

Before the
Administrative Hearing Commission
State of Missouri



REPRODUCTIVE HEALTH SERVICES)
OF PLANNED PARENTHOOD OF THE)
ST. LOUIS REGION,)
)
Petitioner,)
)
vs.)
)
MISSOURI DEPARTMENT OF HEALTH)
AND SENIOR SERVICES,)
)
Respondent.)

No. 19-0879

DECISION

We grant Reproductive Health Services of Planned Parenthood of the St. Louis Region’s (hereinafter, “Planned Parenthood”) application for renewal of its abortion facility license (application).

Procedure

On June 24, 2019, Planned Parenthood filed a complaint appealing the Department of Health and Senior Services’ (hereinafter, “the Department”) denial of its application. On June 25, 2019, Planned Parenthood filed a motion for stay. We granted the motion for stay on June 28, 2019.

On July 8, 2019, Planned Parenthood filed an amended complaint. On July 29, 2019, the Department filed an answer. On August 30, 2019, the Department filed an amended answer. On

September 13, 2019, Planned Parenthood filed a motion for decision on the pleadings, or in the alternative, for summary decision with a memorandum in support. On September 18, 2019, Planned Parenthood filed corrected versions of its motion and memorandum. On September 30, 2019, the Department filed suggestions in opposition to Planned Parenthood's motion. On October 7, 2019, we denied Planned Parenthood's motion.

From October 28-31, 2019, we held a hearing. Attorneys Charles W. Hatfield and Alixandra S. Cossette from Stinson LLP, and Christine Clarke, Hana Bajramovic, and Richard Muniz from Planned Parenthood Federation of America, represented Planned Parenthood. Solicitor General John Sauer, Deputy Attorney General Justin D. Smith, and Assistant Attorney General Emily A. Dodge represented the Department.

This matter became ready for decision on March 16, 2020, when the parties filed their final written arguments.

Findings of Fact

1. Planned Parenthood operates an abortion facility in St. Louis, Missouri. Planned Parenthood held an abortion facility license from the Department at all relevant times until the Department refused to renew it on June 21, 2019. By virtue of our stay order, issued June 28, 2019, Planned Parenthood's license remains in effect pending our decision in this case.

Planned Parenthood's Operational Structure and Staff

2. Planned Parenthood operates as an affiliate of Planned Parenthood Federation of America (PPFA). PPFA publishes medical standards and guidance that its affiliates must follow.

3. Catherine Williams serves as Planned Parenthood's senior vice president of administration and compliance. On October 15, 2018, she assumed the role of interim president until Planned Parenthood filled the position on August 12, 2019. In these positions, Williams was responsible for assuring Planned Parenthood's compliance with state and federal laws as well as PPFA's standards for affiliates.

4. All clinical care provided at Planned Parenthood falls under the oversight of its Chief Medical Officer (CMO).

5. Since July 2019, Dr. Colleen McNicholas serves as Planned Parenthood's CMO. Before becoming CMO, Dr. McNicholas provided abortion care at Planned Parenthood for more than a decade.

6. From September 2018 to July 2019, Drs. David Eisenberg and Tessa Madden served as co-CMOs for Planned Parenthood.

7. Kawanna Shannon serves as Planned Parenthood's director of surgical services. Shannon began working at Planned Parenthood 18 years ago as a medical assistant. For the last three years, she has been involved with the Department's licensure renewal process. Beginning in 2019, Shannon served as Planned Parenthood's primary liaison to the Department for all matters concerning licensure.

8. Anne Daum serves as Planned Parenthood's clinical quality improvement manager. In this position, Daum holds various responsibilities related to Planned Parenthood's quality assurance procedures. Specifically, Daum performs audits for compliance with Planned Parenthood's quality guidelines, schedules quality assurance meetings, and prepares complication report data for presentation at quality assurance meetings.

9. With the exception of its CMO, Planned Parenthood does not directly employ physicians. Since 2006, most physicians who provide care at Planned Parenthood do so through a contract with their primary employer, Washington University in St. Louis, and practice medicine at Barnes Jewish Hospital in St. Louis (BJH). On a more limited scale, Planned Parenthood contracts with physicians unaffiliated with Washington University.

10. Dr. Eisenberg is a board-certified obstetrician and gynecologist. Currently, he works as an associate professor in the Department of Obstetrics and Gynecology at Washington University. He served as Planned Parenthood's CMO from August 2009 until he assumed the

role of co-CMO with Dr. Madden. He continues to provide abortion care at Planned Parenthood as a contracted physician through Washington University.

11. Dr. Madden is a board-certified obstetrician and gynecologist. Currently, she works as the head of the Division of Family Planning in the Department of Obstetrics and Gynecology at Washington University. She continues to provide abortion care at Planned Parenthood as a contracted physician through Washington University.

12. Planned Parenthood's other contracted physicians include Staff A, Staff B, and Staff H. While Planned Parenthood contracts other physicians for services, only these three provided abortion care related to the non-renewal of Planned Parenthood's license.

13. Staff B provided abortion care at Planned Parenthood through an individual contract. Staff B resides and works out of state. As such, Staff B worked at Planned Parenthood less frequently than other contracted physicians. He has not provided any services at Planned Parenthood subsequent to the licensure non-renewal at issue. Dr. McNicholas trained Staff B in abortion care.

14. Staff H has provided abortion care at Planned Parenthood since September 2017 as a contracted physician through Washington University. Staff H works as an assistant professor of obstetrics and gynecology at Washington University.

15. Until spring 2019, residents and fellows¹ provided patient care at Planned Parenthood under the supervision of an attending physician. Washington University School of Medicine has 36 residents equally divided into nine for each year of the four-year program. Fellows provided patient care at Planned Parenthood as part of Washington University's family planning fellowship.

¹ After completing their medical degree, prospective obstetricians and gynecologists complete a mandatory four-year "residency" program during which they provide care under the supervision and instruction of an attending physician. After completing residency, a former resident may opt to continue in a more specialized program of supervised instruction called a "fellowship."

16. Based on their level of training and competence, residents receive progressively more autonomy as they advance through their residency. New residents are closely monitored by the attending physician until the attending physician feels they are competent to conduct a specific procedure with greater autonomy. However, residents will never perform a procedure without direct supervision from a physician with them in the room, though the supervising physician need not be the attending physician.

17. Staff A provided care at Planned Parenthood as a physician fellow through Washington University's family planning fellowship.

The Department's Abortion Facility Licensing Operations and Staff

18. Since 2017, Dr. Randall Williams has served as the Director of the Department. Prior to his tenure as Director, he served as North Carolina's deputy secretary of health and human services and as its state health director.

19. Missouri law charges the Department with regulation of abortion facilities and ambulatory surgical center (ASC) facility licenses. The Department performs its regulatory functions through internal divisions which divide into sections and, in turn, subdivide into bureaus. Abortion facility licensure falls within the purview of the Department's Bureau of Ambulatory Care within the Health Standards and Licensure section of the Division of Regulation and Licensure.

20. At the time of the hearing, the Bureau of Ambulatory Care oversaw 126 ASCs and birthing centers. Planned Parenthood holds the only abortion facility license in Missouri. The Department licenses over 4,000 facilities, including hospitals, nursing centers, day cares, and other entities.

21. Dean Linneman directs the Department's Division of Regulation and Licensure. His division serves as the Department's licensing arm and licenses Missouri hospitals, ASCs,

home health agencies, hospice agencies, nursing homes, certain individual medical professionals, medical marijuana facilities, and others. He has held this position for the last five years.

22. William Koebel serves as the administrator for the Health Standards and Licensure section within the Division of Regulation and Licensure. As administrator, Koebel oversees his section's six bureaus, including the Bureau of Ambulatory Care. These bureaus perform annual licensure inspections and investigations of licensed entities. He has worked at the Department since 2004 as an investigator and manager before assuming his current position in 2017. During his tenure with the Department, Koebel has conducted licensure inspections for hundreds of licensees. However, because of their limited number, he has only conducted three inspections of abortion facilities.

23. David Lanigan serves as the deputy administrator for the Health Standards and Licensure section within the Division of Regulation and Licensure. He has held this position since 2018. Prior to assuming this position, Lanigan worked as a police officer and Medicaid fraud investigator.

24. John Langston served as the administrator of the Bureau of Ambulatory Care from 2011 to 2018. In this position, Langston oversaw inspections of ASCs and abortion facilities. He left this position on July 1, 2018, due to personal frustrations with his abortion facility license responsibilities. He now works as the administrator of the Department's Bureau of Diagnostic Services.

25. Todd Cummins worked as the assistant administrator for the Bureau of Ambulatory Care from June 2018 to June 2019. Cummins now works as a health facilities consultant or "surveyor"² in the Bureau of Ambulatory Care. In these positions, Cummins conducts annual licensure inspections for ASCs and abortion facilities. He has held other positions within the Department since 2000.

² Cummins Depo. at 7.

26. Karen Maine, a registered nurse, works as a nurse surveyor in the Bureau of Ambulatory Care. In this position, Maine conducts inspections and investigations of ASCs and abortion facilities. She has been present at Planned Parenthood's annual inspections since 2015.

Expert Witnesses

27. The Department presented expert testimony from three witnesses: Drs. Donna Harrison, John Thorp, and Randall Williams. Planned Parenthood presented expert testimony from two witnesses: Drs. Daniel Grossman and Colleen McNicholas.

28. Dr. Harrison is a board-certified obstetrician and gynecologist and the executive director of the American Association of Pro-Life Obstetricians and Gynecologists (AAPLOG). Dr. Harrison graduated from the University of Michigan Medical School in 1986 and completed her residency at St. Joseph Mercy Hospital in Ypsilanti, Michigan, in 1990. Dr. Harrison engaged in private practice as an obstetrician and gynecologist for 14 years. While practicing, she worked with a physician organization in Michigan called Southwestern Medical Clinic. She served as the chair of the organization's quality improvement committee for two years. In this position, she oversaw her partners' practices and discussed ways they could improve patient safety or quality issues. Particularly, she focused on decreasing caesarian section rates, optimizing caesarian section timing, and reducing infections. Simultaneously, she served as the chair of Lakeland Regional Health Systems' Department of Obstetrics and Gynecology. In this position, she reviewed unusual or adverse events within the department. Since 2000, she has served primarily in administrative medical roles rather than direct patient care. To retain her board certification, she completes mandatory continuing medical education units. She has remained actively involved in medical research. Her research focuses primarily on adverse events regarding medication abortion. In her career, Dr. Harrison has performed only one abortion. In the context of miscarriage management, Dr. Harrison has performed only two dilation and evacuations. She became executive director of AAPLOG in 2013 and has been

involved in its administration since 2000. Dr. Harrison holds pro-life viewpoints. She believes elective abortions constitute the “willful destruction of an innocent human being.”³ She considers such practices to be homicide. Before she was retained as an expert to review this case, Dr. Harrison issued a public statement that “AAPLOG applauds the actions of the Department of Health and [Senior] Services with respect to Planned Parenthood license.”⁴

Dr. Harrison’s organization, AAPLOG, exists as a pro-life alternative to the American College of Obstetrics and Gynecology (ACOG) – the primary professional organization for obstetricians and gynecologists.

29. Dr. Thorp is a board-certified obstetrician and gynecologist. He holds a Master’s degree in health science from Duke University. He completed his residency and fellowship at the University of North Carolina. He is a member of ACOG. He engages in the active practice medicine. In his career, he has delivered over 4,000 babies. He does not provide abortion services because he believes the practice is immoral.

30. Dr. Williams is a board-certified obstetrician and gynecologist. Prior to his work in government, Dr. Williams engaged in private practice for 30 years. He last practiced medicine in 2015. He is an ACOG fellow. He completed medical school and residency at the University of North Carolina. Dr. Williams holds pro-life viewpoints. He has never provided an abortion due to his ethical principles.

31. Dr. Grossman is a board-certified obstetrician and gynecologist. He has a Bachelor’s degree in molecular biophysics and biochemistry from Yale University and received a medical degree from Stanford University in 1994. He completed his residency in obstetrics and gynecology at the University of California, San Francisco in 1998. Dr. Grossman has worked as

³ Tr. at 195.

⁴ Tr. at 197-198.

an obstetrician and gynecologist at numerous institutions since completing his residency. He served as the vice chair of obstetrics and gynecology and the clerkship director for medical students at St. Luke's Women's Center. He worked with Ibis Reproductive Health, a non-profit research organization. He worked as a clinician with Planned Parenthood in Northern California. In 2015, he joined the faculty of the University of California, San Francisco's Department of Obstetrics and Gynecology and Reproductive Sciences, where he continues to serve as the director of a reproductive health research program. As a faculty member, Dr. Grossman teaches and mentors medical students, residents, and fellows through his clinical services that are based at Zuckerberg San Francisco General Hospital. Dr. Grossman's recent research consists of public health and clinical research in reproductive health. This includes contraception, abortion, medication abortion, and access to reproductive health services. In his work, Dr. Grossman has specifically researched the safety and effectiveness of abortion techniques. He has served as a reviewer for a report on abortion safety conducted by the National Academies of Sciences, Engineering, and Medicine. He is a member of ACOG and has written and reviewed guidance published by the organization. In his current medical practice, Dr. Grossman provides outpatient gynecologic care. This includes family planning, well woman care, care for post-menopausal women, and abortion care (both medical and surgical). Dr. Grossman holds pro-choice viewpoints. He believes that abortion care composes a comprehensive component of women's health care and that physicians have a responsibility to advocate for their patients' access to safe abortion care. Until recently, Dr. Grossman served on the Board of NARAL Pro-Choice America – a non-profit organization that performs education activities related to reproductive care and abortion. In this position, Grossman worked to ensure that the organization's educational programs reflected the best available science on reproductive care. Following the

preliminary injunction issued in this case,⁵ Grossman made a post on social media stating, “[t]his is great news, although patients shouldn’t be put through the panic and fear they may not be able to get an abortion.”⁶

32. Dr. McNicholas is a board-certified obstetrician and gynecologist. She received her osteopathic degree from Kirksville College of Osteopathic Medicine in 2007. She completed her first year of residency at Atlanta Medical Center and her final three years of residency at Washington University. She also holds a Master of Science degree in clinical investigation from Washington University and completed a fellowship in family planning. In addition to her work as Planned Parenthood’s CMO, Dr. McNicholas serves as the director of the Ryan Residency Training Program at Washington University School of Medicine. In this role, she is responsible for medical residents’ mandatory practical training for practice as obstetricians and gynecologists. These requirements include training in abortion care. The residency program lasts four years, and each year has nine residents, for a total of 36 residents. She also supervises Washington University’s two-year family planning fellowship program consisting of 10 to 12 fellows. Dr. McNicholas has authored numerous peer-reviewed publications and research papers in the fields of obstetrics, gynecology, and abortion practice. She is a member of ACOG and the Society of Family Planning. She regularly attends professional conferences for abortion providers. Dr. McNicholas currently provides patients with all facets of gynecologic care, including pre-cancer screening and treatment, abnormal uterine bleeding, family planning, contraceptive care, and abortion care.

⁵ Prior to the opening of the pending case with this Commission, Planned Parenthood filed a lawsuit against the Department in circuit court and obtained a preliminary injunction until this Commission ruled on Planned Parenthood’s motion for stay.

⁶ Resp. Ex. 62. (Hereinafter, Respondent’s exhibits and Petitioner’s exhibits shall be referred to as “RX” and “PX,” respectively).

33. The physicians who perform abortions at Planned Parenthood through Washington University and BJH are all exceptionally competent and well trained. As noted by Dr. Williams:

Barnes-Jewish Hospital is the largest hospital in Missouri, it is recognized nationally in the top 20 very regularly. The Department of Obstetrics where the faculty is coming over to do abortions from, the Department of OB-GYN is one of the top 10 in the country. These are well-trained, board-certified physicians.[⁷]

Planned Parenthood's Abortion Care

34. Planned Parenthood's medical services include abortion care. Between January 1, 2018 and the date of the hearing, Planned Parenthood performed over 4,251 abortions.

35. Abortion care is performed through two general methods: surgical and medication. Put simply, medication abortion occurs through the administration of medicine in pill form, while surgical abortion involves surgical intervention to remove a pregnancy from the uterus.

36. Performed correctly, abortion is a safe and effective procedure. The risk of adverse consequences increases as the pregnancy advances, but not to a degree at which abortion becomes an unsafe procedure at any point within the lawful timelines for an elective abortion in Missouri.

37. Risks associated with abortion procedures include uterine rupture in medical abortion at late gestation, severe bleeding requiring transfusions, uterine perforation during surgical abortions, and damage to the cervix. The risk of uterine rupture is less than 1 in 1,000. The risk of severe bleeding ranges from less than 1 up to 4 in 1,000 at gestational ages beyond 20 weeks. The risk of uterine perforation ranges from less than 1 up to 4 in 1,000 depending on gestational age and clinician experience. Damage to the cervix occurs in less than 1 in 100

⁷ Tr. at 473.

surgical abortions. Abortion also carries a risk of infections of varying severity, often caused by a pre-existing condition.

38. Surgical and medication abortions fail in less than 1 in 100 cases. In less than 5% of cases, patients may require further interventions to complete evacuation of the uterus.

39. Abortions performed at Planned Parenthood fail at a rate of 0.05% – below published national rates for such failures.

40. When a patient presents to Planned Parenthood for abortion care, Planned Parenthood conducts a “72-hour visit” – a reference to Missouri’s mandatory 72-hour waiting period following consent.

41. At the 72-hour visit, the patient checks in and fills out a form with their medical history including prior pregnancies and their outcomes as well as general health information. Planned Parenthood staff then take the patient to its lab where their blood count, blood type, and vital signs are checked. Following this, the patient receives an ultrasound that Planned Parenthood uses to determine the location and gestational age of the pregnancy.

42. After the ultrasound, patients undergo what Planned Parenthood terms “education.” During education, the patient receives information regarding different methods and modes of abortion, the contraceptive needs or desire for the patient, and sedation options for the procedure. After education, a nurse goes over Missouri’s state-mandated checklist using a booklet containing those materials, making sure the patient understands what to expect before, during, and after the procedure.

43. After completing all intake and education steps, the patient meets the physician assigned to provide her abortion care. The physician reviews the patient’s medical history with her, and the two discuss the patient’s individual risks for the procedure based on the patient’s individual risk factors. After this, the physician gives the patient the state-mandated portion of

the risk consent agreement. After the physician answers all of the patient's questions, the patient will sign a consent form and prepare for her next visit.

44. In addition to the state-mandated consent materials, Planned Parenthood provides patients its own informed consent documents that describe the procedure to be performed with all the risks and side effects entailed. This documentation also includes instructions for patients to take care of themselves after the procedure as well as instructions to contact Planned Parenthood in the event of certain occurrences.

45. At least three days later, the patient returns to Planned Parenthood to undergo the abortion procedure. The patient checks in at the front desk and then goes directly to a nurse who confirms their intention to undergo the procedure and that no material changes have occurred since their last visit.

46. Since 2018, Planned Parenthood primarily performs surgical abortions, as opposed to medication abortions. The terms "aspiration" and "dilation and evacuation" or "D&E" refer to surgical abortions. Aspiration refers to the use of suction to remove a pregnancy. Dilation and evacuation differs from an aspiration abortion only in that D&E is used exclusively to describe surgical abortions in the second trimester of pregnancy. Both procedures require aspiration and can, but do not necessarily, involve the use of instrumentation.⁸

47. After checking in and meeting a nurse, patients scheduled to receive a surgical abortion are then directed to a locker room to change into a medical gown before proceeding to the room where the procedure occurs. Here, the nurse reviews procedural safeguards for the procedure and, if the patient has so requested, administers oral sedation. Patients may choose between oral sedation, intravenous sedation, or no sedation.

