BEFORE THE ADMINISTRATIVE HEARING COMMISSION STATE OF MISSOURI

REPRODUCTIVE HEALTH SERVICES OF PLANNED PARENTHOOD OF THE ST. LOUIS REGION, Petitioner, v. MISSOURI DEPARTMENT OF HEALTH AND SENIOR SERVICES, Respondent.	AHC No. 19-0879

PETITIONER'S REPLY SUGGESTIONS IN FURTHER SUPPORT OF MOTION FOR STAY

Petitioner submits the following reply suggestions in further support of its Motion for Stay.

ARGUMENT

Petitioner Reproductive Health Services of Planned Parenthood of the St. Louis Region ("Planned Parenthood") requests a stay to allow Petitioner to continue providing reproductive healthcare during the course of these licensing proceedings. Doing so would preserve the status quo as it has been for over twenty years—with Planned Parenthood providing the people of Missouri with patient-centered reproductive health care, including abortion care—until this Commission has an opportunity to rule on the merits. A stay would give the parties the opportunity to litigate the issues without causing harm to any of the parties or the public.

A stay should issue because Petitioner is likely to succeed on the merits that it is entitled to a license renewal and that the decision by the Missouri Department of Health and Senior Services ("DHSS") to deny Planned Parenthood's license renewal was arbitrary, capricious,

unreasonable, and unlawful. Moreover, Petitioner, the physicians who work at Petitioner's clinic, and most importantly the women of Missouri will be irreparably harmed by even a temporary interruption in service, during which time Missouri will be the first state in the country without a health center providing abortion. Mot. for Stay at 4. The Commission has set an August 1 hearing date and allow service to continue until that hearing can be completed would be of no harm to the state or the public.

I. PLANNED PARENTHOOD IS LIKELY TO SUCCEED ON THE MERITS

Petitioner is likely to succeed on the merits. The State's response brief makes clear that the main issue in this case is the State's position that the license may be denied because certain physicians have declined the State's request to be interviewed. But that position finds support in no legal authority and Respondent's position that the lack of interviews thwarts the investigation is unreasonable, arbitrary and capricious. Planned Parenthood has cooperated with the investigation and provided all the information needed to complete the State's review particularly in light of the state's shifting interpretations of statutory and regulatory requirements and accusations that are grounded in neither fact nor medical science. *See* Mot. for Stay ¶ 60.

A. There is no legal basis for DHSS to deny Petitioner's license on physicians' "failure to cooperate" with interviews because neither the statutes nor regulations authorize licensure denial on this basis.

As part of a license-renewal investigation, DHSS demanded Planned Parenthood produce for questioning multiple non-employee physicians, including residents and a fellow from the Washington University Medical School and its affiliated teaching hospital, for formal, sit-down audio-recorded interviews. *See, e.g.,* Verified Pet. ¶¶ 72, 75, *Reprod. Health Servs. of Planned Parenthood of the St. Louis Region v. Parson* (*"Planned Parenthood v. Parson"*), 1922-CC02395 ("Verified Pet., *Planned Parenthood v. Parson*"). Because these independently-represented doctors declined to submit to questioning, DHSS claimed that it could not conclude its

investigation. The Department refused to act on Petitioner's licensing application until it was ordered to by the Circuit Court of the City of St. Louis. *See* Compl. Ex. D (*Planned Parenthood v. Parson*, June 10, 2019 Order); Def.'s Suggestions in Opp'n to Pl.'s Mot. for TRO at 3, *Planned Parenthood v. Parson.*

Even thereafter, DHSS stuck to its position. When it did issue a denial of Petitioner's license—pursuant to a court order—Respondent's principal basis for denial was Planned Parenthood's "refusal to cooperate" with DHSS's investigation, based on the fact that Planned Parenthood cannot produce non-employee physicians to submit to questioning. *See* Resp't's Suggestions in Opp'n to Mot. for Stay at 14–25. But DHSS lacks the statutory or regulatory authority—and DHSS has pointed to none—to compel testimony or to penalize a facility for failing to produce cooperation by others. That alone is grounds to reverse the Department's position, but the demand for interviews is also arbitrary, capricious and unreasonable.

While DHSS initially claimed it had authority to compel interviews, it did so in reliance on a provision concerning patient complaints. *See* Verified Compl. Ex. E, *Planned Parenthood v. Parson* (citing 19 CSR 30-30.060(7)(C)). But it turns out there *was* no patient complaint—a fact Planned Parenthood only learned after the commencement of litigation. *See* Resp't's Suggestions in Opp'n to Mot. for Stay, Ex. A, originally filed as Def.'s Suggestions in Opp'n to Pl.'s Mot. for TRO, Ex. A (Decl. of William Koebel) ("Koebel Decl.") ¶ 5, *Planned Parenthood v. Parson* (clarifying that the "complaint investigation" was actually a complaint DHSS made to itself).

