multiple doctors are involved in the continuum of care before, during, and after a procedure that anyone of those physicians could provide the required information." Order				

A (TAG)	B (CORRECTIVE ACTION)	C (WHEN)	D (WHO)	E (EVIDENCE OF COMPLIANCE)	F
ID/tag number (L1128)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date	Title of Person Responsible for Correction. No names	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "D"	Evidence/ Exhibit Attachment Numbers or "N/A"
	at 6, Circuit Court of Jackson County, Missouri, Case No. 1716-CV24109 (Oct. 23, 2017). We believe that attending physicians at RHS have been substantially involved in a patient's care, including when a fellow or resident is being trained to provide abortions and throughout each patient's care, and consistent with how physician supervision is understood to function in the context of residency and fellowship regardless of specialty or type of procedure, and therefore, RHS's practices have been fully compliant with the statute, the Department's direction and the Court's order. RHS, however, desires to resolve this issue promptly. To that end, and to ensure Missourians can continue accessing abortion in their home state, RHS will revise its policies to require that when a fellow or resident is providing a procedure under supervision, the supervising physician will provide the state-mandated information required by section 188.027.6, RSMo., at least 72 hours prior and will be physically present in the procedure room during the abortion procedure. Your rejection letter states, inaccurately, that the regulation requires that "[a] pelvic examination must be completed prior to every abortion for the purpose of '*determining the duration of gestation, identifying*				

A (TAG)	B (CORRECTIVE ACTION)	C (WHEN)	D (WHO)	E (EVIDENCE OF COMPLIANCE)	F
ID/tag number (L1128)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date	Title of Person Responsible for Correction. No names	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "**D**"	Evidence/ Exhibit Attachment Numbers or "N/A"
	preexisting medical or other complications, and detecting any factors which could influence the choice of the procedure, anesthesia, or preoperative and postoperative management.'" 19 CSR 30-30.060(2)(D) (emphasis supplied). In fact, that regulation provides in full: A written medical history shall be obtained for each patient. **A health assessment including a pelvic examination shall be performed.** Pregnancy shall be confirmed by clinical evidence and laboratory tests. This information shall be used in determining the duration of gestation, identifying preexisting medical or other complications, and detecting any factors which could influence the choice of the procedure, anesthesia, or preoperative and postoperative management. If the physician determines gestation is beyond the first trimester, an ultrasound examination shall be performed and results shall be recorded in the patient's medical record. (Emphasis added.) The regulation does not specify the time when a pelvic exam must be performed, except that it must be performed before the abortion procedure. The letter states that "[i]nspectors found that pelvic examinations were performed immediately prior to the actual abortion procedure," which the Department now believes is not compliant with the regulation. This change in position is surprising because it has long				

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

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

A (TAG)	B (CORRECTIVE ACTION)	C (WHEN)	D (WHO)	E (EVIDENCE OF COMPLIANCE)	F
ID/tag number (L1128)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date	Title of Person Responsible for Correction. No names	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "D"	Evidence/ Exhibit Attachment Numbers or "N/A"
	determining which procedures the patient qualifies, hemoglobin testing and information on patient preference is considered in determining the choice of procedure. Without significant findings in the above listed evaluations, a pelvic exam provides no additional information that would influence the choice of procedure. The function of a pelvic exam in the abortion context is not to aid in determining type of procedure, but rather to inform the procedural approach in those choosing aspiration abortion. In this context the pelvic exam is critical to determining uterine size and position. Because information obtained from a pelvic examination might change from one day to the next (e.g., the patient's comfort level may change or her uterus may shift), physicians perform the pelvic exam immediately prior to the surgical procedure so that the information is relevant and not stale. Consequently, the information learned from a pelvic exam is most pertinent immediately prior to the abortion and not days before the procedure. The pelvic exam is also most appropriately done on the day of the abortion procedure in an effort to minimize the occurrences of invasive interventions. Pelvic exams, even in medically indicted situations, are not viewed as pleasant. Indeed, the American College of Obstetricians and Gynecologists has observed there is data to suggest that in asymptomatic patients, it is allowable and even preferable to defer pelvic exams during routine				