⁸ Tr. at 808-809.

48. The physician care team will enter the room to perform the procedure and introduce themselves and state the role they will each perform. The team will generally perform a “time out” – a routine medical practice where the patient identifies themselves, their date of birth, and the procedure for which they presented.

49. After the time out, the physician care team begins the procedure with a pelvic exam, followed by aspiration of the uterus.

50. The pelvic exam, or bimanual exam, constitutes a standard component of surgical abortions. Practitioners use the pelvic exam to determine the shape and location of the uterus and estimate gestational age. Pelvic exams are uncomfortable for patients, so abortion providers only employ them as medically necessary. The standard of care for a pelvic exam is to perform it immediately before beginning the surgical procedure.

51. After the pelvic exam, the treating physician dilates the cervix with specialized dilators – long narrow tools with curved ends. With the cervix dilated, the physician aspirates the fetus from the uterus using suction cannulas or suction curettes. The suction force in the curettes originates from a manual vacuum aspirator – essentially, a hand operated pump manipulated to create negative pressure. The aspiration procedure typically lasts three to five minutes.

52. For patients receiving a D&E in their second trimester, Planned Parenthood generally performs the procedure over two consecutive days. On the first day, the treating physician places dilators in the cervix and leaves them in until the patient returns on the second day for aspiration. The dilators slowly absorb fluid and expand, causing the cervix to dilate and soften, making the procedure safer and more comfortable for the patient.

53. Following the aspiration, the physician conducts a “gross exam” of the tissue. During the gross exam, physicians gather everything removed from the uterus to verify that they can see everything they expect to find and identify atypical materials if they are present. To

verify the success of the procedure, physicians look for the presence of villi, the sac, and, in some instances, fetal parts. For gestational ages prior to 10 or 11 weeks, fetal parts will not be present. The contents of the gross exam are always sent to an independent pathology lab to confirm the physician's findings. After verifying the procedure has been completed through the gross exam, the patient is brought to a recovery room for a period determinant on their individual needs and level of sedation. Following recovery, patients are offered a follow-up visit and discharged.

54. In the past, abortion providers have used "sharp" curettes to scrape a pregnancy from the uterine walls. During this practice, correctly determining the version and flexion of the uterus reduced the chance that the treating physician would misdirect these sharp instruments and perforate the uterine wall, potentially exposing the patient to serious danger from bleeding. However, this practice has fallen out of favor, and Planned Parenthood has not used sharp instrumentation at any time in its recent history.

55. Planned Parenthood no longer provides medication abortions as a routine service. Planned Parenthood stopped offering medication abortion in response to a Department directive requiring pelvic exams for medication abortion. Because pelvic exams are invasive, uncomfortable, and unnecessary for medication abortions, Planned Parenthood halted the practice of medication abortions rather than force patients to undergo the procedure. However, Planned Parenthood does, and will perform medication abortions under certain circumstances.

56. A medication abortion is performed by administering two drugs. At the clinic, the patient takes a drug called mifepristone. Mifepristone stops a pregnancy from growing by interfering with the connection between the pregnancy and the uterus. Twenty-four to forty-eight hours later, the patient takes a second drug at home called misoprostol. Misoprostol causes contractions that push the pregnancy lower in the uterus, ultimately expelling it.

57. Patients usually bleed within 24 hours after taking misoprostol. However, it can take longer. If that bleeding does not occur, patients are asked to return to the clinic to assess options for completing the procedure.

58. If a patient's unique uterine anatomy makes a surgical abortion difficult or untenable, practitioners may use medication abortion drugs as a supplement or alternative to the surgical procedure. The misoprostol has the effect of softening the cervix and changing the angles of the uterus, thereby making an aspiration abortion easier. For this reason, misoprostol is even used to facilitate full-term deliveries.

Planned Parenthood's Internal Policies,
Complications, and Quality Assurance

59. Planned Parenthood delivers post-abortion care reports to the Department for each abortion it performs. These reports include any complications that Planned Parenthood identifies in the course of abortion care.

60. Planned Parenthood maintains an internal policy of identifying and defining each complication it must report to the Department. The complications defined in this policy correspond with the complications listed in the Department's standard reporting form. Because the Department does not define the complications, Planned Parenthood created these definitions based on generally accepted medical definitions.

61. The Department's standard complication report form instructs the facility to check complication boxes for "all that apply" to a given patient's care. The listed complications include, among others, "failed abortion, Pregnancy undisturbed."⁹

62. Planned Parenthood holds quarterly quality assurance meetings. The quality assurance team is composed of Planned Parenthood's president, CMO, vice president of administration and compliance, director of surgical services, clinical quality improvement manager, two board members, and several other members of Planned Parenthood management

⁹ RX 7.

with responsibilities related to patient care. Quality assurance meetings typically last between 90 and 150 minutes.

63. At the quality assurance meeting, the quality assurance team discusses issues related to Planned Parenthood's administration and patient care, including patient services, customer service, staff training, quarterly or monthly reports, and Missouri's mandatory Quality Assessment and Performance Improvement Plan (QAPI).

64. Daum prepares a spreadsheet for each quality assurance meeting with complication report data from the previous quarter. These complications are presented to the quality assurance team during the QAPI portion of the meeting. Although Daum presents all of these complications at the meeting, not all of them receive specific attention or discussion. Prior to the quality assurance meeting, the CMO reviews the complication data and identifies particular instances that require specific attention for quality care improvement. The CMO will then review the patient's chart, request medical records from other institutions where the patient received care, present their findings at the meeting, and lead a discussion of the issues identified with the quality assurance team. After discussion among clinical staff, the quality assurance team will implement changes of policy or training as the clinical staff deems necessary. The treating physician is not required to attend the meeting to discuss complications the quality assurance team encountered. However, the CMO will subsequently discuss care with the treating physician, if necessary. Planned Parenthood informs its physicians of all the complications identified during their treatment and requires them to acknowledge those occurrences in writing through a quarterly process where they "sign off" on the occurring incident.¹⁰

¹⁰ Tr. at 843.

65. Independent of Missouri’s QAPI requirement, PPFA mandates its affiliates to maintain a “Risk Quality Management Program” for the purposes of managing and reducing risks in patient care. This policy includes tracking of “adverse events and complications.”¹¹ To this end, the CMO reviews and discusses occurrences beyond those in mandatory complication reports. These incidents include missed ectopic pregnancies, adverse reactions to medications, vasovagal events, and sentinel events. A sentinel event is a patient safety event, unrelated to the natural course of a patient’s illness or condition that results in death, permanent harm, or severe temporary harm. “Severe temporary harm” refers to life-threatening harm that requiring a higher level of care, transfer to a higher level of care, or additional major surgery or treatment.¹²

66. The quality assurance team only discusses complications the CMO identifies as significant or unusual. For example, complications that result in unusual bleeding or a hospital transfer merit discussion by the quality assurance team. By contrast, the quality assurance team does not discuss commonly known abortion complications. For instance, a failed medication abortion – absent other circumstances – constitutes a known occurrence in quality abortion care and does not require significant attention. For known occurrences like this, Planned Parenthood does not need to conduct significant reviews because it is already prepared to handle them when they arise.

67. Dr. Williams believes Planned Parenthood “does a good job looking at their complications.” However, he would like them to improve their quality assurance process with regard to discussion of adverse outcomes.¹³

The Department’s Regulatory Process for Abortion Facilities

68. The Department renews licenses for abortion facilities, ASCs, and birthing centers annually. To determine these facilities’ eligibility for renewal, the Department conducts

¹¹ PX 72 at 18.

¹² PX 266 at 1.

¹³ Tr. at 492-493.

licensure inspections or surveys. The Department also conducts investigations of specific concerns identified with its licensees. Although Department staff sometimes interchange these terms colloquially, inspections and investigations represent distinct processes. The terms “inspection” or “survey” refer to the annual process where a survey team from the Department goes to a licensed facility to determine regulatory compliance. An “investigation” refers to a limited review of a particular area of concern identified with a licensee. Both processes involve visits from Department surveyors who seek to identify deficiencies in the licensee’s regulatory compliance.

69. Most of the facilities the Department regulates, including ASCs, receive Medicaid or Medicare funding and are therefore subject to the certification requirements of the federal Centers for Medicare and Medicaid Services (CMS). CMS publishes guidance for surveyors in Appendix L of its State Operations Manual. CMS publishes guidance for investigations in Chapter 5 of the State Operations Manual. Planned Parenthood does not receive Medicare or Medicaid funds, and CMS guidance does not apply. Nevertheless, inspectors from the Department use the procedures proscribed by CMS in Chapter 5 and Appendix L to conduct licensure surveys at Planned Parenthood.

70. Prior to an inspection, the survey team meets and assigns specific tasks to identify a licensee’s regulatory compliance. They arrive unannounced at the licensed facility and conduct an entrance meeting with the staff to identify the reason for their visit and what they will need to see from the facility. The inspection typically lasts two to three days. Throughout the inspection, inspectors will observe staff, review records, and conduct interviews to determine regulatory compliance. Records are selected at random initially, and if problems are identified, the Department will request more. At the end of the inspection, inspectors will conduct an exit meeting with facility staff and discuss potential deficiencies they identified.

71. CMS guidelines do not explicitly require surveyors to conduct interviews during the survey. However, it advises that interviews “provide another method to collect information and to verify and validate information obtained through observations, record review, and review of other documents. Informal interviews are conducted throughout the duration of the survey. The information obtained from interviews may be used to determine what additional observations, interviews, and record reviews are necessary.”¹⁴ CMS advises surveyors to take meticulous notes of interviews, but does not advise recording the interviews. Furthermore, CMS guidelines advise that interviews “should be brief and to the point.”¹⁵

72. Within ten business days after an inspection or investigation, the Department delivers a “statement of deficiencies” to the licensee. The licensee must then submit a “plan of correction” addressing the Department’s concerns within ten days. The Department will either accept or reject these plans of correction as it deems appropriate. If the plan is accepted, the Department may conduct a revisit to observe the implementation of the correction if it deems a revisit necessary.

73. The Department’s statements of deficiencies are drafted collaboratively by the inspection team, with each team member drafting the portion of the statement correspondent to their inspection responsibilities. A draft of the statement of deficiencies is then circulated through supervisory staff, and a final version is sent to the facility.

74. In the plan of correction, the licensee responds to each identified deficiency with details of how it plans to correct it, including policy or procedural changes it will make. Upon receipt of the plan of correction, the inspection team meets again to determine if the plan of correction satisfies the state’s licensing requirements. Generally, each point of the plan of

¹⁴ PX 79 at 18.

¹⁵ PX 79 at 19.

correction is evaluated by the team member who identified the deficiency. If the Department rejects the plan of correction, it gives the licensee an opportunity to revise the plan of correction. This process may repeat several times.

75. CMS guidance states that the statement of deficiencies represents the “official document that communicates the determination of compliance or noncompliance” to the facility. CMS instructs drafters of the statement of deficiencies to “[w]rite each deficiency statement in terms specific enough to allow a reasonable, knowledgeable person to understand what regulatory requirements were not met” and to “[r]efrain from making clinical judgments. Instead, focus on the ASC’s policies and procedures as well as how they were or were not implemented by the ASC’s medical and other staff.”¹⁶

76. Regarding plans of correction, CMS guidelines state that a facility may submit objections to cited deficiencies with its plans of correction. In such instances, CMS instructs the inspecting body to “consider objections and accompanying documentation that attempt to refute the factual accuracy of the survey findings” and, “if the added evidence is convincing” remove the deficiency.¹⁷

77. CMS guidance states that revisits are not required following plans of correction. The purpose of a revisit is to “determine the ASC’s current compliance with ... requirements that the ASC was previously cited for noncompliance.”¹⁸ Thus, the surveyors’ task during a revisit is to “determine current compliance with the regulatory requirements that were cited during the previous survey and ensure that the implementation of the written plan of correction submitted by the ASC and accepted by the [Department] was effective in maintaining long term compliance.”¹⁹

¹⁶ PX 79 at 27.

¹⁷ PX 79 at 25.

¹⁸ PX 79 at 4.

¹⁹ PX 79 at 21.

78. The Department conducts investigations of licensees in response to external complaints and at its own behest. To instigate an investigation internally, the Department documents a “complaint” in its internal complaint reporting system describing the underlying concern causing the investigation.

79. When an investigation concerns clinical issues, nurse surveyors perform the Department’s investigations because they have greater experience in clinical matters relative to ordinary surveyors. Generally, the complainant would not serve as the primary investigator for an internally created complaint.

80. The Department’s surveyors and licensing staff refer to Chapter 5 of CMS’s State Operations Manual for guidance in conducting investigations.

81. Although Chapter 5 of CMS’s State Operations Manual contains guidance for complaint investigations, the guidance provided therein clearly concerns external complaints by third parties as opposed to internal concerns identified from an inspecting body. Chapter 5 contains no references to internal investigations specifically and frequently refers to complainants in a manner that suggests they are not affiliated with the investigating body. For instance, Chapter 5 indicates that complainants “[i]n some instances . . . may request anonymity,” and refers to “information about the complainant” like “name, address, telephone, etc.”²⁰

82. Chapter 5 of the State Operations Manual provides instructions for the investigation process. CMS requires investigations to be unannounced and begin with an entrance conference, upon which, the investigators must “advise the [facility] of the general purpose of the visit.” CMS guidance for complaint investigations advise the investigators to keep the complainant’s identity confidential, but this guidance does not suggest that this

²⁰ PX 245 at 7-8.

confidentiality provision should shield the surveying body from disclosing its own concerns.

CMS advises:

It is important to let the facility know why you are there, but to also protect the confidentiality of those involved in the complaint ... For example, in the case of a hospital, critical access hospital or ambulatory surgical center, if the complaint is that a patient developed a life-threatening infection in a post-surgical wound, do not tell the facility the exact complaint. Rather, tell them it is a situation related to infection control for surgical patients. Another example, in the case of a long term care facility, would be when a complaint that food that is intended to be served hot is always served cold. In this case, do not tell the provider the exact complaint. Rather, tell them it is a situation related to dietary requirements. [21]

83. Chapter 5 of the State Operations Manual does not require interviews, but states “interviews can be done in any order necessary.” More specifically, CMS instructs:

Interview the person who made the complaint. If the complainant is not at the facility at the time of the survey, he/she should be interviewed by telephone, if possible. Also, interview the person the complaint is about. Then, interview any other witnesses or staff involved. In order to maintain the confidentiality of witnesses, change the order of interviews if necessary. It may not always be desirable to interview the person who made the complaint first, as that may identify the person as the complainant to the facility.[22]

84. The Department employs only seven full-time inspectors to perform these inspections and investigations. Due to budget and staffing constraints, the Department does not perform licensure inspections for ASCs every year, even though it is required to do so by law. As of October 15, 2019, the Department oversaw 126 active ASC licenses. Twenty-four of those ASCs had not been inspected in more than three years; 66 had not been inspected since at least 2017.

85. As Department Director, Dr. Williams personally reviews each complication report and hospital transfer from Planned Parenthood. He holds regular meetings with the

²¹ PX 245 at 21-22.

²² PX 245 at 56.

Department's administration to review these reports and transfers. He does not perform similar reviews for ASCs.

Planned Parenthood's Licensure History

86. The Department conducts a licensure inspection for Planned Parenthood every year. Planned Parenthood received its first license from the Department more than 20 years ago. In each year prior to 2019, Planned Parenthood has applied for and received licensure renewal from the Department.

87. Planned Parenthood's annual license expires on May 31 every year. As such, the Department usually inspects Planned Parenthood shortly after New Year's Day to allow enough time to go through correction plan procedures.

88. In the years 2013 and 2015-2018, Langston led inspections at Planned Parenthood. His inspection teams in these years consisted of himself, a fire safety and construction surveyor, and two nurse surveyors. In later years, a third nurse surveyor joined the inspection team, and Koebel joined the inspection team in 2018.

89. In Langston's recollection, in the beginning, Planned Parenthood's medical records were difficult to navigate, and only select staff from the Department were capable of navigating the system. As such, one nurse was designated with the sole task of reviewing records. However, as annual reviews continued and Department inspectors became more familiar with the system, the process became easier. During his tenure, Langston's inspection team always found that Planned Parenthood maintained adequate medical records.

90. During inspections, Langston would move from place to place to observe his surveyors and field questions and objections from the facility's staff. In his recollection, the staff was cooperative. He sensed frustration from Dr. Eisenberg and then CEO Mary Kogut, but would not characterize them as uncooperative. Shannon and other staff were sometimes slow to

provide documentation out of concern that doing so was not allowed or appropriate, but this was common among facilities he regulated. Langston understood that conflicting points of view on the issue of abortion, as well as the media attention that entails, contributed to Planned Parenthood staff's concern towards the inspection and renewal process.

91. Langston routinely interviewed co-CMO Dr. Eisenberg as part of these inspections. In 2018, other physicians agreed to sit for interviews with him. Langston specifically recalled interviewing Dr. McNicholas, prior to her tenure as CMO, about issues regarding informed consent.

92. Langston oversaw complaint investigations at Planned Parenthood as well. All complaint investigations by the Department are unannounced in accordance with the CMS guidelines used by the Department.

93. The Department would typically receive five to ten complaints a year regarding Planned Parenthood. Most of these complaints came from pro-life protestors. When protestors observed emergency transportation from Planned Parenthood, they would presume impropriety and file a complaint with the Department. Because the Department was required to take action following such complaints, regardless of their merit, the Department arranged with Planned Parenthood for them to self-report such instances. On one occasion in 2017 or 2018, a complaint originated directly from an inspection of Planned Parenthood. This occurred because a patient required emergency transport while an inspection was underway.

94. The Department never initiated its own complaint investigation of Planned Parenthood prior to 2019.

95. During Langston's tenure as administrator of the Bureau of Ambulatory Care, the Department began increasing its focus on the regulation of abortion facilities. When he became administrator in 2011, abortion facilities constituted only a small portion of his responsibilities.

When he left his position in 2018, Langston felt the Department's focus on abortion facilities grew to a point where he spent an outsized portion of his time working on abortion facilities relative to the number of entities he regulated. In 2015, Langston began having frequent interactions with the director's office, correspondent with increased attention on abortion laws from the Missouri legislature and its Sanctity of Life subcommittee. When Dr. Williams became Director in 2017, Langston received increased feedback on clinical issues at Planned Parenthood, which Langston attributed to William's experience as a medical doctor. The growing focus of his work on abortion facilities, in conjunction with the social contentiousness surrounding abortion, contributed to his decision to leave the Bureau of Ambulatory Care.

96. Due to the controversial nature of abortion care and laws, the inspection and licensing process at Planned Parenthood was more contentious than at ASCs and other facilities regulated by the Department. Unsurprisingly, Planned Parenthood staff and state regulators expressed divergent opinions regarding the actual level of this contentiousness or who was to blame for this contentiousness.