DHSS now argues that because it has the broad ability to investigate, it must have the authority to deny a license when there is a refusal to participate in the investigation (whether by the facility in question or individual doctors). Neither statute nor regulation grants DHSS that authority.

Significantly, the statutes do confer that precise authority upon *other* agencies. *See, e.g.*, §§ 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, RSMo. (Board of Nursing, same); §§ 340.264.2(4)(l)–(m) and 340.280, RSMo. (Veterinary Medical Board, same). *See also Bodenhausen v. Mo. Bd. of Registration for Healing Arts*, 897 S.W.2d 649, 653 (Mo. Ct. App. 1995).

Because the "legislature has elsewhere been fully capable of clearly articulating" this authority, it cannot be implied that the State possesses the power to compel interviews absent statutory language. *State v. Reprod. Health Servs. of Planned Parenthood of St. Louis Region, Inc.*, 97 S.W.3d 54, 61 (Mo. Ct. App. 2002); *see also Wolff Shoe Co. v. Dir. of Revenue*, 762 S.W.2d 29, 32 (Mo. 1988) (recognizing "rule of statutory construction that 'the express mention of one thing implies the exclusion of another'" (quoting *Harrison v. MFA Mut. Ins.*, 607 S.W.2d 137, 146 (Mo. banc 1980))). Had the legislature wanted DHSS to be able to discipline or deny this license for failure to require cooperation of others, it would have said so. But it did not.

Planned Parenthood itself *has* cooperated with DHSS to the extent possible, providing all patient records requested (as well as policies and other documentation) and has further produced its co-Medical Director and incoming Chief Medical Officer for interviews. Mot. for Stay ¶ 60. The State does not dispute that Planned Parenthood provided all records requested, made the facility available for inspection and facilitated interviews with the two doctors in charge of patient care. Contrary to Respondent's contentions, these physicians do not simply "serve as supervisory physicians" at Planned Parenthood, Resp't's Suggestions in Opp'n to Mot. for Stay at 11, but rather oversee *all* patient care there (alongside two doctors DHSS has not sought to interview) and further

provide a substantial amount of direct patient care. *See* Verified Pet. ¶ 71, *Planned Parenthood v. Parson.*

Furthermore, Planned Parenthood has no power to compel independently-contracted physicians to sit for interviews, particularly where, as here, such physicians are represented by independent counsel. Indeed, those physicians' attorneys counseled their clients against sitting for interviews with DHSS precisely because DHSS would not provide any meaningful information about the topics to be discussed. For example, one of the physician's attorneys noted in a successful motion to quash a subpoena of a resident physician at the Circuit Court:

> [T]he State has purposefully remained circumspect about the need to interview the Residents, despite an apparent months-long dialogue with Planned Parenthood about specifically defined concerns. It bears repeating that the Residents are not employed by Planned Parenthood or even affiliated in any way that carries any legal significance . . . . When asked repeatedly for information regarding the nature of the investigation, the State demurred, offering no substantive information about the inquiry. To be clear, it was the State's chosen strategy that prevented interviews with the residents.

Mem. of Law in Supp. of Mot. to Quash Subpoena & for Protective Order ("Resident Physicians Br.") at 7, attached hereto as Exhibit A.

Moreover, unlike in any other medical context, Missouri's abortion statutes include unique criminal penalties and DHSS was clear that physicians agreeing to be interviewed by DHSS may, as a result of those interviews, be referred for criminal investigation. *See* Mot. for Stay ¶ 58 (citing Verified Pet. ¶¶ 64–65, 69, 73, 84, *Planned Parenthood v. Parson*). As noted by the resident physicians' counsel, "it is disingenuous for the State to pretend that calculation has no relevance here." Resident Physicians Br. at 6. The residents physicians' counsel went on to note:

> Although it is clear there can be criminal liability for not complying with Missouri's abortion laws, it remains unclear whether the State has pivoted from investigation to accusation against the Residents, which would trigger the right to criminal counsel.

Id.

This risk is especially great because of DHSS's repeatedly shifting view of these physicians' obligations under state law. During the course of this licensing process, DHSS has repeatedly changed its long-standing interpretation of statutory and regulatory requirements, in one instance shifting its position on when pelvic exams must be provided *twice in a matter of months.*[1] Another about-face concerns requirements for resident physicians providing care under the supervision of an attending physician.[2] Under these circumstances, it is hardly surprising that resident physicians would refuse to sit for audio-recorded interviews before an agency with a history of suddenly (and arbitrarily) changing its interpretations, retroactively deeming past conduct a potential regulatory (or even criminal) violations. And this especially so when DHSS seeks to interview these physicians about care they provided before Planned Parenthood changed its practices to comply with DHSS's new demands relating to the pelvic and same-doctor requirements—care DHSS now appears to suggest was not compliant with state law and regulatory requirements.