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

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

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

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

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	For these reasons and because the Department's refusal to proceed with its investigation in a reasonable manner threatens to close the sole remaining abortion provider in the state, thereby denying Missouri women their constitutional right to abortion, RHS respectfully requests the Department to reconsider its position—for the benefit of the Missourians it is supposed to serve.				
L-1131	Provide more specific information regarding the frequency and type of audits that will be completed to ensure compliance is maintained.	4/30/19	Director of Surgical Services & CQI Manager	2019 Tag L1131 Audit to be completed weekly for 4 weeks, monthly for 5 months and once more after a year to report that tagged items remain compliant. The Infection Prevention Audit completed on a monthly basis includes as one of its checks: Check documentation for HDL Log completed prior per use.	L1131 Audit Infection Prevention Audit

EXHIBIT N

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired and Voice dial: 711
Randall W. Williams, MD, FACOG
Director

Michael L. Parson
Governor

May 23, 2019

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

Re: Response to Revised Plan of Correction

Dear Ms. Williams:

We are in receipt of your revised Plan of Correction, dated yesterday, regarding the ongoing deficiencies noted in our letter of May 20, 2019. The Department accepts the revised Plan of Correction in reference to the deficiency identified in L-1103 regarding pelvic examinations not being performed at a time that could influence the choice of the procedure on the condition that the proposed change is implemented immediately and monitoring of ongoing continued compliance with this requirement is also implemented immediately. The Department also accepts the revised Plan of Correction in reference to the deficiency identified in L-1131 regarding infection-control standards. However, your response fails to address continuing concerns regarding quality of care, standard of care, and statutory and regulatory compliance. These continuing concerns include, but are not necessarily limited to, the following:

First, your proposed Plan of Correction regarding compliance with the same-physician requirement of Missouri's informed consent law fails to comport with the requirements of that statute. The statute provides that "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 . . . [ ]" the immediate and long-term medical risks to the woman as specified in the statute. § 188.027.6, RSMo (emphasis added). Under the statute, the physician who performs the physician portion of the informed consent must be the same physician who "performs or induces" the abortion. Your response contends that the Circuit Court of Jackson County stated that, under the State's interpretation of the statute, "when multiple doctors are involved in *the continuum of care* before, during, and after a procedure that any one of those physicians could provide the required information." May 22 POC, at 5 (quoting Judgment/Order at 6, in Case No. 1716-CV24109 (Oct. 16, 2017)) (emphasis added). Respectfully, to the extent that the Circuit Court was attributing this interpretation to the State, it misconstrued the State's position, which is set forth in our brief in that case (which you also quote): "When there are two or more physicians who are substantially involved in *performing or inducing* the abortion, any one of those physicians may satisfy section 188.027.6 by providing informed consent." May 22 POC, at 5. Moreover, your Plan of Correction fails to note that the Circuit Court explicitly rejected the interpretation on which you now rely. In the same paragraph you quote, the Court stated that this interpretation "expands the language of subsection 6 beyond its written words." In other words, the interpretation on which you now rely was never advanced by the State and was rejected by the Circuit Court. Under the statute, where two or more physicians are involved in performing or inducing an abortion, the informed-consent process must

be performed by a physician who is actively involved in "performing or inducing" the abortion, not merely (as your response indicates) "substantially involved in a patient's care." Thus, your proposed revision to address this issue—*i.e.*, to require that the physician who performed the informed consent process must be "physically present" during the abortion procedure—is insufficient. To "perform or induce" the abortion under the statute, the physician who performed the informed consent process, at the very least, must play a substantial and active role in performing or inducing the abortion—mere physical presence is not enough. Contrary to your response, moreover, our May 20 letter did not acknowledge that there were no deficiencies with regard to Patient #7 and Patient #10. We acknowledged in the letter that your proposed Plan of Correction characterized the supervising physicians as actively participating in inducing the abortions for these patients. However, we specifically noted that we have been unable to verify the extent of your compliance with this requirement given that several physicians have refused to participate in interviews and that the Plan of Correction failed to provide adequate assurance of compliance and identify the systemic changes necessary to assure that the deficient practice would not recur.