97. During his five years surveying Planned Parenthood, Cummins recalled that Planned Parenthood staff were often slow to comply with requests for documents or interviews. In his words, it was "sometimes some length of time" for staff to complete their duties before the interview and "sometimes it took a while to get to talk to the person you wanted to talk to." In contrast to other facilities, "Staff seemed to be particularly involved in their duties for longer periods of time at [Planned Parenthood]."²³

98. Shannon recalled the 2017 inspection as "smooth."²⁴ She recalled that Langston, in particular, communicated well with the staff. In 2018, she felt "the dynamic of the inspections

²³ Cummins Depo. at 58.

²⁴ Tr. at 1086.

totally changed.”²⁵ She recalled that Koebel seemed uninformed about abortion facility regulations and women’s anatomy. Additionally, she noted that Koebel often interrupted Planned Parenthood staff during chart reviews. Koebel conducted the review in a more hostile and accusatory manner than Langston had the previous year. She recalled Koebel accusing one of Planned Parenthood’s physicians of changing the way the state’s consent guidance was explained in a manner to force consent to abortions.

99. By contrast, nurse surveyor Maine recalled Planned Parenthood staff were cooperative with her and the actual inspections were uncontentious. However, she did recall that the exit conference for Planned Parenthood’s 2018 inspection became contentious because Planned Parenthood disagreed with the surveyor’s findings.

Patient Care

100. In refusing to renew Planned Parenthood’s license, the Department cites care provided to four patients at Planned Parenthood during the 12-month period preceding the expiration of its license: Patient 1, Patient 2, Patient 3, and Patient 12.

Patient 1

101. Patient 1 presented for an abortion at Planned Parenthood in 2018. She underwent Planned Parenthood’s routine intake procedure. Dr. McNicholas performed her 72-hour consent. Patient 1 received an ultrasound during her initial visit. Based on the ultrasound and Patient 1’s last menstrual cycle, Dr. McNicholas estimated Patient 1’s pregnancy had a gestational age of seven weeks and four days and recorded this finding in her medical records.

102. Patient 1 returned a week later for her procedure. As such, her pregnancy had gestationally aged to eight weeks and four days. Patient 1 reported no changes in her health and no bleeding after her first visit. Patient 1 requested and received an oral sedative before the procedure.

²⁵ Tr. at 1087.

103. Dr. McNicholas left the room, and a fourth-year resident performed the procedure under the direct supervision of Staff A. Although Dr. McNicholas was not in the room at the onset of the procedure, she remained immediately available in the surgical suite where the procedure took place.

104. The resident performed a pelvic exam on Patient 1. Based on her pelvic exam, the resident estimated Patient 1's pregnancy had reached a gestational age of "less than 6 weeks."²⁶ Having been correctly instructed that ultrasound findings represent a far superior method for estimating gestational age, the resident and Staff A continued with the procedure.

105. The resident and Staff A selected cannula size for the procedure based on the more reliable ultrasound estimate mirroring the practices taught to them by their attending physician, Dr. McNicholas. Cannula size is measured numerically, and Dr. McNicholas uses a cannula size number one less than the estimated gestational age. Patient 1's estimated gestational age was eight weeks, four days, so the physician care team used a size seven cannula.

106. The resident attempted dilation and placement of the cannula. After deploying the cannula, neither she nor Staff A observed any products of conception. Since this was abnormal, Staff A intervened and restarted the process.

107. Staff A conducted a second pelvic exam and attempted to place the dilator and cannula. Again, Staff A was unable to reach the pregnancy. Staff A called upon Dr. McNicholas for assistance and requested transvaginal ultrasound guidance.

108. Dr. McNicholas attempted the procedure using ultrasound guidance. Additionally, Dr. McNicholas used a variety of techniques she had learned from her years of practice, but was unable to complete the procedure after 30 minutes of the physician care team's efforts.

²⁶ RX 43 at 18.

109. Dr. McNicholas determined the difficulty with Patient 1's aspiration abortion attempt stemmed from her unique anatomy. Using the transvaginal ultrasound, Dr. McNicholas determined that Patient 1's uterus was "incredibly retroflexed."²⁷ The interior of Patient 1's uterus curved back towards her bowels to such an extent that her pregnancy could not be reached using the ordinary tools for an aspiration abortion.

110. The terms used to describe uterine position are "version" and "flexion." "Version" refers to the general angle of a uterus within the pelvis, whereas "flexion" refers to the angle at which the path *within* the uterus travels. Relative to the normal position of a uterus, an "anteverted" uterus rests further forward toward the bladder, while a "retroverted" uterus rests further backward toward the rectum. Relative to a normally positioned uterus, the canal within an "anteflexed" uterus follows a curve forward toward the bladder, whereas the canal within a "retroflexed" uterus curves backward towards the rectum. Version and flexion generally correlate so that an anteverted uterus is usually anteflexed and vice versa. Although less common, the version and flexion of the uterus can differ from each other.

111. Failure to correctly identify version or flexion of the uterus does not represent a deviation from the standard of care for surgical abortions. Determining flexion and version during the pelvic exam benefits the physician performing the procedure by giving a sense of the layout and location of pregnancy within the uterus. However, the pelvic exam cannot reliably determine uterine flexion, and the difference between flexion and version are subtle. Physicians can more reliably identify flexion during the dilation procedure or other instrumentation of the uterus. As such, the failure to identify flexion or version during the pelvic exam does not have any significant bearing on the success or safety of a surgical abortion.

112. A retroflexed uterus does not represent a contraindication for an aspiration abortion, and it was possible for Dr. McNicholas to have completed the procedure with more

²⁷ Tr. at 767.

time and effort. However, because of the unexpected results and long delay in the procedure, Dr. McNicholas made the decision to stop the procedure and reassess options with the patient. After a discussion with the patient, Dr. McNicholas and Patient 1 agreed to proceed with a medication abortion.

113. Dr. McNicholas reviewed the protocol for medication abortions with Patient 1 and administered her mifepristone medication. Dr. McNicholas gave Patient 1 instructions for the medication and what to observe over the next few weeks, and scheduled a follow-up appointment the next week.

114. Dr. McNicholas summarized Patient 1's treatment in the medical record as follows:

[Patient] with an [sic] very acutely retroflexed uterus and the pregnancy at the fundus. Although the canal and path was able to be appreciated with eth17F Pratt dilator, the angle and traction on the cervix was quite uncomfortable to the patient. The position of the uterus made [ultrasound assistance] ineffective. [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 [surgical abortion] and proceed with [medication abortion]. Discussed and explained with patient.[²⁸]

115. Staff A described Patient 1's treatment in the medical record as follows:

Uterus anteverted but retroflexed. Dilated to 21Fr and 7mm cannula passed. MVA deployed with no tissue or blood returned. Ultrasound brought to room. Attempted again to pass dilator with visualization with both transvaginal and transabdominal ultrasound views utilized. Unsuccessful in attempt to visualize dilator on US so procedure abandoned. Will plan for medication abortion.[²⁹]

116. As Patient 1's attending physician, Dr. McNicholas was responsible for the care Patient 1 received through the resident and physician fellow Staff A. Allowing learning physicians to conduct care without direct supervision, after they have demonstrated competence, represents a normal, necessary part of medical practice. Part of a fellow's education is learning

²⁸ RX 43 at 4.

²⁹ RX 43 at 20.

to teach their practice. As such, a fellowship necessarily requires the fellow to teach and guide residents through procedures. This also represents a normal, necessary part of medical practice.

117. Immediately following Patient 1's procedure, Dr. McNicholas thoroughly discussed Patient 1's unique outcome with Staff A and the resident. Dr. McNicholas and the treating team discussed what happened during the procedure and the specific maneuvers she attempted without success in reaching her pregnancy.

118. Dr. McNicholas indicated in Patient 1's medical records, in a section marked "Supervising provider review," that she was "present for the procedure and agree[s] with the treatment and follow up plan(s)."³⁰

119. The resident and Staff A's initial treatment of Patient 1 had no effect on the outcome of the procedure. Even Dr. McNicholas, with her extensive experience, was unable to complete Patient 1's abortion using aspiration.

120. The discrepancy between Patient 1's gestational age as measured by pelvic exam and ultrasound likely stemmed from her unique anatomy in conjunction with the inherent inaccuracy of estimation by pelvic exam. Based on the position of the uterus, the resident and Staff A likely could not feel the pregnancy adequately enough to make a more accurate estimation.

121. The resident and Staff A's incorrect estimation of gestational age by pelvic exam had no effect on the outcome of Patient 1's procedure. The resident and Staff A appropriately relied on the more accurate ultrasound measure in conducting the procedure. Although the discrepancy between their estimated gestational age and the actual gestational age most likely stemmed from Patient 1's retroflexed uterus, Patient 1's care team took every appropriate step to locate the pregnancy and attempt the procedure. Specifically, they determined uterine position

³⁰ RX 43 at 4.

while using ultrasound to dilate and administer the cannulas. Because Planned Parenthood does not use sharp instrumentation, this process did not entail any significant risk of harm to the patient beyond the discomfort ordinarily associated with surgical abortions.

122. Two days later, Patient 1 called Planned Parenthood to inform her physician that she had not passed the pregnancy, and she returned for an appointment the next day.

123. Patient 1 received another ultrasound that confirmed her continuing pregnancy, and Dr. McNicholas performed an ordinary consent procedure before attempting a surgical abortion. Dr. McNicholas did not perform a second 72-hour consent. Patient 1 opted for and received moderate, intravenous sedation prior to her procedure. Dr. McNicholas recorded Patient 1's sedation in her medical records.

124. Dr. McNicholas noted in Patient 1's medical records that she was "confident and clear about decision to have the abortion" and "demonstrates understanding and is prepared for the abortion."³¹

125. Dr. McNicholas performed a pelvic exam before the procedure and recorded that Patient 1's uterus was retroverted and retroflexed. Dr. McNicholas completed Patient 1's surgical abortion without issue or difficulty. She conducted a gross tissue exam, observed villi and sac, and delivered the sample to the pathology lab.

126. Patient 1's records reflect that this abortion attempt took eight minutes. Dr. McNicholas summarized Patient 1's procedure in her medical records as "completed without difficulty," and she elaborated, "[Status post] failed [surgical abortion] discomfort and uterine [sic] position. Attempted [medication abortion] without success. Use of [intravenous sedation and ultrasound] guidance was able to evacuate without [difficulty]. Extremely [retroverted] and Retroflexed."³²

³¹ RX 44 at 13.

³² RX 44 at 14.

127. The care Patient 1 received at Planned Parenthood did not deviate from the standard of care.

128. Dr. McNicholas completed a single post-abortion care report for Patient 1, and Planned Parenthood timely delivered it to the Department by certified mail. Dr. McNicholas checked the box for “failed abortion, pregnancy undisturbed” and noted that the outcome of the complication was “aspiration.”³³

129. The failed medication abortion constitutes the sole reason Dr. McNicholas submitted the complication report. She does not consider the first attempt to aspirate Patient 1’s uterus a failed abortion such as that it would require a complication report.

130. Planned Parenthood’s internal definitions for complications define “failed abortion, pregnancy undisturbed” to apply to “any patient who the clinician diagnoses with a continuing pregnancy with ongoing fetal growth and/or cardiac activity on ultrasound.”³⁴

131. PPFA’s model standards and guidelines describe the timing for a failed abortion as “Postoperative (immediately or delayed).”³⁵

132. Regarding why Patient 1’s first abortion attempt did not constitute a failed abortion, Dr. McNicholas stated, “I think the common understanding amongst abortion providers is that if you know the procedure is not complete and you initiate another method of abortion, we would not consider that a failed abortion.”³⁶ Dr. McNicholas defined a “failed abortion” as “a situation where a patient who left the institution believing her abortion was completed and then later found out it was not.”³⁷

133. Furthermore, Dr. McNicholas expressed concern that considering a situation like Patient 1’s first surgical abortion attempt a “complication” may lead to inaccurate reporting of

³³ PX 160 at 7.

³⁴ PX 159.

³⁵ RX 33 at 48.

³⁶ Tr. at 852.

³⁷ Tr. at 851.

the procedure's safety in that it conflates a relatively banal, appropriate care decision with a more serious complication.

134. At the hearing, Dr. Williams acknowledged that stopping the surgical procedure in favor of a medication abortion was an “accepted practice”³⁸ and the validity of Dr. McNicholas’ concerns about grouping that decision in with more serious complications. As such, he revealed that the Department will revise its forms in the future to distinguish between failed abortions that are recognized immediately or at a later date. In his words:

Well, I think to Planned Parenthood’s credit that a -- a failed abortion that is not recognized is certainly much more concerning. I think they've also raised the concern that they are concerned that it would alter the data such that the more continue -- the more concerning, continuous delayed recognition, to them, is much more serious, and so we would ask them to reflect, just dividing those up going forward, so that we're all on the same page.^[39]

135. Additionally, Dr. Williams acknowledges there is a “gray” area for what he would consider a failed abortion. For instance, if a procedure was not completed due to an inability to dilate the cervix, he admits he might give differing answers “on a different day.”⁴⁰ For Dr. Williams, this “gray” area falls somewhere on the continuum of the extent to which efforts to complete the surgical abortion occurred.

136. To correct this problem in the future, Dr. Williams stated the Department will revise its complication report form to include a specific box for immediately recognized failed abortions.

137. Because Planned Parenthood documented a complication for Patient 1’s failed medication abortion, her case was reviewed during a quarterly quality assurance meeting as one of the failed medication abortions that occurred over the pertinent review period. However,

³⁸ Tr. at 474.

³⁹ Tr. at 486.

⁴⁰ Tr. at 600.

Patient 1's case was not discussed in significant detail like other treatments involving more serious complications.⁴¹

Patient 2

138. In 2018, Patient 2 reported to Planned Parenthood for an elective abortion. Staff B performed her 72-hour consent.

139. Patient 2 reported, and Staff B recorded, that Patient 2 had twelve prior pregnancies with six continued to term. Patient 2's record contains no indication that she encountered abnormal circumstances during these pregnancies.

140. Staff B recorded Patient 2's body mass index as 34.96 – indicating morbid obesity.

141. Staff B recorded in Patient 2's medical records that she “desires to know if multiple gestations are identified.” Patient 2 received an ultrasound, and Staff B recorded Patient 2's gestational age as nine weeks, four days. Staff B noted that her pregnancy was “single.”⁴²

142. Five days later, Patient 2 returned to Planned Parenthood for her procedure. Staff B performed a surgical abortion. Staff B performed a gross examination of the tissue and noted villi, sac, and fetal parts and confirmed a successful aspiration abortion. The patient was then discharged.

143. Planned Parenthood sent the contents from the gross examination to an independent pathology lab. The lab confirmed the presence of fetal parts.

144. Nineteen days after her procedure, Patient 2 called Planned Parenthood to report concerns of a continuing pregnancy. The nurse fielding the call scheduled an appointment two days later. Staff B recorded in her records, “[Patient 2] called stating ‘I dont [sic] believe the

⁴¹ PX 178 at 3.

⁴² RX 45 at 4.

[abortion] worked, my stomach is still getting bigger, I'm still throwing up! I just don't think he got it all.”⁴³

145. Patient 2 did not arrive for her appointment. She called Planned Parenthood again 15 days later, and the nurse fielding the call scheduled an appointment for her that day. Staff B recorded, “[Patient 2] called stating ‘I need to talk to someone because I still don't believe it worked, my doctor doesn't even believe it worked because I'm still getting a [positive pregnancy] test.’ ... [Patient 2] called back a second time stating ‘my doctor is sending me to you guys now because I'm having pelvic pain, I'm weak, and I can't stop throwing up.’”⁴⁴

146. Patient 2 arrived at Planned Parenthood that day for an appointment with Staff B and received an ultrasound. Staff B confirmed her ongoing pregnancy and recorded her gestational age as 15 weeks, one day. A second surgical abortion was scheduled for the next day.

147. Patient 2 arrived at Planned Parenthood the next day to have her second procedure. Staff B performed an ordinary medical consent for the procedure. He recorded in her medical record that he informed her “about what to expect emotionally and physically before, during, and after procedure.” He further recorded Patient 2 felt, “Sad/angry/afraid/ambivalent feelings but clear about decision” and that “[Patient 2] demonstrates understanding and is prepared for the abortion.”⁴⁵

148. Staff B provided Patient 2 with Planned Parenthood's internal consent documentation and included it in her medical records.

149. Again, after performing the abortion, Staff B performed a gross exam and documented the presence of villi, sac, and fetal parts. Planned Parenthood sent the sample to the independent pathology lab, which confirmed the findings and success of the procedure.

⁴³ RX 48 at 2.

⁴⁴ RX 48 at 4.

⁴⁵ RX 49 at 4-5.

150. Patient 2 developed an infection after the procedure – a normal complication of surgical abortions – and presented to BJH three days later. BJH diagnosed the infection, prescribed antibiotics, and kept her admitted to observe her progress. After a day, Patient 2 continued to show symptoms of the infection, so Dr. Madden re-aspirated her uterus at BJH.

151. Planned Parenthood documented these developments in Patient 2’s medical record, stating:

[Status post failed surgical abortion with Staff B] where despite exam of [products of conception] in procedure room being [consistent with] completed [abortion] and [pathology report consistent with parts of conception] (Villi, membranes, fetal parts) [patient] returned [at a later date] where ongoing [intrauterine pregnancy] was identified [consistent with] failed [surgical abortion]. She had apparently uncomplicated aspiration procedure (15wks) and was [discharged] home per routine. She then presented to [BJH] where she was evaluated and [diagnosed] with [post-abortion] endometritis and admitted for [intravenous antibiotics]. As of today, [five days] from reaspiration, she continues to have fevers and will continue on inpatient [intravenous antibiotics] and have suction [dilation and curettage] in OR with Dr. Madden at BJH per report. Will continue to [follow up] on her status.^[46]

152. Planned Parenthood discussed Patient 2’s case at its next quarterly quality assurance meeting. Co-CMO Dr. Madden led the discussion of complications. The quality assurance team agreed that the most likely explanation for Patient 2’s continuing pregnancy was a failure by Staff B to identify a twin pregnancy. This explains why both Staff B and the pathology lab separately confirmed the success of the first procedure, but she remained pregnant.

153. The quality assurance meeting’s minutes state, “Reviewed [Patient 2 re-aspiration] visit followed by [treatment at] hospital [dilation and curettage and intravenous] Antibiotic, complication report completed at [second] visit. Cardiac Motion, [upon return to

⁴⁶ RX 50 at 3.

Planned Parenthood], most likely a pregnancy missed of a twin[.]”⁴⁷ Planned Parenthood also document discussing Patient 2’s infection at the quality assurance meeting.

154. Missing a twin on an ultrasound constitutes an exceptionally rare, but not unheard of, occurrence. Dr. Madden testified that she had never encountered that situation before at Planned Parenthood, but had been aware of such incidences since her residency and fellowship.

155. Dr. Williams agrees that the most likely explanation for Patient 2’s continuing pregnancy was an undiagnosed twin. However, he elaborates that this failure likely stemmed from a failure by Staff B to identify a uterine abnormality such as a bicornuate uterus or a uterine septum. The term “bicornuate uterus” refers to a single uterus with an unusual shape that separates the uterus into two cavities.

156. A uterine abnormality represents a possible cause for a physician to miss a multiple pregnancy. However, Staff B had no cause to suspect such an abnormality, particularly considering Patient 2’s history of multiple pregnancies without any indication of such an abnormality. As Dr. McNicholas explained, such abnormalities do not simply develop over time, and she finds it implausible that Patient 2 could have such without knowing or reporting it considering her many prior pregnancies. This is because both of these anomalies are associated with outcomes that Patient 2 never experienced in her prior pregnancies – specifically, pre-term delivery.

157. Obesity can also cause difficulty in identifying multiple pregnancies. Patient 2 was morbidly obese. However, missing a twin is still a rare occurrence in such circumstances.

158. Given these factors, Drs. McNicholas and Grossman agreed that the most likely explanation for Patient 2’s continuing pregnancy was a missed twin.

159. In Dr. McNicholas’ opinion, Staff B’s failure to identify the presence of a twin on Patient 2’s ultrasound was a mistake – possibly attributable to focusing on ascertaining the

⁴⁷ PX 178 at 4.

location and gestational age of the pregnancy. Having trained Staff B, Dr. McNicholas knew Staff B was a well-qualified, competent abortion provider. However, she acknowledges that even with the best policies and standards of care, mistakes sometimes occur.

160. Dr. Harrison disagrees with the conclusion that Patient 2 had a missed twin based on the unlikelihood of such occurrences, but failed to offer a more convincing explanation.

161. While reviewing Patient 2's care during the quality assurance process, Dr. Madden took note of the physician who provided care. She did not feel this incident spoke significantly to Staff B's competence as an abortion provider. If an individual physician's care correlated to multiple unusual complications of the same type, this would prompt Dr. Madden to conduct deeper consideration during the quality assurance program. Dr. Madden could not recall any instance of such a pattern in a physician's care during her tenure.

162. Dr. Williams testified that his primary concern with Patient 2's treatment was what he perceived as insufficient quality assurance review. To resolve his concerns, he would be satisfied if Planned Parenthood expanded its quality assurance review to include multiple physicians, including the treating physician, for any sentinel event (hospitalizations, transfusions requiring surgery, failed surgical abortions, and other serious occurrences). He does not think the treating physician needs to attend the actual meeting so long as the CMO speaks with the physician and reports back to the quality assurance team.

163. Then co-CMO Dr. Eisenberg spoke with Staff B regarding Patient 2's continuing pregnancy under the auspices of Planned Parenthood's quality assurance program.

164. Planned Parenthood did not perform a root cause analysis to determine the cause of Patient 2's continuing pregnancy. A "root cause analysis" refers to an intensive review of the patient treatment. In Dr. Grossman's understanding, a root cause analysis includes review from a neutral party and interviews with all people involved in the patient's care. Dr. Grossman

believed that it is important to note and track unique cases and complications in order to look at trends over time and evaluate physicians. However, he does not believe more extensive review was warranted for an isolated incident like Patient 2.

165. Patient 2's case represents a significant anomaly. It is impossible to prove or disprove any single theory for Patient 2's continuing pregnancy. However, a mistake by Staff B in failing to identify the twin represents the most plausible explanation under the circumstances, and, as evidenced by the rarity of such occurrences, Planned Parenthood's current procedures are appropriate and sufficient for identifying uterine abnormalities and multiple pregnancies. This single mistake does not demonstrate an institutional failure on behalf of Planned Parenthood. Given the rarity of this occurrence and the extremely low likelihood that it will recur, Planned Parenthood has taken sufficient steps to ensure quality care for future patients by flagging this issue and discussing it during their quality assurance review.

166. Except for Staff B's failure to diagnose Patient 2 with a multiple pregnancy, Patient 2 received appropriate treatment within the standard of care.

167. Staff B has not provided abortion care at Planned Parenthood since this incident, nor is he scheduled to perform further care at Planned Parenthood in the future.

Patient 3

168. In 2018, approximately one month prior to Patient 1's initial visit, Patient 3 presented for an abortion at Planned Parenthood. She underwent Planned Parenthood's routine intake procedure. Dr. McNicholas performed her 72-hour consent. Patient 3 received an ultrasound that indicated a gestational age of six weeks and zero days.

169. Six days later, Patient 3 returned to Planned Parenthood to undergo a surgical abortion. As was the case with Patient 1, Staff A performed the procedure under Dr. McNicholas' supervision. Again, Dr. McNicholas did not stay in the room with Staff A during the actual procedure, but she remained present and immediately available in the surgical suite.

170. Dr. McNicholas indicated in Patient 3's medical records in a section marked "Supervising provider review" that she was "present for the procedure and agree[s] with the treatment and follow up plan(s)."⁴⁸

171. After the procedure, Staff A performed a gross examination, observed villi and sac, and Patient 3 was discharged. Planned Parenthood sent the contents from the gross examination to an independent pathology lab. The lab confirmed the presence of villi and sac.

172. Thirty days later, Patient 3 called Planned Parenthood to report concerns that she had a continuing pregnancy. The nurse fielding the call scheduled an appointment for Patient 3 four days later. Dr. McNicholas documented in the medical record:

Received call from Call Center spoke [with patient] who states she just left her [physician's office and] the [physician] states she is 12 weeks [pregnant]. [Re-aspiration] procedure scheduled for [four days later]. [Pre-operation] instructions reviewed [with patient] who voiced understanding.^[49]

173. Patient 3 returned to Planned Parenthood four days later for her second surgical abortion procedure. She received a second ultrasound, and Dr. McNicholas recorded that she had a gestational age of 11 weeks.

174. Dr. McNicholas performed an ordinary, medical consent for a surgical abortion, but did not repeat Missouri's 72-hour consent process. Dr. McNicholas recorded that Patient 3 was "informed about what to expect emotionally and physically before, during, and after procedure," was "[s]creened for risk factors," and "demonstrates understanding and is prepared for the abortion."⁵⁰ Dr. McNicholas provided Patient 3 with Planned Parenthood's internal consent documentation and included it in her medical records.

175. Dr. McNicholas performed Patient 3's second surgical abortion procedure without difficulty or issue. Following the procedure, she conducted a gross exam and observed villi, sac,

⁴⁸ RX 52 at 23.

⁴⁹ RX 54 at 1.

⁵⁰ RX 54 at 11-12.

and fetal parts. Planned Parenthood sent the sample to an independent pathology lab, which confirmed her findings. Dr. McNicholas documented seeing “all” fetal parts and that the procedure was “completed without difficulty” or “complication” in Patient 3’s medical record.⁵¹

176. Dr. McNicholas completed a complication report for Patient 3, and Planned Parenthood timely submitted it to the Department.

177. Dr. McNicholas and Staff A have no recollection of discussing Patient 3’s first procedure. However, Dr. McNicholas noted that reviewing such failed abortions “is part of the normal practice” at Planned Parenthood.⁵²

178. Because of Patient 3’s surgical abortion, her care was flagged for review and presented at Planned Parenthood’s next quality assurance meeting. However, her treatment received only cursory acknowledgment, as co-CMO Dr. Madden did not consider it significant enough to merit deeper analysis.

179. Staff A and the pathology lab’s incorrect conclusion that the procedure was successful may have stemmed from Patient 3’s early gestational age. For surgical abortions at an early gestational age, fetal parts are not visible. As Dr. McNicholas explained to Department investigators, it possible to observe villi during the gross exam, but not have removed the entire pregnancy.

180. The pathology reports Planned Parenthood received contained no red flags to alert Planned Parenthood they were hastily or otherwise incorrectly prepared. Patient 3’s pathology report contains details specific to her, including the age of her pregnancy and size of the sample contents. The same was also true of the pathology report for Patient 2.

181. Additionally, the fact that Staff A was involved in both Patient 1 and Patient 3’s care during the same period of time creates no reason to suspect a pattern of failed abortions or

⁵¹ RX 54 at 13.

⁵² Tr. at 843.

other concerns about her competency as an abortion provider. If Staff A had two failed abortions like Patient 3's, that would create cause for concern. However, as Dr. Williams acknowledged, the failed initial procedure on Patient 1 differs substantially from Patient 3's failed abortion. In the former, the procedure was abandoned voluntarily with full knowledge of Patient 1's unique circumstances, whereas Patient 3's failed abortion represents a rare, unexpected failure of a reliably consistent procedure.

182. Drs. Grossman and McNicholas expressed no concerns about the care provided to Patient 3.

183. Dr. Williams expressed a similar concern regarding quality assurance for Patient 3 as with Patient 2. He believes Patient 3's treatment required more attention during the quality assurance process. He would be satisfied if Planned Parenthood included the treating physician, directly or indirectly, in the quality assurance process – particularly since the same fellow was involved in another failed abortion attempt on Patient 1.

184. Dr. Harrison expressed many concerns with Patient 3's care. First, Dr. Harrison expressed concern with the way Dr. McNicholas documented her "presence" for the procedure, the fact that Staff A was involved in care for two failed procedures on Patients 1 and 3, and the lack of more detailed review during quality assurance. Additionally, Dr. Harrison expressed concern that superficial similarities in Patient 2 and Patient 3's pathology reports suggested the lab did not actually analyze the samples. Instead, she posited that the lab merely returned a template without performing the test.

185. Planned Parenthood rightly identified this complication during its quality assurance procedures. Although complications like this are rare, they are known and anticipated in abortion care. A single instance does not suggest an institutional failure of policy or procedure, nor does a single failed abortion suggest a deviation from the standard of care.

Planned Parenthood’s decision to not devote significant attention to this complication was appropriate under the circumstances.

186. Residents and fellows no longer perform services at Planned Parenthood.

Patient 12

187. Patient 12 was referred to Planned Parenthood by an out-of-state health care provider that lacked the capacity to provide her abortion care. The out-of-state health care provider informed Planned Parenthood that Patient 12 “desires termination” and that there was “concern for accreta.” The provider indicated that Patient 12 had a gestational age of 19 weeks, two days – a second trimester pregnancy. Additionally, the provider noted that Patient 12 did not have insurance, but did have access to National Abortion Federation funding.

188. A “placenta accreta” is a rare and serious condition characterized by the growth of the placenta into the myometrium – the muscular wall of the uterus. Placenta accreta carries the risk of bleeding throughout the pregnancy. Removing the placenta intact during birth or an abortion without causing significant bleeding is almost impossible.

189. In reproductive health care, placenta accreta is considered a “maternal indication,” meaning that it presents a serious risk to the health or life of the prospective mother. As such, a placenta accreta constitutes a sufficient cause for a therapeutic abortion. The term “therapeutic abortion,” as opposed to an “elective” abortion, refers to an abortion performed for the health and safety of the mother.

190. Patients who have received a prior caesarian section in conjunction with a history of “placenta previa”⁵³ face an elevated risk of an accreta. Approximately 3% of patients with these conditions develop an accreta.

191. Placenta previa and a prior caesarian section, absent an accreta, do not significantly alter the risks involved in a surgical abortion.

⁵³ A placenta previa describes a condition in which the placenta overlies the opening of cervix (the “os”).

192. Due to the concern for accreta noted in Patient 12's referral, Patient 12 did not initially report to Planned Parenthood's outpatient facility. Instead, Planned Parenthood referred her directly to BJH to evaluate her for a potential accreta. This referral is consistent with Planned Parenthood's standard practices for such concerns. Staff H assumed responsibility for Patient 12's care at BJH.

193. BJH will only perform an abortion if the patient has a maternal indication. BJH does not provide elective abortions. As such, BJH needed to evaluate Patient 12 for an accreta before it could perform her abortion. If BJH did not identify an accreta or any other maternal indication, then Planned Parenthood would perform the abortion at its outpatient facility.

194. When Patient 12 presented at BJH, she received an ultrasound to identify a potential accreta. The physician responsible for the ultrasound documented in BJH medical records that Patient 12 did have a placenta previa. In the same record, the physician wrote under a section marked "Indications," "Placenta accreta in second trimester."⁵⁴ This notation referred to the reason for the tests performed rather than a diagnosis of placenta accreta.

195. Multiple points in BJH's records for Patient 12 contain the language "Diagnosis: Placenta accreta in second trimester" or a diagnosis code followed by the words "placenta accreta." Immediately under these notations, the medical records contain the note "added automatically from request for surgery" and in one instance "^ # concern for accreta."⁵⁵ These notations reflect the reason Patient 12 presented to BJH. BJH does not have a diagnosis code for a *suspected* placenta accreta.

196. Patient 12's ultrasound included a technique called "Doppler color flow." Doppler color flow is the standard method used to determine the presence or absence of an accreta. Although Doppler color flow cannot exclude the presence of an accreta with certainty, it

⁵⁴ RX 55 at 10.

⁵⁵ RX 55 at 3, 5, 15, & 16; RX 58 at 2, 11; PX 60 at 92.

offers the best available method for doing so. Studies have shown that Doppler color flow correctly rules out placenta accreta in 96% of cases.

197. In some cases, magnetic resonance imaging (MRI) may help identify a potential accreta, but an MRI is not as accurate as a Doppler flow ultrasound. For this reason, BJH did not perform an MRI on Patient 12.

198. During these ultrasound procedures, the patient lays on a bed while the physician places an ultrasound probe on her belly, and the ultrasound machine records a 2-D image of the uterus. A button on the machine activates the Doppler color flow; this technology will highlight vasculature in red or blue depending on the type of blood vessel.

199. The BJH physician who performed the ultrasound described the procedure under a section marked “Method” as follows: “Transabdominal and transvaginal ultrasound examination. View: Transvaginal ultrasound required for measurement of placenta implantation.”⁵⁶ Under a section marked “Impression,” the physician described the findings as follows:

Fetal biometry is [consistent with] gestational age. The placenta is anterior and previa. It is implanted over the area of the [caesarian section] scar, but *there are no cardinal findings [consistent with] accreta, no large vessels or vascular lacunae. The lower myometrium over the scar area appears intact.*

[Intrauterine pregnancy] at 20 weeks and 4 days

Anterior placenta previa - *cannot exclude possible accreta on the basis of this scan, but there are no highly suspicious findings for such.*^[57]

200. While BJH medical records do not contain the words “Doppler color flow,” its use can be inferred from the purpose of the procedure and the ubiquity of its use in detecting placenta accreta. Regarding this ubiquity, McNicholas testified:

⁵⁶ RX 55 at 11.

⁵⁷ RX 55 at 12 (emphasis added).

[T]here are some assumptions we make when we order a test that are performed as routine -- as inclusive in that test. And when we ask an order for evaluation of the placenta, it is understood that in order to make a determination about the cardinal findings of placenta accreta, one must do an evaluation of Doppler.

And I know that to be true because, one, I practice very closely with these ultrasound specialists. I have for the last ten years and we have an incredibly collaborative experience between the two specialties. At times when the ultrasound specialists have noted things that are of concern, they call and will actually show me the images and that's true of this patient too.^[58]

201. After performing the ultrasound, the BJH physician discussed the findings with Dr. Eisenberg and sent her findings to Staff H. Staff H reviewed the ultrasound report and found it reassuring that Patient 12 most likely did not have an accreta. Staff H knew ultrasounds cannot guarantee the absence of an accreta, but she recognized that the ultrasound had not displayed anything to suggest a possible accreta and correctly understood the report as a reassuring indication that Patient 12 most likely did not have an accreta based on the best available measurements. As such, Staff H, in consultation with her colleagues in BJH's family planning division, determined that Patient 12 did not have a maternal indication for a therapeutic abortion.

202. After the ultrasound, Patient 12 reported to Staff H for abortion care. Staff H introduced herself to Patient 12 and assessed her decision making about having an abortion. Patient 12 expressed a desire to proceed with an abortion. Staff H reviewed Patient 12's medical history with her. Staff H then discussed the risks, benefits, and alternatives to continuing the pregnancy with Patient 12, and went through Missouri's mandatory 72-hour consent process. Staff H documented her consent discussion as follows:

Options for the pregnancy were discussed with the patient, including continuation of pregnancy, medically induced abortion by labor induction, and surgically induced abortion by dilation and evacuation (D&E). Given the increased risk to maternal health or life endangerment from placenta previa, history of cesarean

⁵⁸ Tr. at 829-830.

section, and possible placenta accreta, the patient desires not to continue the pregnancy. She is requesting an abortion by standard D&E.

As the physician who is to perform or induce the abortion, I have informed the patient orally and in-person of the immediate and long-term medical risks associated with the proposed abortion method including infection; risk of hemorrhage, possibly requiring blood transfusion; risk of uterine or cervical injury, possibly requiring laparotomy or hysterectomy; risk of failure including need for additional medical or surgical procedures; possible harm to subsequent pregnancies or the inability to carry a subsequent child to term; and possible adverse psychological effects associated with the abortion were reviewed in detail. Need for cervical ripening with misoprostol and pre-operative osmotic dilator placement were also discussed; the accompanying risks of infection, bleeding, injury, rupture of membranes, and preterm labor were reviewed. She understands these risks and agrees to above. I have discussed the immediate and long-term medical risks associated with the estimated gestational age of the fetus, and the woman's medical history and medical conditions. We discussed that her underlying medical conditions including anterior placenta previa would increase her risks associated with the procedure, but that the risk of continuation of pregnancy is greater than proceeding with termination. I have discussed the immediate and long-term medical risks associated with the anesthesia and medication to be administered and provided her with the Anesthesia Information Sheet.^[59]

203. Staff H specifically asked and received consent from Patient 12 for “elective termination of pregnancy” at Planned Parenthood.⁶⁰

204. Staff H’s decision regarding Patient 12’s qualifications for a therapeutic abortion at BJH had financial implications for Patient 12. Patient 12 lacked insurance and did not possess significant financial resources. If Patient 12 qualified for a therapeutic procedure at BJH, she could offset her medical costs using National Abortion Federation funding. However, that funding is not available for elective procedures at Planned Parenthood.

205. On the day before her scheduled abortion at Planned Parenthood, in consideration of Patient 12’s financial means, Staff H sent an e-mail to a BJH colleague with the inquiry, “Is it

⁵⁹ RX 58 at 17.

⁶⁰ RX 56 at 27.

better/possible for her to be done at [BJH] on Thursday at 21w6d, or does she not have enough of an indication since all she has is a previa? Otherwise, she does not have funds for planned parenthood.” Staff H copied Dr. Madden on the e-mail.⁶¹

206. Dr. Madden responded to Staff H’s inquiry by asking, “Just to clarify, did [Patient 12’s] scan show suspicion for accreta? Which is what it says in [the referral] e-mails?” Staff H answered by stating, “There was no suspicion of accreta on her formal ultrasound, but that is why she was referred to us. She’s at [Planned Parenthood] now so I think we’ve worked it out.”⁶²

207. Approximately one week after her consent, Patient 12 presented for her procedure at Planned Parenthood. In Planned Parenthood’s medical records, Staff H recorded that Patient 12 presented to Planned Parenthood “for elective termination of pregnancy” and that she was “[c]onfident and clear about decision to have the abortion.”⁶³

208. In the week preceding her scheduled abortion at Planned Parenthood, Patient 12 was admitted to a hospital in Arkansas with vaginal bleeding. She was stabilized in the hospital and sent home. On the day of her procedure, Staff H was aware of Patient 12’s hospital admission, but was not concerned for an increased risk in proceeding with planned care because her condition was stabilized and she was returned home.

209. Patient 12 reported to Planned Parenthood for the first day of her procedure. In accordance with Planned Parenthood’s standard practices for second trimester, surgical abortions, Staff H planned to perform the procedure over two days.

210. A physician fellow, under Staff H’s supervision, began Patient 12’s treatment by placing dilators (laminaria) in her cervix. Upon placement of the third dilator, Patient 12 began bleeding in manner faster than would be ordinarily expected. After observing bleeding, Staff H

⁶¹ RX 17 at 1.