In addition, the continued refusal of several physicians to cooperate in interviews regarding our ongoing complaint investigation obstructs our ability to verify that your facility "is in compliance with all requirements of applicable statutes and regulations," as required before a license can be renewed under 19 CSR 30-30.050(2)(I). Previously, we have requested that seven physicians who have provided patient care at your facility participate in interviews regarding medical records retrieved from your facility during the complaint investigation. Five of those physicians have refused to participate in interviews at all. Three of those five physicians who have refused to participate in interviews are not residents, but fully qualified physicians who have an ongoing professional relationship with your facility. You have taken the position that you lack authority to compel these physicians to participate in interviews because they are independent contractors, not employees. But it is the duty and responsibility of your facility to cooperate and ensure that all physicians who provide patient care at your facility are available for interviews during the Department's investigation. The physicians' refusal to cooperate in interviews is unprecedented and departs from longstanding practice at your facility and virtually every other regulated facility. And you have provided no clear indication of what steps you have taken, if any, to secure the cooperation of these physicians.

Instead, you have offered to produce for interviews two attending physicians, Dr. Eisenberg and Dr. McNicholas, on the ground that they supervised the care provided by the other physicians that the Department is seeking to interview. As I have repeatedly advised RHS, interviewing the attending or supervising physicians before interviewing the physicians who actually provided patient care contradicts well-established investigative standards that we apply in all investigations. Investigative standards dictate that the individuals directly involved in patient care should be interviewed first, followed by interviews of supervisors or managers with less direct involvement in the incidents being reviewed. By requesting that we interview the attending physicians before we have been able to interview the other five physicians, you are effectively requesting special treatment, and a departure from well-established investigative practices that we apply to other facilities in similar investigations.

That said, in the interest of achieving a resolution of these issues as quickly as possible, we are willing to interview Dr. McNicholas and Dr. Eisenberg immediately, as early as tomorrow morning, May 24. To be clear, we are agreeing to interview the attending physicians out of order under protest, emphasizing

that this is a departure from investigative practices followed in similar investigations at other facilities. And we emphasize that we are ***not*** withdrawing our request to interview the other five physicians whom we have requested for interviews. In addition to producing Dr. McNicholas and Dr. Eisenberg, we also require that you make the other requested physicians available—especially the three fully qualified physicians who have an ongoing professional relationship with your facility—without any further delay. As noted in my May 20 letter, our complaint investigation has identified a large number of potential deficient practices requiring explanation by the physicians directly involved in patient care, as well as the attending physicians. Moreover, we reserve the right to seek follow-up interviews with Dr. McNicholas and Dr. Eisenberg in the event that we have additional questions following the interviews of the other physicians.

Please respond promptly with the availability of Dr. McNicholas and Dr. Eisenberg for interview.

Sincerely,

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

EXHIBIT O

[redacted]

From: Koebel, William
Sent: Saturday, May 25, 2019 2:27 PM
To: 'Robert T. Haar' <roberthaar@haar-woods.com>
Cc: 'Sandman, Jennifer' <jennifer.sandman@ppfa.org>
Subject: RE: Interviews of Dr. McNicholas and Dr. Eisenberg

Mr. Harr – Thanks. David Lanigan and I will plan on seeing you at 2:00 p.m. on Tuesday. Although we will try to be as quick as possible, I can't guarantee that the interviews will only last one hour, and I expect the doctors to be available longer, if needed. Thanks again.

William Koebel, Administrator
Section for Health Standards and Licensure
P.O. Box 570
Jefferson City, MO 65102-0570

From: Robert T. Haar <roberthaar@haar-woods.com>
Sent: Friday, May 24, 2019 5:31 PM

To: Koebel, William <William.Koebel@health.mo.gov>
Cc: 'Sandman, Jennifer' <jennifer.sandman@ppfa.org>
Subject: Interviews of Dr. McNicholas and Dr. Eisenberg

Mr. Koebel,

Dr. McNicholas is available for an interview at our offices at 2 pm on Tuesday, May 28. Dr. Eisenberg will be available for an interview at our offices at 3 pm that day. Our offices are located in Suite 1620, 1010 Market St. in downtown St. Louis.

Robert Haar