⁶² RX 18 at 1.

⁶³ RX 56 at 27.

called Dr. Madden for assistance. Dr. Madden advised placing more dilators to tamponade the bleeding. The placement of additional dilators stopped the bleeding.

211. Patient 12 lost 200-300 milliliters of blood at Planned Parenthood. Although the bleeding had stopped, Staff H, with the advice of Dr. Madden, decided to transfer Patient 12 to BJH for a therapeutic abortion out of concern for continued bleeding from the dilators abutting the placenta.

212. An ambulance transferred Patient 12 to BJH. BJH is located approximately four minutes away from Planned Parenthood. Because Planned Parenthood is so close to BJH, it was capable of quickly transferring Patient 12 to BJH for radiological interventions if the placement of additional dilators failed to stop the bleeding.

213. At the hospital, Staff H decided, with Patient 12's consent, to accelerate the procedure and complete the evacuation that day due to patient discomfort from contraction-like symptoms. Staff H described the "Assessment and Plan" for her procedure at BJH as follows:

[Patient identifying information redacted] female at 21w5d who desires surgically induced abortion and is [status post] laminaria placement today complicated by bleeding in setting of known placenta previa.

1) Placenta previa in second trimester: she desires induced therapeutic abortion by standard D&E. She was counseled on pregnancy options and desires to proceed with termination of pregnancy. Consents were signed. I intend to perform a standard D&E.[⁶⁴]

214. Staff H administered Misoprostol to soften the cervix and aid with removal of the placenta. In anticipation of further bleeding, Staff H placed an order for blood products if needed. Patient 12 received full anesthesia prior to her procedure.

215. Staff H and Staff A performed the procedure at BJH. Staff A performed the majority of the dilation and evacuation under Staff H's direct supervision.

⁶⁴ RX 58 at 18.

216. Immediately after removing the dilators, Patient 12 resumed bleeding. Observing that bleeding had resumed, Staff A expeditiously proceeded to remove Patient 12's placenta. Despite the bleeding, the treating physicians had no difficulty removing Patient 12's placenta. Staff A completed the procedure by removing clots and debris from the uterus using a suction machine. The surgical abortion lasted approximately 15-20 minutes.

217. Ordinarily, the removal of the placenta causes the uterus to cramp and stop bleeding. However, Patient 12 suffered a postprocedure "uterine atony" – an unusual occurrence characterized by the uterine muscles' failure to cramp as they should following the evacuation of vagina during vaginal delivery, caesarian section, or abortion.

218. Immediately after completing the procedure, Staff A and Staff H turned their focus to managing Patient 12's bleeding. Patient 12 lost a significant amount of blood during her procedure at BJH. Staff H immediately called for the blood products she had ordered, and the anesthesia team administered said blood products. Staff H administered a device called a "Foley Balloon" – a catheter inflated in the uterus to stop bleeding using compression. Staff A performed a bimanual massage of the uterus – another bleeding management technique. Following these efforts, Patient 12 was transferred to BJH's radiology department where she received a uterine artery embolization to control her bleeding.

219. Patient 12 had suffered a hemorrhage. BJH records indicate she lost 1800 milliliters of blood. Due to blood loss, Patient 12 became hemodynamically unstable with hypotension, meaning that her vital signs were not within normal limits. Her blood pressure was dangerously low.

220. Patient 12 most likely did not have an accreta. Only a hysterectomy can conclusively confirm an accreta or its absence. However, Patient 12's ultrasound showed no findings to indicate an accreta. With the benefit of hindsight, Drs. Grossman, McNicholas, and Williams agree she did not likely have an accreta.

221. Dr. Madden, Staff H, Staff A, and BJH radiologists and anesthesiologists saved Patient 12's life by quickly reacting to unexpected events during Patient 12's treatment. Dr. Madden, Staff H, and Staff A quickly recognized and controlled Patient 12's bleeding at Planned Parenthood and rightly made the decision to transfer her to BJH, where she could resume the procedures with sufficient support systems to respond to the complications she eventually suffered; Staff H prepared for a possible hemorrhage by ordering blood products; Staff A and Staff H completed the procedure quickly to minimize blood loss and reacted immediately when her bleeding continued by taking ameliorative actions and directing anesthesiologists to administer blood products; and finally BJH radiologists brought her bleeding under control.

222. After completing the therapeutic abortion at BJH, Staff H documented the "Indication for the Procedure" in BJH's medical records as follows:

The [Patient] is [age redacted] at 21w5d with pregnancy complicated by placenta previa. Due to this, she desired to have therapeutic termination of pregnancy and she signed the appropriate statement/consent forms 72 hours prior to placement of laminaria. She initially had presented to Reproductive Health Services for laminaria placement on [date redacted]. She had brisk vaginal with laminaria placement and had vaginal packing placed at the clinic. EBL at the outside clinic was approximately 200-300 ml. She was transferred to BJH by ambulance and was not actively bleeding with stable vitals. She was given misoprostol for additional cervical ripening prior to completion of the D&E procedure.^[65]

223. At the time of the hearing, Patient 12's case was scheduled for discussion at Planned Parenthood's next quarterly quality assurance meeting.

224. Dr. Harrison expressed two general concerns regarding Patient 12's treatment. First, she believes that Planned Parenthood erred by treating Patient 12 in its outpatient facility because, in her readings of Patient 12's records, BJH had not done enough to exclude the

⁶⁵ RX 58 at 56.

possibility of an accreta. Second, Dr. Harrison believes that Staff H did not appropriately counsel Patient 12 on her options and the nature of her risks during her consent process.

225. Regarding the decision to begin Patient 12's procedure at Planned Parenthood, Dr. Harrison expressed particular concern about the absence of specific notation of Doppler color flow and the inclusion of the phrase "cannot exclude possible accreta" in the ultrasound report. Harrison contends that BJH should have performed an MRI in conjunction with this ultrasound. Additionally, Harrison noted that at multiple points in these records the "diagnosis" of "placenta accreta" appeared. Harrison agrees that placenta previa alone does not constitute a maternal indication, but believes these elements in the record show a high risk for a placenta accreta.

226. Dr. Williams likewise believes that Staff H incorrectly assessed Patient 12's risk for an accreta and contends that if she had applied appropriate medical guidance, she would have made the decision to perform the procedure in a hospital. He believes that cited deficiencies related to this failure would be resolved if Planned Parenthood followed appropriate medical guidance that he interpreted, in his own clinical judgment, to necessitate treatment in a hospital setting.

227. Drs. Grossman and McNicholas believe Staff H appropriately determined that Patient 12 did not have a high risk of accreta.

228. Planned Parenthood and the Department's experts cite the same guidance to support their positions on Patient 12's risk for accreta. In 2012, the Society of Family Planning published clinical guidelines for the management of post-abortion hemorrhage. These guidelines outline categories of risk relevant to the appropriate setting for an abortion procedure. For patients with a "high risk" of hemorrhage, "strong consideration should be given to referring them to higher-acuity site [like a hospital]," whereas most patients with a "moderate risk can be

cared for in an outpatient setting.” However, “clinicians should use their clinical judgment in deciding whom to refer.”⁶⁶

229. According to the Society of Family Planning, the factors for the “moderate risk” classification are: two or more prior caesarian sections, prior caesarian section and previa, bleeding disorder, history of hemorrhage not requiring transfusion, increasing maternal age, gestational age greater than 20 weeks, fibroids, and obesity. The factors for “high risk” are accreta diagnosis or concern, history of hemorrhage requiring transfusion, and any of the moderate risk factors at the discretion of the clinician.⁶⁷

230. Based on these criteria, Patient 12 fell into the “moderate risk” category based on her caesarian section and previa, late gestational age, and potentially a bleeding disorder based on the incidence of vaginal bleeding in the week prior to the procedure. Although Planned Parenthood had an initial concern for accreta, the reassuring ultrasound eliminated that concern. As such, Staff H appropriately exercised her clinical judgment to proceed with the procedure at Planned Parenthood. Staff H met the standard of care in proceeding with the abortion at Planned Parenthood.

231. Except for the decision to begin treatment at Planned Parenthood, Dr. Williams agrees with the course of care Staff H and the other BJH physicians provided Patient 12. Dr. Williams acknowledged under cross-examination that different physicians may have differing opinions regarding whether it was appropriate to treat Patient 12 in an outpatient facility. In Dr. Williams’ clinical judgment, he would lean toward treating patients like Patient 12 in a hospital. However, he understands that other physicians disagree and believes that Patient 12’s case falls in a somewhat “gray area,” and that no standard practice exists for Patient 12’s particular set of circumstances.⁶⁸

⁶⁶ PX 14 at 6.

⁶⁷ PX 14 at 5.

⁶⁸ Tr. at 653-654.

232. Regarding Patient 12's consent for her procedure, Dr. Harrison believes she did not receive a correct appraisal of her risk for an accreta and should have been informed of the comparative benefits of hospital and outpatient treatment. More significantly, Dr. Harrison believes the records indicate that Patient 12 wished to take her pregnancy to term and that Staff H inappropriately swayed her to have an abortion by representing it was necessary for her health. As support for this concern, Harrison relies particularly on a notation in BJH records that Patient 12 "desires therapeutic abortion" or "desired to have a therapeutic termination of pregnancy."⁶⁹

233. Patient 12 did receive a therapeutic abortion at BJH. Aside from the noted "desire" for a therapeutic abortion, all of the explicit documentations of a therapeutic abortion were entered into her medical records after her transfer from Planned Parenthood. Staff H recorded that Patient 12's procedure was "elective" at multiple points in Patient 12's records prior to her transfer to BJH.⁷⁰

234. Dr. Williams initially shared Dr. Harrison's concern regarding whether Patient 12 actually sought an elective abortion. However, after reviewing Staff H's deposition, he finds her credible in her representation that Patient 12 sought an elective abortion.

2019 Inspection and Investigations

235. In January 2019, the Department initiated an internal complaint investigation of Planned Parenthood. Lanigan, Maine, and another surveyor went to Planned Parenthood unannounced to request medical records. Shannon provided these records and the Department resolved its concerns without issue or notice of deficiency. The Department believed Planned Parenthood had failed to submit required pathology reports for patient abortions. After reviewing Planned Parenthood's records, the Department determined that these patients never had abortion procedures, so pathology reports were not required.

⁶⁹ RX 58 at 18, 56, & 132.

⁷⁰ RX 56 at 27; RX 57 at 10; RX 58 at 129-130.

236. In February 2019, the Department issued a second internal complaint investigation of Planned Parenthood. Maine returned with another surveyor requesting another medical record. Again, the Department's concerns were resolved without issue or notice of deficiency. The Department conducted this investigation because it determined Planned Parenthood had failed to submit a pathology report for one of its patients' (later identified as Patient 3) two abortion procedures. Planned Parenthood had received the pathology report, but failed to submit it. It produced the report to investigators who determined, after reviewing Patient 3's record, that there were no deficient practices or evidence of regulatory violations.

237. Ordinarily, if the Department wished to review records from Planned Parenthood apart from an annual inspection, it made such a request through an encrypted e-mail. Planned Parenthood would then submit the requested documentation electronically.

238. On March 11, 2019, Department surveyors arrived at Planned Parenthood to conduct its annual licensure inspection. Cummins, Lanigan, Maine, and two other nurse surveyors performed the inspection.

239. Cummins served as the inspection team leader and Lanigan came as a representative from the Department's administration. Cummins assigned Maine to review a random sampling of patient records, complication reports, and documentation of medical emergencies.

240. Upon arrival, Shannon greeted the inspection team and led them to a conference room for their entrance meeting.

241. Shannon recalled that tensions seemed high from the outset. By contrast, Cummins recalled that Planned Parenthood employees were less cooperative than those at ASCs. Maine, however, found Planned Parenthood's staff polite and cooperative. In fact, Maine felt the 2019 inspection was less contentious than previous years.

242. During her record review, Maine identified two records as potential deficiencies. First, she determined that Planned Parenthood physicians performed pelvic exams on the date of the procedure, as opposed to the date of the 72-hour consent. Second, Maine noted in one case that although one physician performed a patient's 72-hour consent, a resident under their supervision performed the actual procedure.

243. Regarding the "same physician" consent issue, Maine found two cases in her record review where an attending physician performed the consent but a fellow performed the procedure. One of these records was for the patient now identified as Patient 1.

244. On the second day of the inspection, Department surveyors interviewed then-CMO Dr. Eisenberg about the concerns Maine identified. Dr. Eisenberg acknowledged that fellows performed the abortion procedures under the supervision of the physician responsible for the patient's care. Dr. Eisenberg also acknowledged that Planned Parenthood performed pelvic exams immediately prior to performing surgical abortions. Surveyors interviewed a second physician at Planned Parenthood who stated, "[r]outinely, they performed the time out, the pelvic exam, administered the medication, and then performed the procedure."⁷¹

245. Planned Parenthood believed its prior practices with fellow and resident care were appropriate because the attending physicians were substantially involved in the procedure. Planned Parenthood believed its practice of performing pelvic exams immediately prior to the procedure was appropriate because it was consistent with the best medical practices for pelvic exams. The Department had never cited Planned Parenthood for these practices in the past.

246. During the inspection, other surveyors called attention to small issues that prior inspectors had not cited previously. This included issues with a pass-through window, a door, and a shelf. Those issues were quickly resolved following the inspection.

⁷¹ PX 61, p. 9.

247. The inspection lasted three days. On the last day, the inspectors held an exit interview with Planned Parenthood administration. The inspectors and staff resolved the small issues concerning the physical amenities of the facility there. The inspectors informed Planned Parenthood of their suspected deficiencies concerning pelvic exams and the “same physician” requirement for consent.

248. On March 27, 2019, the Department submitted its first statement of deficiencies to Planned Parenthood. The Department cited Planned Parenthood for deficiencies related to the same physician requirement and pelvic exam timing. Additionally, the Department cited deficiencies unrelated to direct patient care, such as not holding a fire drill within the last 12 months and the absence of certain suction equipment in areas of the facility.

249. In the March statement of deficiencies, the Department determined that Planned Parenthood’s practice of performing pelvic exams on the date of the procedure violated 19 CSR 30-30.060(2)(D). The Department determined that Planned Parenthood’s practice of having fellows or residents who had not conducted the 72-hour consent perform abortions under the supervision of the consenting physician violated § 188.027.6.⁷² As factual support for the latter, the Department described two instances of patient care as follows:

Review of [patient’s] medical record showed:

-On [date withheld], 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 [date withheld], [Staff A], MD, administered Mifepristone (stops the pregnancy from growing and is the first of two medications administered in a medication-induced abortion).

* * *

-On [date withheld], [Dr. McNicholas] signed the facility's document titled, "State of Missouri Department of Health and Senior Services Informed Consent Checklist - Abortion."

⁷² Statutory references are to RSMo 2016, unless otherwise noted. Statutory references to Chapter 197 are to RSMo Supp. 2018 except where otherwise noted.

-On [date withheld], [Staff A] attempted a surgical abortion, which was unsuccessful.

-On [date withheld], [Staff A] administered Mifepristone.

-A separate document generated by [Dr. McNicholas] 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)."[⁷³]

250. In preparing this statement of deficiencies, the Department identified another issue with Patient 1. Specifically, the Department noted that Planned Parenthood had not submitted a complication report for Patient 1, but had attempted and failed to perform a surgical abortion prior to performing a medication abortion that also failed. The Department reasoned that Planned Parenthood had failed to submit a statutorily mandated complication report.

251. The Department did not cite Planned Parenthood for this deficiency. Instead, it opened an internal complaint investigation. Koebel entered the internal complaint into the Department's internal record system on March 29, 2019. The purpose of this complaint was to determine if Planned Parenthood had failed to submit other complication reports.

252. On April 2, 2019, Koebel and Lanigan arrived at Planned Parenthood to perform the Department's investigation. Koebel and Lanigan began the investigation by meeting with Shannon, Daum, and a Planned Parenthood nurse practitioner. Koebel and Lanigan represented to Shannon that they were there to investigate a complaint made against Planned Parenthood.

253. Shannon requested the identity of the complainant from the investigators. Koebel refused to divulge that the Department had initiated the investigation. As justification for this refusal, Koebel represented that the complainant's identity was confidential. The investigators

⁷³ PX 61 at 4-5.

requested certain patient records and refused to provide any other information regarding the nature or origin of the investigation.

254. Koebel based his record request on patients with similar courses of treatment to Patient 1 – specifically, patients for whom multiple abortion attempts occurred for a single pregnancy. Koebel identified these patients with the assistance of the Department’s Division of Community and Public Health – the division responsible for collecting abortion records, including complication reports and tissue reports. These requests included records for patients now identified as Patient 2 and Patient 3.

255. Koebel’s record requests included the missing complication report for Patient 1. Daum could not locate the complication report in Patient 1’s records, so she went to another portion of the facility to retrieve the paper copy of the report. Daum produced the report and a certified mail receipt indicating it was filed. Despite seeing the certified mail receipt, Koebel believed Daum had falsified the report.

256. Planned Parenthood submitted a single complication report for Patient 1, and the report did not note the failed attempt to perform a surgical abortion. The Department’s investigation revealed no other instances of a failure to submit a complication report.

257. During the investigation, Koebel requested physicians’ personal phone numbers and specifically demanded Staff B’s phone number for an interview – the treating physician for Patient 2. Shannon discussed this request with Planned Parenthood’s interim president Catherine Williams. Williams suggested, rather than providing personal phone numbers for physicians, Planned Parenthood would get Staff B on the phone for an interview if it was conducted in her presence. Koebel refused this offer.

258. In an effort to address Koebel’s requests for interviews, Shannon arranged a phone call with Koebel and a Planned Parenthood attorney. The attorney asked Koebel the

reason for the investigation, but Koebel refused to answer. No provision of CMS's guidelines precluded him from divulging the subject matter of the Department's investigation. To the contrary, Chapter 5 of the CMS guidelines affirmatively directs investigators that they should let the facility know why they are there.

259. Planned Parenthood's staff cooperated with the investigation, but the interactions between investigators and staff were tense. By Lanigan's admission, the timing of the investigation was "horrible" because Planned Parenthood's plan of correction was due soon thereafter.⁷⁴ Planned Parenthood staff accused the investigators of intentionally interfering with their plan of correction. Later, the Department extended Planned Parenthood's deadline to submit a plan of correction.

260. The Department's investigation led to a separate investigation of the licensed, independent pathology lab to whom Planned Parenthood sent tissue samples. For Patient 2 and Patient 3, Planned Parenthood submitted fetal tissue samples following surgical abortions, and the pathology lab confirmed the success of these procedures. However, Patient 2 and Patient 3 both returned to Planned Parenthood with ongoing pregnancies. The Department investigated the pathology lab and cited it with a deficiency related to its examination of fetal tissue.

261. During this time period, Planned Parenthood self-reported Patient 12's hospital transfer, and the Department subsumed her treatment into its investigation.

262. On April 9, 2019, Planned Parenthood submitted a plan of correction for the Department's March statement of deficiencies. In its plan of correction, Planned Parenthood presented an analysis of the Department's legal basis for its deficiencies and argued that its practices complied with pertinent statutes and regulations.

⁷⁴ Lanigan Depo. at 145.

263. On April 11, 2019, Koebel sent an e-mail to Williams requesting physician interviews. Koebel advised Williams that the interviews must occur in a specific order to “protect the integrity of our investigation.”⁷⁵

264. Koebel later reached out to Planned Parenthood and individual physicians, through their attorneys, to procure interviews. Koebel refused to give any context for the investigations and demanded that the interviews occur in a specific order.

265. Drs. Eisenberg and McNicholas voluntarily agreed to interviews, and Planned Parenthood agreed to make a nurse it employed directly available for interviews. Koebel refused these offers because they did not coalesce with the order he desired for interviews.

266. Because of Koebel’s aggressive interview strategy, and the fact that violations of physician consent law at issue carried possible criminal consequences, the other physicians refused his requests on advice of counsel.

267. On May 8, 2019, Koebel and Lanigan returned to Planned Parenthood to request more records. Koebel requested all patient records from the same day Patient 1 received treatment. The purpose of this request was to create a timeline for a physician’s whereabouts to test the accuracy of a supervisory note that indicated her presence for Patient 1’s procedure.

268. On May 20, 2019, the Department denied Planned Parenthood’s April plan of correction. Additionally, the Department warned Planned Parenthood it could not complete its investigation until the physicians who provided services for it agreed to be interviewed.

269. With respect to the physician consent deficiency, the Department stated:

Regarding patient #10, the Statement of Deficiencies (SOD) misidentified [Staff A] 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

⁷⁵ RX 35 at 81.

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.^[76]

270. Regarding the pelvic exam deficiency, the Department stated:

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.^[77]

⁷⁶ PX 30 at 1.

⁷⁷ PX 30 at 1-2.

271. On May 22, 2019, Planned Parenthood submitted a revised plan of correction. Although it maintained the appropriateness of its consenting practices and pelvic exams, Planned Parenthood acquiesced to the Department's concerns. Planned Parenthood agreed to have attending physicians physically present in the room for all procedures performed by residents and fellows. Additionally, Planned Parenthood agreed to perform a pelvic exam at the 72-hour consent period in addition to immediately before the procedure. Planned Parenthood advised the Department that it cannot compel physicians it did not directly employ to go against the advice of counsel and submit to interviews.

272. On May 23, 2019, Koebel sent a response on behalf of the Department. The Department accepted Planned Parenthood's plan of correction for pelvic exams and other cited deficiencies, but denied the plan of correction for physician and resident consent issues. The Department denied the latter on the grounds that the consenting physician must be "actively involved" in the procedure, not just physically present.⁷⁸ Additionally, Koebel repeated his demand for physician interviews in a certain order by stating:

[Y]ou 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 [Planned Parenthood], 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.^[79]

⁷⁸ RX 35 at 146-147.

⁷⁹ RX 35 at 147.

273. No investigator had ever previously requested interviews from Planned Parenthood in a particular order.

274. On May 28, 2019, Koebel relented and agreed to interview Drs. Eisenberg and McNicholas. Koebel demanded to audio record these interviews, and the physicians agreed.

275. Koebel asked Dr. Eisenberg a series of questions regarding residents and fellows at Planned Parenthood. Dr. Eisenberg explained Planned Parenthood's relationship with Washington University residents and fellows. He explained that residents and fellows were always supervised by an attending physician, but could perform certain procedures without direct supervision correspondent to their experience and competency.

276. Koebel asked Dr. Eisenberg if he expects a complication report for an "abandoned" surgical abortion and changed to a medication abortion.⁸⁰ Dr. Eisenberg responded in the negative; he believed the complication report is only required for a failed abortion that arises after completing the procedure.

277. Koebel asked Dr. Eisenberg if he expects physicians to identify multiple pregnancies in an ultrasound. Dr. Eisenberg stated it depends on the purpose of the ultrasound. Particularly, Dr. Eisenberg noted that physicians may only focus on determining the gestational age of the pregnancy especially at early gestational ages. If a physician identifies multiple pregnancies, he or she should document it.

278. Koebel asked Dr. Eisenberg if he expects a second 72-hour consent for continuing pregnancy after a failed abortion attempt. Dr. Eisenberg did expect a second consent if the same physician performs the procedure. Physicians do their own consenting process correspondent to the individual facts of each pregnancy in such circumstances, but they do not repeat the state's mandatory checklist.

⁸⁰ RX 36 at 11.

279. Koebel asked Dr. Eisenberg generally what Planned Parenthood should do for a patient who reports a continuing pregnancy. Dr. Eisenberg stated Planned Parenthood should bring the patient back to complete the procedure.

280. Finally, Koebel asked Dr. Eisenberg whether it is appropriate to treat a patient with prior caesarian section and history of previa in an outpatient facility. Eisenberg stated it depends on circumstances, and that Planned Parenthood uses evidenced-based testing to evaluate such a patient.

281. Koebel asked Dr. McNicholas about her notation that she was “present” for Patient 1’s and Patient 3’s procedures. Dr. McNicholas acknowledged she is not always present in the room for the procedure, but that she is present and immediately available in the surgical suite.

282. Koebel asked Dr. McNicholas about the size discrepancy between Patient 1’s gestational age as measured on the date of her first procedure and her second procedure after taking misoprostol. Dr. McNicholas explained that misoprostol can change the orientation of the uterus resulting in different measurements. Koebel did not ask about the size discrepancy between the ultrasound and pelvic exam.

283. Koebel asked Dr. McNicholas whether she directly oversees her fellows’ gross tissue exams. Dr. McNicholas stated she does not always oversee these exams.

284. Koebel asked Dr. McNicholas how Patient 3 could have a continuing pregnancy if her gross examination indicated a successful procedure. Dr. McNicholas explained that fetal parts are not visible at early gestational ages and that it was possible to have observed villi, but failed to remove the entire pregnancy.

285. Koebel asked Dr. McNicholas about Planned Parenthood’s communications with the independent pathology lab. Dr. McNicholas explained that Planned Parenthood does not

typically have communication with the pathology lab beyond the exchange of samples and test results.

286. Koebel did not ask Dr. McNicholas any questions related to Patient 2 or Patient 12.

287. Also on May 28, 2019, Planned Parenthood filed a lawsuit in circuit court seeking a temporary restraining order and injunction to compel the Department to renew its license.

288. On June 10, 2019, the circuit court ordered the Department to make a decision regarding Planned Parenthood's license renewal application.

289. On June 13, 2019, the Department issued its final statement of deficiencies.

290. The Department included a cover letter with the statement of deficiencies that summarized the Department's "most serious deficiencies" for Patients 1, 2, 3, and 12.⁸¹

291. Regarding Patient 1, the Department described its concerns as follows:

A pelvic exam was performed by a medical resident on "Patient 1" prior to a surgical abortion that failed to detect that the uterus was severely retroflexed, increasing the risk of the procedure, including the risk of failed abortion. A physician fellow then attempted a surgical abortion, which failed. [Planned Parenthood] then attempted a medication abortion on the same patient, which also failed. A physician then performed a third attempted abortion-a second attempt at surgical abortion which succeeded. The Department never received a timely complication report for either of the two failed abortions, though [Planned Parenthood] claims it prepared one for the failed medication abortion, which the Department first received while onsite for the investigation at [Planned Parenthood] on April 2 and 3, 2019. Two of the three physicians involved in this incident-including all those with direct knowledge of the initial failed procedure-have refused to be interviewed. This incident raises a series of grave concerns, including but not limited to:

a. It appears clear that the resident who performed the failed pelvic exam was inadequately supervised. If a pelvic exam had been completed by the physician who ultimately performed the successful surgical abortion after the two abortions that failed, the patient likely would not have undergone the two prior abortions. This is a reason why the Department enforces statutes and rules

⁸¹ RX 38 at 2.

consistent with the standard care as practiced by other physicians to prevent harm to patients. The rule requires a pelvic exam before the procedure is scheduled to help determine what type of procedure to be done and the best way to perform that procedure based on these preoperative findings, including in this case a pelvic exam. This also guides the preoperative counseling provided to the patient regarding risks and benefits for her particular clinical situation.

b. Both the failed surgical abortion and the failed medication abortion plainly constituted complications requiring the submission of a complication report, yet the Department never received a complication report as required by law for either failed abortion.

c. The physician fellow who performed the failed surgical abortion had another failed surgical abortion within a close timeframe, yet no issue was raised with [Planned Parenthood]'s quality assurance.

d. As discussed in our prior Statements of Deficiencies, [Planned Parenthood] did not comply with the same physician requirement as to this patient, as well as several other patients.^[82]

292. Regarding Patient 2, the Department described its concerns as follows:

A surgical abortion was performed on “Patient 2” by a physician. The fetus was at 10 weeks’ development. The physician who performed the abortion noted in the medical records that he or she identified some fetal parts to confirm the success of the abortion. The pathology lab also confirmed the presence of fetal parts. Yet the surgical abortion had failed, resulting in a continuing pregnancy. The patient contacted [Planned Parenthood] approximately three weeks later, reporting the continuing pregnancy. [Planned Parenthood] did not schedule a second attempt at abortion for over two weeks during which time the pregnancy progressed from first trimester to second trimester. [Planned Parenthood] performed the second abortion attempt without providing any additional informed consent, even though the five weeks delay resulted in material changes, both in the degree of risk to the patient and in fetal development. [Planned Parenthood]'s quality assurance process reported that the first failed attempt was likely [due] to the presence of a “twin,” even though no twin was detected in a pre-abortion ultrasound. In a peer-reviewed study of 65,045 first-trimester surgical abortions, there were 46 failed abortions, a rare complication, reviewed, in which none were cited as twin pregnancies. There was no evidence of quality control to assess the multiple failed abortions at [Planned Parenthood], limiting the opportunity to prevent failed abortions

⁸² RX 38 at 2.

from occurring in the future. Two days after the second abortion attempt, the patient was admitted to the hospital via the Emergency Department and became septic because of complications that arose subsequent to the second abortion after the previous failed abortion. The physician involved in this incident has refused to be interviewed. This incident raises a series of grave concerns, including but not limited to the following:

a. The affirmative but incorrect report by the physician that fetal parts were identified raises grave concerns about the accuracy of reporting.

b. The same concern is raised by the pathology lab's affirmative but incorrect report.

c. There was no communication with the pathology lab whatsoever after the continuing pregnancy was identified.

d. Because this physician travels to St. Louis from out of town, the delay in scheduling the second attempt appears to have been driven by the physician's convenience, rather than the patient's best interest.

e. The failure to provide an updated informed consent before the second attempt at surgical abortion violates both Missouri law and basic medical standards.

f. The quality assurance review of this incident by [Planned Parenthood] failed to provide a satisfactory explanation of the incident.^[83]

293. Regarding Patient 3, the Department described its concerns as follows:

A similar series of events happened with respect to “Patient 3” after a failed surgical abortion. Both the physician who performed the failed abortion--who was the same fellow who performed the failed abortion on Patient--and the pathology lab incorrectly reported that the abortion had been successful after reviewing the products of conception. The patient returned to [Planned Parenthood] with a continuing pregnancy about 5 weeks later. No updated informed consent process was provided to the patient prior to the second surgical abortion. No communication occurred with the pathology lab to seek an explanation for this second failure to detect a failed abortion. The physician fellow involved in this incident has refused to be interviewed. This incident raises several grave concerns similar to those discussed above with respect to “Patient 2.” In addition, as discussed in our prior Statements of Deficiencies, [Planned Parenthood] also violated the same-physician requirement in this incident.^[84]

⁸³ RX 38 at 2-3.

⁸⁴ RX 38 at 3.

294. Regarding Patient 12, the Department described its concerns as follows:

The treatment provided to “Patient 12” raises particularly grave concerns. Patient 12 was recommended to have a therapeutic abortion after 21 weeks’ gestation. The patient was examined by an [Planned Parenthood] physician at a hospital, who concluded that the patient had placenta previa--which in the majority of cases resolves as the uterus grows and the placenta moves up--and/or placenta accreta, along with a history of C-section. An ultrasound was performed which did not have findings to completely exclude or confirm placenta accreta. If a surgical abortion is to be performed, given the high risks of such a procedure, an ACOG Committee Opinion states that a second-trimester abortion on such a patient should be performed at a facility with blood products and the capacity for interventional radiology and/or hysterectomy; [Planned Parenthood] lacks all three. For unexplained reasons, the physician nevertheless referred the patient to [Planned Parenthood]’s facility for the second-trimester abortion, where that physician attempted the abortion at a gestational age of 21 weeks and five days. The abortion attempt failed, and it resulted in massive uncontrolled bleeding and an emergency transfer of the patient to the hospital. The patient lost over two liters of blood, underwent a uterine artery embolization, and was described in hospital records as “critically ill.” This complication was both life-threatening and potentially preventable, and the physician’s conduct appears to have potentially deviated from standard care in a manner that inflicted serious patient harm. The physician involved in this incident has refused to be interviewed, and no other physician has first-hand knowledge of the treatment.^[85]

295. The Department’s formal statement of deficiencies delineates particular deficiencies by their statutory or regulatory underpinnings.

296. Planned Parenthood submitted a plan of correction on June 18, 2019, in which it reversed its decision to perform two pelvic exams on patients.

297. On June 21, 2019, the Department delivered a letter to Planned Parenthood denying its renewal application. In the denial letter, the Department accepted Planned Parenthood’s plans of correction for deficiencies related to communication with the pathology lab, the same physician consent requirement, and for failure to include dates and times on certain medical records.

⁸⁵ RX 38 at 3-4.

298. The Department considered the remaining deficiencies unresolved. In brief, these deficiencies concern:

- Failure of Planned Parenthood to procure physician interviews.
- Failure to file complication reports for the surgical abortion attempt on Patient 1.
- Failure to perform a pelvic exam during the 72-hour consent process.
- Failure to accurately document the size and orientation of Patient 1's uterus and consequently failing to successfully aspirate her uterus.
- Failure to ensure a prompt follow-up appointment with patients who reported continuing pregnancy.
- Failure to provide informed consent for second procedures after initial failed abortions.
- Failure to ensure proper care in a safe environment for Patient 12.
- Failure to provide proper counseling and informed consent to Patient 12.
- Failure to document the particular physician who gave patients medication abortion drugs.
- Inaccurate documentation concerning attending physicians' "presence."
- Failure to file physical complication reports with the Department.
- Insufficient quality assurance practices.

299. Department investigators drafted each of their statements of deficiencies in conjunction with Dr. Williams. The clinical judgments expressed in the statements of deficiency belong to Dr. Williams.

300. The Department subsequently amended its regulations to allow abortion providers to only perform pelvic exams when, in their professional judgment, they are indicated.

Conclusions of Law

This Commission has jurisdiction to hear Planned Parenthood's complaint.⁸⁶ Section 197.215 provides that the Department shall renew a license for an abortion facility that meets the requirements established in §§ 197.200 through 197.240. The Department denied Planned

⁸⁶ Section 197.221, RSMo 2016.

Parenthood’s application, citing multiple allegations of statutes and regulations applicable to abortion facilities. As the party seeking renewal, Planned Parenthood holds the burden of proving it is entitled to renewal of its license.⁸⁷

Planned Parenthood argues it meets all the requirements to hold a license. Additionally, Planned Parenthood contends the Department’s denial of Planned Parenthood’s license was contrary to law, arbitrary and capricious, not based on substantial evidence, unreasonable, and unconstitutional. The Department denies that Planned Parenthood meets the qualifications for license renewal or that it acted unconstitutionally. The Department supplements these arguments with eight affirmative defenses.

We decide the issue that was before the Department, which is Planned Parenthood’s application for renewal.⁸⁸ We exercise the same authority that has been granted to the Department.⁸⁹ Therefore, we simply decide the application *de novo*.⁹⁰

Credibility

This Commission must judge the credibility of witnesses, as well as the weight and value of the evidence.⁹¹ We have the discretion to believe all, part, or none of the testimony of any witness.⁹² When there is a direct conflict in the testimony, we must make a choice between the conflicting testimony.⁹³ Our findings of fact reflect our credibility assessments.

With regard to the expert witnesses presented by the Department and Planned Parenthood, we have broad discretion in determining the admission of evidence, including expert

⁸⁷ Section 621.120.

⁸⁸ *Department of Soc. Servs. v. Mellas*, 220 S.W.3d 778 (Mo. App. W.D. 2007).

⁸⁹ *J.C. Nichols Co. v. Director of Revenue*, 796 S.W.2d 16, 20 (Mo. banc 1990).

⁹⁰ *State Bd. of Regis’n for the Healing Arts v. Trueblood*, 368 S.W.3d 259, 264 (Mo. App. W.D. 2012). “*De novo*” is defined as “anew; afresh; a second time.” BLACK’S LAW DICTIONARY 392 (5th ed. 1979).

⁹¹ *Faenger v. Petty*, 441 S.W.3d 199, 204 (Mo. App. W.D. 2014).

⁹² *Dorman v. State Bd. of Regis’n for the Healing Arts*, 62 S.W.3d 446, 455 (Mo. App. W.D. 2001).

⁹³ *Harrington v. Smarr*, 844 S.W.2d 16, 19 (Mo. App. W.D. 1992).

testimony.⁹⁴ Section 490.065 is the relevant statute of admissibility. The parties presented expert testimony from five obstetricians and gynecologists. Planned Parenthood CMO Dr. Colleen McNicholas and Dr. Daniel Grossman testified on behalf of Planned Parenthood. Department Director Dr. Randall Williams, Dr. Donna Harrison, and Dr. John Thorp testified on the Department's behalf.

In making our credibility assessments, this Commission is conscious of the societal ethical dilemma abortion care entails. All of the Department's experts hold openly pro-life viewpoints, and all of Planned Parenthood's experts hold openly pro-choice viewpoints. By way of contrast, Dr. Grossman believes physicians have a responsibility to advocate for their patients' access to safe abortion care, whereas Dr. Harrison considers it homicide. Before reviewing the facts of this case, both of the aforementioned experts made public statements in support of their retaining parties.

We understand that these authentically and strongly held moral beliefs may color these experts' interpretation of patient care. However, these ethical considerations fall well outside the purview of our review. As the neutral adjudicator of this dispute, we hold a responsibility to apply statutes and regulations correctly and ascertain facts fairly. To this end, we make our credibility determinations for these experts based on objective, measurable factors. In reviewing expert testimony, we first looked for consistency with the opinions of other experts, published research in evidence, and the specific facts of the case as indicated by medical records and fact witnesses.

Each expert presented informative testimony. Dr. Harrison and Dr. Williams provided important testimony regarding gynecological care generally.⁹⁵ However, only Drs. Grossman

⁹⁴ *Moheet v. State Bd. of Regis'n for Healing Arts*, 154 S.W.3d 393, 401 (Mo. App. W.D. 2004), citing *Rigali v. Kensington Place Homeowner's Ass'n*, 103 S.W.3d 839, 844 (Mo. App. E.D. 2003).

⁹⁵ We found Dr. Thorp's testimony largely cumulative of Drs. Harrison's and Williams' opinion.

and McNicholas actually provide abortion care and have done so extensively for many years. Political concerns disregarded, abortion is a medical procedure – it involves physicians consulting with patients, conducting surgical procedures, administering medication, and providing general care. Our review of the record illustrated that Drs. McNicholas and Grossman were better acquainted with the actual procedures and practices of abortion providers – for instance, the use or disuse of Doppler color flow and sharp curettage. Our findings of fact reflect our credibility assessments for these experts.

Planned Parenthood’s Qualifications for Renewal of Licensure

Planned Parenthood argues it is entitled to licensure by attacking the specific deficiencies cited by the Department as grounds for its non-renewal. In its answer, the Department references numerous incidents that it contends preclude it from renewing Planned Parenthood’s abortion facility license.

Section 197.215.2 governs the renewal of abortion facilities’ licenses. It provides in relevant part:

Upon receipt of an application for a license, or the renewal thereof, the department shall issue or renew the license if the applicant and program meet the requirements established under sections 197.200 to 197.240. Each license shall be issued only for the persons and premises named in the application. A license, unless sooner suspended or revoked, shall be issued for a period of one year.

The Department may only deny a license if it finds a “substantial failure” to comply with §§ 197.200 through 197.240, if the applicant or its affiliate persons have been found guilty of certain crimes, or if the applicant’s licensure status or records indicate that granting a license would be detrimental to the public interest.⁹⁶ In this case, the Department denied Planned Parenthood’s license under the first provision. As stated in the Department’s denial letter:

Under section 197.220 RSMo, the Department finds-based on the serious, extensive unresolved deficiencies cited in the SOD and the

⁹⁶ Section 197.220.

absence of an acceptable corrective-action plan from [Planned Parenthood] with respect to those deficiencies- that *there has been a substantial failure to comply with the requirements of sections 197.200 to 197.240 RSMo*. The Department therefore denies RHS's application for a license renewal. This denial does not preclude RHS from resubmitting an application for license at any time, provided outstanding deficiencies are resolved.[⁹⁷]

Planned Parenthood avers that it meets all requirements for licensure. The Department only contests those requirements identified in its amended answer.⁹⁸ These requirements reflect the unresolved findings in the Department's final statement of deficiencies. The Department's final statement of deficiencies cites numerous violations. The word "substantial" is not defined in Chapter 197. In construing statutes, we are to accord words their plain and ordinary meaning.⁹⁹ We find the meaning in the dictionary.¹⁰⁰ "Substantial" means "being that specified to a large degree or in the main."¹⁰¹ Because the Department may only refuse renewal for substantial failure to comply, we restrict our consideration of these deficiencies to those deemed "most important" in the Department's denial letter and those related to the conduct described in the Department's amended answer. We address these issues in turn.

Physician Interviews

The Department contends Planned Parenthood has failed to comply with § 197.230 and 19 CSR 30-30.060(1)(A)¹⁰² because it failed to produce physicians for interviews as directed by the Department.

Section 197.230.1 provides:

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

⁹⁷ RX 41 at 4.

⁹⁸ When an applicant for licensure files a complaint, the agency's answer provides notice of the grounds for denial of the application. *Ballew v. Ainsworth*, 670 S.W.2d 94, 103 (Mo. App., E.D. 1984).

⁹⁹ *Delta Air Lines, Inc. v. Dir. of Revenue*, 908 S.W.2d 353, 355 (Mo. banc 1995).

¹⁰⁰ *Id.* at 356.

¹⁰¹ WEBSTER'S THIRD NEW INT'L DICTIONARY 2280 (unabr. 1986).

¹⁰² All references to "CSR" are to the code of state regulations current as of March 31, 2018. These were the regulations in effect at all times relevant to the findings of this decision.

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.^[103]

Regulation 19 CSR 30-30.060(1)(A)8 provides:

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.

No provision of Chapter 188, Chapter 197, or Title 19, Division 30 of the Department's regulations contains any language regarding "interviews." Section 197.230.1 allows the Department to make or cause investigations to be made as it sees fit, but provides no explicit authority for what those investigations must entail. We find nothing to preclude the Department from making negative inferences from the absence of these interviews as it has in this case. However, the absence of these interviews in itself does not constitute a failure to comply with licensure requirements.

The Department warns that this interpretation effectively neuters its investigative power over abortion facilities and makes § 197.230.1 meaningless. Consequently, it argues we cannot read the statute as such because the legislature would not intend to "enact a meaningless provision."¹⁰⁴ We do not share these concerns.

Section 197.230.1's provision that the Department may conduct "inspections and investigations as it deems necessary" means just that. The clause "as it deems necessary" refers to the Department's authority to conduct investigations. The Department may visit facilities, the

¹⁰³ Emphasis added.

¹⁰⁴ *Edwards v. Gerstein*, 237 S.W.3d 580, 581 (Mo. banc 2007).

Department may request records, the Department may request interviews, etc. However, that authority does not compel any certain action on the part of the investigated licensee.

Other statutory directives concerning investigatory powers bolster this interpretation. If the legislature intended to grant authority to compel cooperation or deny a license based on lack of cooperation, as is the case in other instances, it would have also done so for abortion facilities.¹⁰⁵ As Planned Parenthood notes, the legislature has deemed failure to cooperate with investigations to be cause for discipline or denial of licensure for physicians, nurses, and veterinarians.¹⁰⁶

In addition to the professional licensing bodies cited by Planned Parenthood, we note that the legislature has explicitly enacted requirements for the Department's other licensees that closely resemble the Department's implicit reading of § 197.230.1. Specifically, ambulance licensees who employ or supervise certain medical personnel "shall cooperate with the department's efforts to monitor and enforce compliance by those individuals subject to the requirements of sections 190.001 to 190.245."¹⁰⁷ Also, licensed daycares "shall cooperate with the investigation and inspection by providing access to the adult day care program, records and staff."¹⁰⁸ The legislature has demonstrated it can compel the Department's licensees to cooperate with investigations and make staff available, but it has chosen not to for abortion facilities.

Of course, if a facility refuses to cooperate or obstructs the Department's investigation, it does not escape consequences. For instance, if a licensee stopped inspectors at the door, the Department obviously could not verify that the facility met the requirements for licensure or issue a license. However, the Department does not need unlimited authority to determine a

¹⁰⁵ See *Abbott Ambulance v. St. Charles Cty. Ambulance Dist.*, 193 S.W.3d 354, 361 (Mo. E.D. App. 2006).

¹⁰⁶ Sections 334.100.2(4)(m)–(n), and 334.127, RSMo (authorizing Board of Registration for the Healing Arts to issue subpoenas and take licensure action for failure to comply); §§ 335.066.2(6)(h)–(i) and 335.097 (Board of Nursing, same); §§ 340.264.2(4)(l)–(m) and 340.280 (Veterinary Medical Board, same).

¹⁰⁷ Section 190.196.2.

¹⁰⁸ Section 192.2225.

licensee’s qualifications for licensure, and instances of refusal or obstruction must be viewed in light of all the facts and circumstances before the Department. The simple fact that Planned Parenthood failed to ensure its contracted physicians submitted to interviews does not violate § 197.230.1.

Failure to File Complication Reports for Patient 1

The Department contends it had cause to deny renewal under § 188.052.2, 19 CSR 10-15.020, and 19 CSR 30-30.060(3)(H) because Planned Parenthood failed to file a complication report for its unsuccessful attempts to perform a surgical abortion for Patient 1. The Department can only refuse license renewal based on a substantial failure to comply with §§ 197.200 to 197.240.¹⁰⁹ The Department does not plead which of these sections authorizes it to refuse a license for a violation of § 188.052.2, 19 CSR 10-15.020, or 19 CSR 30-30.060(3)(H). However, we discern they may constitute a cause for denial through § 197.225, as regulations to “assure quality patient care and patient safety.”¹¹⁰

Section 188.052.2 provides:

An individual complication report for any post-abortion care performed upon a woman shall be completed by the physician providing such post-abortion care. This report shall include:

- (1) The date of the abortion;
- (2) The name and address of the abortion facility or hospital where the abortion was performed;
- (3) *The nature of the abortion complication diagnosed or treated.*

Regulations 19 CSR 10-15.020 and 19 CSR 30-30.060(3)(H) incorporate § 188.052.2 into the Department’s regulations for abortion facilities.

All parties agree that a “failed abortion” constitutes a complication. The dispositive issue for this deficiency is whether an immediately recognized, abandoned effort to perform an

¹⁰⁹ Section 197.200.

¹¹⁰ Section 197.225.1.

abortion constitutes a failed abortion. Neither Chapter 188 nor the Department’s regulations define “complication.” The Department publishes a standard form that lists particular complications with boxes that may be checked by an abortion facility, but the form does not define the complications. In order to comply with § 188.052, Planned Parenthood has drafted its own definitions based on generally accepted medical definitions.

Planned Parenthood’s internal definitions for complications define “failed abortion, pregnancy undisturbed” to apply to “any patient who the clinician diagnoses with a continuing pregnancy with ongoing fetal growth and/or cardiac activity on ultrasound.”¹¹¹ PPFA’s model standards and guidelines describe the timing for a failed abortion as “Postoperative (*immediately or delayed*).”¹¹² Given these definitions, we believe that the abandoned procedure on Patient 1 did constitute a failed abortion, and thus violated § 188.052. However, we do not consider this single violation a substantial violation.

As Dr. Williams acknowledges, there is a “gray” area for what he would consider a failed abortion. This “gray” area falls somewhere on the continuum of the extent to which efforts to complete the surgical abortion occurred. Considering the facts of Patient 1’s care, it is easy to see why Dr. McNicholas would not identify this attempt as a failed abortion. But for Patient 1’s unique uterine anatomy, Dr. McNicholas and the rest of the care team would have succeeded – and could have succeeded if they persisted in their effort. However, out of concern for the patient’s comfort, they changed modalities. Given the unique circumstances underlying this incident and the reasonable viewpoint that it was not a failed abortion, we find it unlikely to represent a pattern of non-compliance or willful concealment by Planned Parenthood. Furthermore, Dr. Williams represented at hearing that the Department will revise its form to differentiate between failed abortions recognized immediately and those diagnosed on a later

¹¹¹ PX 159.

¹¹² RX 33 at 48 (emphasis added).

date. Given this, we find no reason for concern with this isolated violation and do not deem it to be substantial.

Failure to Maintain Accurate Records

The Department contends it had cause to deny renewal under 19 CSR 30-30.060(3)(B), which provides, “The facility shall maintain a medical record according to professional standards for each patient.”

The Department initially cited multiple instances of Planned Parenthood’s record keeping, including Dr. McNicholas’ practice of noting she was “present” for procedures, but not in the room with patients. The Department pled that Planned Parenthood submitted an acceptable plan of correction for this deficiency. As such, we deem any possible violation of 19 CSR 30-30.060(3)(B) to be unsubstantial and, therefore, not grounds to deny license renewal.

Failure to Provide Statutory Informed Consent to Patient 2 and Patient 3

The Department contends it has cause to deny renewal under § 188.027 and 19 CSR 30-30.060(2)(B)-(C), based on Planned Parenthood’s practice of not repeating 72-hour consent procedures for patients who experienced failed abortions and returned to complete them. Section 188.027.1 provides:

Except in cases of medical emergency, no abortion shall be performed or induced on a woman without her voluntary and informed consent, given freely and without coercion. Consent to an abortion is voluntary and informed and given freely and without coercion if, and only if, at least seventy-two hours prior to the abortion[.]

Regulation 19 CSR 30-30.060(2)(B)-(C) incorporates § 188.027.1 into the Department’s regulations for abortion facilities.

Section 188.027 requires a 72-hour waiting period for an *abortion*, not each abortion attempt. Statutes must be construed to give effect to the legislature’s intent and avoid

unreasonable results.¹¹³ If we accept the Department's interpretation, unreasonable results would arise. We need not look any further than the case of Patient 1 as an example. As the Department has shown, Patient 1 suffered three failed abortion attempts in quick succession. Under the Department's interpretation, Patient 1's procedure must have stopped after the resident abandoned her efforts to aspirate the uterus. If this were the case, then Patient 1 could not return until at least three days later, and then she would have been sent home again after Staff A discontinued her efforts and *again* after Dr. McNicholas attempted and failed. Aside from clear logistical frustrations this interpretation creates for patients, this also exacerbates the safety concerns that informed consent requirements seek to minimize.

One of the reasons the Department advances the necessity for a second consent is the fact that abortion risks increase with gestational age. This position justifies providing the patients an assessment of the risks for their procedures, but not delaying the procedure longer and, ostensibly, causing her greater risks as the pregnancy advances. Furthermore, this interpretation compromises patient safety by providing an incentive for patients and physicians to continue in a potentially compromised abortion effort for fear that they may have to wait another three days to attempt a different approach.

Additionally, it is worth noting that both Patient 2 and Patient 3 did receive standard medical consents for their second procedures. Staff B recorded in Patient 2's medical record that he informed her "about what to expect emotionally and physically before, during, and after procedure." Staff B provided Patient 2 with Planned Parenthood's internal consent documentation and included it in her medical records. Dr. McNicholas did the same for Patient 3. Embracing the Department's interpretation would not provide any added safety or consent benefit to these patients, but it would cause potential harm. Given this unreasonable result and the plain

¹¹³ *State ex rel. Nixon v. Karpierz*, 105 S.W.3d 487, 491 (Mo. banc 2003).

language of the statute that refers to a single “abortion” rather than an attempt or procedure, we find that Planned Parenthood has not violated § 188.027.

*Failure to Maintain and Administer
Policies to Ensure Safe Care*

The Department contends it had cause to deny renewal under 19 CSR 30-30.060(1)(A)1 for failing to provide acceptable care in a safe environment, to provide quality care, and to follow standards of care. This contention concerns the appropriateness of the care provided to Patients 1-3 and 12.

Regulation 19 CSR 30-30.060(1)(A)1 states:

The governing body^[114] 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.

The Department cited numerous occurrences and decisions made by Planned Parenthood physicians as evidence that Planned Parenthood’s administration does not have or does not administer sufficient policies to ensure the care its patients receive is safe and within the standard of care. The Department does not cite any particular written or implicit policy that evinces this deficiency. Instead, it relies on four instances of care it considered unsafe or outside standards of care. Based on this, Planned Parenthood argues that the Department has failed to state a cause to deny renewal because 19 CSR 30-30.060(1)(A)1 applies to standards of care in administration and policy. As summarized by Planned Parenthood:

The Department has made clear that it has not cited Planned Parenthood for deficient policies, but rather for “negative outcomes that occurred to patients.” That is, the Department is citing Planned Parenthood largely for a supposed failure of individual physicians to follow the standard of care—but it is not

¹¹⁴ Governing body means an individual owner, partnership, corporation or other legally established authority in whom the ultimate authority and responsibility for management of the ambulatory surgical center is vested. 19 CSR 30-30.060(1)(H).

citing Planned Parenthood for failing to follow the standard for administration of policies. The regulation requires that the policies be administered in accordance with the standard of care, but the Department offered no testimony about the standard of care for administration of policies ... Without knowing the standard of care for administration of the policies, the Commission cannot determine that the standard was not followed.^[115]

We find Planned Parenthood's position unpersuasive. Regulation 19 CSR 30-30.060(1)(A)1 requires Planned Parenthood to ensure its policies are "administered in a manner to provide acceptable care in a safe environment and in accordance with all ... standards of care." Although the language is somewhat ambiguous, we understand it to mean that the administration of policies should provide care in accordance with all standards of care. It is not enough for the administration to have policies for providing acceptable care, the administration must actually administer and implement policies that accomplish that directive.

The Department's failure to cite specific policies does not preclude their success. We could, as the Department suggests, infer from a pattern of unsafe care or deviations from standard of care that Planned Parenthood has failed to administer policies sufficient to reach those ends. Therefore, we must review the instances of patient care the Department cites as deficient and consider, based on the extent and severity of these putative violations, whether Planned Parenthood has violated 19 CSR 30-30.060(1)(A)1.

Absent a statutory definition, the plain meaning of words used in a statute, as found in the dictionary, is typically used.¹¹⁶ The term "safe" means, "secure from harm, injury, or risk."¹¹⁷ We must determine "standards of care" based objective standards, but no particular formula exists for such standards.¹¹⁸ We may determine that conduct violates a standard of care without

¹¹⁵ Pet'r Brief at 156-57.

¹¹⁶ *E&B Granite, Inc. v. Dir. of Revenue*, 331 S.W.3d 314, 318 (Mo. banc 2011).

¹¹⁷ WEBSTER'S THIRD NEW INT'L DICTIONARY UNABRIDGED 1998 (1986).

¹¹⁸ *Wodohodsky v. Hall*, 573 S.W.3d 645, 651 (Mo. App. S.D. 2019), citing *Hickman v. Branson Ear, Nose & Throat, Inc.*, 256 S.W.3d 120, 123-24 (Mo. banc 2008).

expert testimony if an inexperienced person could draw a fair and intelligent opinion from the facts.¹¹⁹ With these principles in mind, we consider each instance of patient care in turn.

*Failure to Investigate Gestational Age
Discrepancy for Patient 1*

The Department argues that Dr. McNicholas, Staff A, and the resident failed to provide safe care within the standards of care to Patient 1 by failing to investigate the discrepancy between Patient 1's gestational age as measured by pelvic exam and ultrasound. On the date of the procedure, Patient 1's pregnancy had a gestational age of eight weeks, four days. However, the resident estimated her gestational age by pelvic exam as less than six weeks.

The Department contends that if the physicians had investigated this discrepancy prior to instrumenting Patient 1's uterus, they would have determined her uterus was retroflexed and been more likely to succeed in their initial attempt. The Department argues these failed attempts placed Patient 1 in danger of uterine perforation.

We find no evidence that the failure to investigate this size discrepancy deviated from the standard of care or made Patient 1's care unsafe. This incorrect estimation of gestational age by pelvic exam had no effect on the outcome of Patient 1's procedure. The resident and Staff A appropriately relied on the more accurate ultrasound measure in conducting the procedure. Although the discrepancy between their estimated gestational age and the actual gestational age most likely stemmed from Patient 1's retroflexed uterus, Patient 1's care team took every appropriate step to locate the pregnancy and attempt the procedure. Specifically, they determined uterine position while using ultrasound to dilate and administer the cannulas. Because Planned Parenthood does not use sharp instrumentation, this process did not entail any significant risk of harm to the patient beyond the discomfort ordinarily associated with successful surgical abortions. Given the rarity of Patient 1's uterine anatomy and the safety of

¹¹⁹ *Perez v. State Bd. of Regis'n for the Healing Arts*, 803 S.W.2d 160, 164 (Mo. App. W.D. 1991).

instrumenting the uterus, we find it unnecessary that Planned Parenthood should adopt more rigorous policies or practices than it already does for determining flexion. With respect to this issue, we find no cause to deny Planned Parenthood’s renewal application under 19 CSR 30-30.060(1)(A)1.

Failure to Ensure Accuracy of Gross Tissue Exams

The Department contends Planned Parenthood failed to provide safe care within the standard of care by failing to ensure the accuracy of gross tissue exams for Patient 2 and Patient 3’s first surgical abortion attempts. The Department advances this argument in two parts. First, it claims Planned Parenthood failed to follow up with the pathology lab to ensure the accuracy of its tests. Second, the Department contends that Staff A and Staff B likely failed to appropriately conduct their procedures and gross exams. As stated by the Department:

[Planned Parenthood] contends that these failures were the result of innocent mistakes, not the failure to provide quality care and comply with standards of care, because in both cases, the pathology lab also reported that the first attempt had been successful. However, the pathology lab was found to have a condition-level deficiency in its procedures for reviewing fetal tissue samples, indicating that its procedures were unreliable. [Planned Parenthood] failed to detect this problem because it failed to communicate with the pathology lab even after two patients returned with continuing pregnancies despite the pathology lab’s report that their prior abortions had been successful—which is a separate deficiency for which [Planned Parenthood] submitted an acceptable plan of correction.^[120]

We find this position unpersuasive. At the time, Planned Parenthood had no reason to doubt the validity of the pathology results because, in the thousands of abortions it provided since 2018, no other comparable occurrence had arisen with the independent pathology lab. Although the Department later cited the lab for a deficiency related to its fetal tissue exams, Planned Parenthood had no reason to suspect these deficient practices.

¹²⁰ Resp. Brief at 125.

Concerning physicians' failure to ensure their patients' uteri were evacuated, the Department argues that Staff A and Staff B, "through carelessness, failure to exercise reasonable care, or some other reason—failed to ensure the two patients' uteruses were empty and erred in their examination of the fetal tissue."¹²¹

We disagree with respect to Patient 1. As Dr. McNicholas explained to Koebel, fetal parts are not visible at early gestational ages, and it was possible Staff A observed villi, but failed to remove the entire pregnancy. Given Planned Parenthood's high success rate for surgical abortions, a single complication such as this does not create cause for concern. Failed surgical abortions are a rare, but known, complication and they do not occur at an unusual rate at Planned Parenthood.

Concerning Patient 2, we agree that her continuing pregnancy likely stemmed from error or carelessness on the part of Staff B. Missed twins constitutes an exceptionally rare occurrence in obstetrics and gynecology. Patient 2's obesity may have contributed to an erroneous reading of the ultrasound. However, given the fact that Patient 2 expressly desired to know if she had multiple gestations and the rarity of this failure, we find the most likely explanation lies with Staff B's carelessness in reviewing her ultrasound.

We do not, however, find that Staff B's error provides sufficient evidence that Planned Parenthood, as an institution, has failed to ensure safe and appropriate care. Dr. Madden reviewed Patient 2's care and presented it for review at Planned Parenthood's quality assurance meeting. With the facts available to her, she and the quality assurance team reasonably concluded that the most plausible explanation for Patient 2's ongoing pregnancy was a missed twin. The quality assurance team did not consider a uterine abnormality possible because Staff B would have become aware of it through Patient 2's numerous prior pregnancies. Although Staff B did

¹²¹ *Id.*

not attend the quality assurance review meeting, Dr. Eisenberg spoke with him regarding Patient 2's continuing pregnancy under the auspices of Planned Parenthood's quality assurance program. As such, Staff B became aware of his mistake and is therefore on notice to avoid it in the future.

Given these facts, we do not find Planned Parenthood failed to ensure safe and appropriate care in ensuring the accuracy of its gross tissue exams. With respect to this issue, we find no cause to deny Planned Parenthood's renewal application under 19 CSR 30-30.060(1)(A)1.

Beginning Patient 12's Treatment in an Outpatient Facility

The Department argues Staff H failed to provide safe care within the standard of care for Patient 12 by performing her surgical abortion at Planned Parenthood instead of BJH. The Department advances three arguments to illustrate this point. First, it contends that Staff H erred in considering Patient 12's ultrasound reassuring for the absence of an accreta and should have followed up with the physician who performed the ultrasound to resolve the ambiguity of their finding. Second, even if the ultrasound was reassuring, Staff H should not have performed the procedure in an outpatient setting because other factors indicated a risk for hemorrhage. Third, even if Staff H determined that treatment in an outpatient facility was appropriate, she should have counseled the patient about the risks of performing the procedure.

We do not share the Department's concerns. Patient 12 received an ultrasound with Doppler color flow – the best available metric for evaluating her risks for accreta. The ultrasound report showed no cardinal findings consistent with accreta. The report also indicated that it could not exclude the possibility of accreta. Only a hysterectomy can conclusively diagnose an accreta, but studies have shown Doppler color flow ultrasound correctly rules out accreta in 96% of cases. This finding certainly presents reassuring evidence that Patient 12 did not have an accreta. Furthermore, Staff H is a highly competent and well trained physician

working in an elite hospital for obstetric and gynecological care. We find no cause to doubt her readings of the ultrasound report, given that it is consistent with published research and expert testimony presented to this Commission.

Regarding Patient 12's other risk factors for a surgical abortion, we acknowledge that she presented with these risk factors. However, the evidence presented by both the Department and Planned Parenthood indicates that Staff H properly exercised her discretion to proceed with the abortion at Planned Parenthood. Patient 12 met several risk factors that placed her at a "moderate" risk for a hemorrhage. Published guidance indicates that such a risk may make hospital treatment appropriate, but only at the discretion of the clinician. That guidance also states that these factors could place the patient at "high" risk of hemorrhage, thus indicating the necessity of hospital treatment. However, the guidance explicitly states that determination rests in the clinician's discretion. We find no cause to second guess Staff H's discretion in this case. Even Dr. Williams acknowledged that reasonable physicians could make different determinations regarding the setting for Patient 12's abortion. Although he would have decided differently, Dr. Williams believes that Patient 12's case falls in a somewhat "gray area," and that no standard practice exists for Patient 12's particular set of circumstances. As such, we find no cause for concern with Staff H's decision to perform the procedure at Planned Parenthood.

Finally, the record does not reflect a failure by Staff H to counsel the patient about the risks of performing the procedure. The record reflects that Staff H provided appropriate consent to Patient 12 and discussed the risks particular to her procedure. After evaluating her ultrasound, Staff H met with Patient 12 and assessed her decision making about having an abortion. Patient 12 expressed a desire to proceed with an abortion. Staff H reviewed Patient 12's medical history with the patient. Staff H then discussed the risks, benefits, and alternatives to continuing the pregnancy with Patient 12, and went through Missouri's mandatory 72-hour consent process.

This discussion included the unique risks Patient 12 faced. Staff H documented discussing “the increased risk to maternal health or life endangerment from placenta previa, history of cesarean section, and possible placenta accreta” in Patient 12’s medical records. Staff H specifically asked and received consent from Patient 12 for “elective termination of pregnancy” at Planned Parenthood. We find no cause for concern with Patient 12’s informed consent. With respect to this issue, we find no cause to deny Planned Parenthood’s renewal application under 19 CSR 30-30.060(1)(A)1.

Staff H’s Recommendation of a “Therapeutic Abortion” for Patient 12

In the Department’s amended answer, it alleges that Staff H “advised Patient 12 that she should have a therapeutic abortion of a wanted child in the 21st week of gestation based on her history of C-section and possible abnormal placentation” when a therapeutic abortion was not necessary.¹²² In the alternative, the Department argues that if Staff H did not counsel Patient 12 to have a therapeutic abortion, she erroneously documented otherwise in Patient 12’s medical records. In the Department’s words:

In her deposition, Staff H testified that she had not counseled Patient 12 to have a therapeutic abortion, and that the abortion was elective from the outset of her interactions with Patient 12. This testimony, if true, resolves the Department’s concern that Patient 12 was erroneously counseled to have a therapeutic abortion for medical reasons of a wanted second-trimester unborn child. But it exchanges that concern for an even greater concern about the entry of incorrect information in Patient 12’s medical records.^[123]

The record does not support these contentions. In Planned Parenthood’s medical records, Staff H recorded that Patient 12 presented to Planned Parenthood “for elective termination of pregnancy” and that she was “[c]onfident and clear about decision to have the abortion.”

¹²² Amended Answer at 16.

¹²³ Resp. Brief at 131.

Although the records include the notation that Patient 12 *desired* a therapeutic abortion, there is no indication that Staff H counseled her to have one. The record only reflects that Staff H advised her of the risks associated with her unique circumstances, and that Patient 12 made the decision to continue with the abortion. After reviewing Staff H's deposition testimony, Dr. Williams no longer has any concern that this was not an elective procedure.

Based on a complete reading of Patient 12's medical records, we find no cause to suspect anything else, even with her documented desire for a "therapeutic abortion." Patient 12 did eventually receive a therapeutic abortion at BJH. Staff H recorded that Patient 12's procedure was "elective" at multiple points in Patient 12's records prior to her transfer to BJH.¹²⁴ Furthermore, we also note that Patient 12 may have in fact desired a "therapeutic" abortion for non-medical reasons. Specifically, if she had received a therapeutic abortion, she could have offset her medical expenses with National Abortion Federation Funds. As such, we find no reason to doubt the accuracy of these records.

We find no cause for concern in Staff H's consultation with Patient 12 or the notations in her medical record. With respect to this issue, we find no cause to deny Planned Parenthood's renewal application under 19 CSR 30-30.060(1)(A)(1).

*Failure to Give Meaningful Quality
Assurance Review to Patients 1-3*

In its last stated grounds for denial, the Department contends Planned Parenthood failed to perform sufficient quality assurance measures in violation of 19 CSR 30-30.060(8)(C), which provides:

The QAPI^[125] program shall show evidence of action the facility took regarding problems identified and shall identify opportunities for improvement.

¹²⁴ RX 56, p. 27; RX 57, p. 10; RX 58, p. 129-130.

¹²⁵ "Quality assessment and performance improvement." 19 CSR 30-30.060(8)(A).

Regarding Patient 1 and Patient 3, the Department contends:

[Planned Parenthood’s] quality-assurance process included no discussion of their failed abortions other than providing them in a statistical report of the number of failed abortions at the facility during the relevant quarter. As to Patient 1, there was no discussion of the fact that she experienced five abortion attempts in four days, and that she experienced both failed surgical and failed medication abortions in three days. There was no discussion of the fact that the same physician in training, the fellow Staff A, performed failed surgical abortions on both Patient 1 and Patient 3 within the same short time frame. Indeed, given [Planned Parenthood’s] internal tracking policies, there was no way for the Medical Director preparing for the quality-assurance meeting to know either that Patient 1 had experienced a failed surgical abortion, or that Staff A was involved in the treatment of Patients 1 and 3 in any way. Because [Planned Parenthood] did not submit a complication report on the failed surgical abortion, it was not reported as such in [Planned Parenthood’s] internal spreadsheet for tracking quality-assurance issues. And [Planned Parenthood’s] internal tracking spreadsheet does not document the involvement of residents and fellows at all.¹²⁶

Regarding Patient 2, the Department contends:

[Planned Parenthood’s] quality-assurance process provided only minimal and cursory review. The only discussion reflected in the meeting minutes is that of the “missed twin” explanation for the failed surgical abortion, which was unconvincing for the reasons discussed above. In addition, the meeting minutes reflect no discussion of causes or explanation for the severe infection suffered by Patient 2. This omission is striking because Dr. McNicholas conceded that Patient 2’s infection constituted a “sentinel event” warranting in-depth review under [Planned Parenthood’s] own criteria, yet Dr. Madden (who was the co-Medical Director in charge of the quality-assurance meeting) testified that she thought Patient 2’s hospitalization for infection was not “significant or unusual” and did not warrant review at all. Dr. McNicholas testified that medical records from the hospital should have been obtained, reviewed, and discussed as part of the in-depth analysis of Patient 2’s infection, yet Dr. Madden has no recollection of obtaining or reviewing such records. In fact, Dr. Madden professed to be unfamiliar with [Planned Parenthood’s] own policies and criteria for sentinel events.¹²⁷

¹²⁶ Resp. Brief at 134-35.

¹²⁷ *Id.* at 135.

As part of the QAPI program, the abortion facility must perform a “documented review” of “[c]omplications, including number and percentage of patients affected by the most common types of complications” and “[s]pecific review of any significant or unusual complications.”¹²⁸ Reading these regulations together, 19 CSR 30-30.060(8) requires the facility to discuss and identify all complications, but it only needs to conduct significant review of the most serious or unusual complications.

Planned Parenthood identified complications for Patient 1 and Patient 3 during its quality assurance review, but it did not discuss them in detail. For known occurrences like this, Planned Parenthood does not need to conduct significant reviews because it is already prepared to handle them when they arise. The complications encountered by Patient 1 and Patient 3 – failed abortions – do not rise to the level of significant or unusual. As such, their quality assurance practices are sufficient in this respect. The Department’s concerns regarding the failure to identify Patient 1’s failed abortions correspond to the definition of “failed abortion” discussed in this decision. Although we determined this to be an error, these complications are not of the sort that would require detailed discussion, and the mere failure to flag them in a quality assurance meeting does not constitute a substantial failure by Planned Parenthood to comply with the qualifications for licensure. Furthermore, now that the Department intends to amend its complication reporting form to include such complications specifically, there is no longer any cause to believe that Planned Parenthood will fail to identify these complications in future quality assurance meetings.

Planned Parenthood did conduct a specific review of Patient 2’s case at its quarterly quality assurance meeting. The Department argues that this review is insufficient because the missed twin explanation is implausible and the minutes of the meeting do not show a discussion

¹²⁸ 19 CSR 30-30.060(8)(B)3-4.

of the infectious causes. As discussed above, we find Planned Parenthood’s conclusion regarding a missed twin reasonable, and even if some other error occurred, Staff B has been alerted to his failure by discussion with Dr. Eisenberg. As documented in the meeting minutes, this discussion did include the infection Patient 2 encountered. The text of 19 CSR 30-30.060(8)(B)4 requires Planned Parenthood to document specific review of unusual or significant complications. Planned Parenthood documented that it discussed the infection. We find this notation sufficient to reflect that Planned Parenthood did conduct a specific review of these matters as required by 19 CSR 30-30.060(8).

Our only concern with Planned Parenthood’s quality assurance process rests in its failure to “show evidence of action the facility took regarding problems identified” as required by 19 CSR 30-30.060(8)(C). Specifically, although Planned Parenthood performed the requisite reviews for Patient 2’s failed abortion, it failed to document addressing the concern with Staff B. As Dr. Williams testified at hearing, this level of involvement by the treating physician would satisfy his concerns with Planned Parenthood’s quality assurance review.

As such, we find that Planned Parenthood has failed to comply with 19 CSR 30-30.060(8)(C). However, we do not consider this violation a substantial failure sufficient to deny Planned Parenthood’s license. Ultimately, we have no concerns with the substance of Planned Parenthood’s quality assurance review, and there are no other indications of deficient practices. We do not feel that one error in documentation merits denial of its license.

Summary of Causes for Denial

Our review of the record reflects only two instances where Planned Parenthood failed to comply with the requirements of §§ 197.200 to 197.240. Planned Parenthood failed to file a complication report for Patient 1 as required by § 188.052.2, 19 CSR 10-15.020, and 19 CSR 30-30.060(3)(H); and Planned Parenthood failed to document the action the facility took regarding

Staff B's treatment of Patient 2 in violation of 19 CSR 30-30.060(8)(C). We found that those violations, individually, did not constitute a *substantial* failure to comply with §§ 197.200 to 197.240, as is required to deny Planned Parenthood's license renewal under § 197.200.

Considering these two violations together, we reach the same conclusion. Planned Parenthood has demonstrated that it provides safe and legal abortion care. In over 4,000 abortions provided since 2018, the Department has only identified two causes to deny its license. As such, we determine that Planned Parenthood has substantially complied with §§ 197.200 to 197.400. Therefore, Planned Parenthood is entitled to renewal of its abortion facility license.

Planned Parenthood's Constitutional Claims

Planned Parenthood alleges that the Department's actions violate the Missouri Constitution's guarantees of equal protection before the law, substantive due process, procedural due process, and the right to be free from unlawful searches and seizures.

For purposes of Planned Parenthood's constitutional claims based upon the Missouri Constitution, this Commission does not have authority to decide constitutional issues.¹²⁹ However, we recognize that Planned Parenthood has raised the issues in this case and thus preserved them to be argued before a court at a later time, if necessary.¹³⁰

The Department's Affirmative Defenses

The Department sets forth eight affirmative defenses to Planned Parenthood's complaint. We address each defense in turn.

Defenses I-VI: Failure to State a Claim

The Department argues Planned Parenthood's complaint fails to state a claim for relief and should be denied as a matter of law because:

¹²⁹ *Sprint Communications Co., L.P. v. Dir. of Revenue*, 64 S.W.3d 832, 834 (Mo. banc 2002); *Cocktail Fortune, Inc. v. Supervisor of Liquor Control*, 994 S.W.2d 955, 957 (Mo. banc 1999); *Williams Cos. v. Dir. of Revenue*, 799 S.W.2d 602, 604 (Mo. banc 1990) (*overruled on other grounds by General Motors Corp. v. Dir. of Revenue*, 981 S.W.2d 561 (Mo. banc 1998); and *Fayne v. Dep't. of Soc. Servs.*, 802 S.W.2d 565, 567 (Mo. App. W.D. 1991).

¹³⁰ *See Tadrus v. Mo. Bd. of Pharmacy*, 849 S.W.2d 222, 225 (Mo. App. W.D. 1993).

1. Planned Parenthood fails to allege facts sufficient to establish that [the Department] acted arbitrarily, capriciously, unreasonably, or illegally on any basis.
2. The Department has statutory and regulatory authority to seek and require interviews with health care providers, including Planned Parenthood and its physicians, and to condition approval of a license upon compliance with this requirement.
3. [Planned Parenthood] has not established that [it] is in compliance with all applicable statutes and regulations, and the Department was unable to determine Planned Parenthood's compliance with all applicable statutes and regulation because of the physicians' refusal to be interviewed.
4. Planned Parenthood and its physicians have refused to cooperate in a valid ongoing investigation regarding patient health and safety and statutory and regulatory compliance.
5. The Department is entitled to draw and did draw adverse factual inferences from the refusal of [Planned Parenthood] and its physicians to cooperate in [the Department's] investigation.
6. The Department has authority to initiate and conduct inspections and investigations as it deems necessary.^[131]

Regarding the first defense, Planned Parenthood has averred it meets the qualifications for licensure and the Department only contests certain specified instances of alleged violations. We have analyzed the facts pertinent to these causes and found that Planned Parenthood qualifies for licensure. There is no need to address claims of arbitrariness and capriciousness.

Regarding the second through sixth defenses, we have determined that neither the physicians' refusal to comply with interviews nor Planned Parenthood's inability to procure said interviews constitutes a violation of §§ 197.200 through 197.400 or the regulations enacted thereunder. As such, it does not represent a cause for denial in itself. As we noted in our discussion of these interviews, we agree that the Department may make adverse inferences from these refusals. However, those refusals – a part of its decision to deny renewal – are subject to our review under § 197.221. We exercise *de novo* review, and need not make the same inferences. Furthermore, we found that § 197.230.1 does not provide the Department the authority to compel interviews. We deny these affirmative defenses.

¹³¹ Amended Answer at 28-30.

Defense VII: No Constitutional Right to an Abortion in Missouri

The Department raises this defense “to the extent that Petitioner bases any request for relief on a putative right to abortion rooted in the Missouri constitution.”¹³² As previously stated, we lack authority to decide constitutional issues. We have noted Planned Parenthood’s constitutional claims and consider them preserved for appeal.

Defense VIII: Other Constitutional Claims

The Department contends that Planned Parenthood has failed to state a claim for relief for the Department’s alleged violation of the Missouri and federal constitutions’ provisions concerning equal protection, substantive due process, and unreasonable searches and seizures. As previously stated, we lack authority to decide constitutional issues. We have noted Planned Parenthood’s constitutional claims and consider them preserved for appeal.

Summary

We find that Planned Parenthood has demonstrated it meets the requirements for renewal of its abortion facility license. Although we found violations of two provisions of law, we cannot deny Planned Parenthood’s license because those findings do not constitute substantial failures to comply with §§ 197.200 through 197.400. The Department has failed to raise an affirmative defense sufficient to justify this denial. As such, we grant Planned Parenthood’s application to renew its abortion facility license.

SO ORDERED on May 29, 2020.


SREENIVASA RAO DANDAMUDI
Commissioner

¹³² Amended Answer at 30.