B. Respondents provide no reasonable basis for denying the license based on lack of interviews of these physicians and it is arbitrary and capricious to demand their compliance as a condition of licensure.

Not only does DHSS lack the authority to deny Petitioner a license due to the fact that third parties will not sit for interviews, but DHSS's refusal to license without interviews is baseless and

[1] *See* Mot. for Stay ¶¶ 27–32 (noting DHSS suddenly began requiring, as part of this year's licensing renewal process, that abortion providers be required to perform invasive and medically irrelevant pelvic exams on women seeking abortions and that, despite Petitioner's protestations that such was traumatizing for patients, DHSS did not relent until it faced a substantial public outcry).

[2] *See Id.* ¶¶ 33–35 (noting that DHSS suddenly reversed its previously expressed that a resident physician may provide abortion care under the supervision of an attending physician without also participating in the provision of state-mandated information to the patient at least seventy-two hours prior to the abortion).

unreasonable. *See Ard v. Shannon Cty. Comm'n*, 424 S.W.3d 468, 480 (Mo. Ct. App. 2014) ("'Arbitrary and capricious' has been defined as 'willful and unreasoning action, without consideration of and in disregard of the facts and circumstances.'" (quoting *Beverly Enterprises-Mo. Inc. v. Dep't of Soc. Servs., Div. of Med. Servs.*, 349 S.W.3d 337, 345 (Mo. Ct. App. 2008))); *Beverly Enterprises-Mo.*, 349 S.W.3d at 345 ("[A]n agency that completely fails to consider an important aspect or factor of the issue before it may be found to have acted arbitrarily and capriciously." (quoting *Barry Serv. Agency Co. v. Manning*, 891 S.W.2d 882, 892 (Mo. Ct. App. 1995))).

1. The requested physician interviews are not a normal part of an investigation process.

Even if DHS had legal authority to compel interviews or deny a license because individuals decline interviews, denying the license on these particular facts is arbitrary and capricious. Contrary to DHSS's contention that such interviews are "a routine part of an investigation," in Planned Parenthood's experience they are unprecedented.[3] As made clear by Petitioner's co-Medical Director—a board-certified obstetrician–gynecologist and Associate Professor in the Department of Obstetrics and Gynecology at the Washington University School of Medicine in St. Louis, Missouri, and the Director of the Benign Gynecology Resident Service at its affiliated teaching hospital—DHSS has *never* before asked its doctors to sit for remotely similar interviews, in the complaint investigation context or any other context. Mot. for Stay, Ex. A (Declaration of Dr. David Eisenberg) ("Eisenberg Decl.") ¶¶ 1–2.

[3] DHSS bases this contention on the declaration testimony of William Koebel. *See* Koebel Decl. ¶ 8. Given Dr. Eisenberg's testimony—discussed in detail below—that DHSS has never before requested physician interviews like the ones demanded here, DHSS is wrong to claim that Mr. Koebel's testimony on this point is "uncontradicted." Resp't's Suggestions in Opp'n to Mot. for Stay at 15.

Indeed, in Dr. Eisenberg's decade of experience undergoing abortion-facility licensing inspections, DHSS has never asked for interviews of multiple physicians (*id.* ¶¶ 5–9, 14); never tape-recorded interviews (*id.* ¶ 10); and has routinely relied on information from the medical director to resolve complaint investigations regardless of which physician treated the patient (*id.* ¶¶ 7–8, 12).[4] Indeed, Dr. Eisenberg testified that in his years of conversations with other Planned Parenthood medical directors from across the country, and roles at Washington University School of Medicine and its affiliated teaching hospital, he has never heard of any remotely similar interviews or interview requests. *Id.* ¶¶ 13, 14.

2. DHSS has no plausible need to interview the physicians on the claimed patient care issues it identifies.

As is clear from its denial letter (Compl. Ex. G), at bottom DHSS bases its demand to question doctors on a small number of rare but known medical complications—well within the normal range for such procedures, *see* Decl. of Colleen P. McNicholas, DO, MSCI, FACOG, in Supp. of Pet'r's Suggestions in Further Supp. of Mot. for Stay (attached as Exhibit B) ("McNicholas Decl.") ¶¶ 11–12. However, the State has full information on these incidents, including full patient medical records and audio-recorded interviews with Planned Parenthood's

[4] As Dr. Eisenberg explained, in the past when DHSS wanted information about a patient complication, it has routinely reached out to him as the Medical Director and asked for follow-up information about the patient's care in the form of medical records and/or an informal oral conversation. Eisenberg Decl. ¶ 8; *see also id.* ¶ 9 ("I cannot think of a situation where DHSS has ever requested a formal sit-down interview with me or with any of our physicians—much less with a list of physicians, or in a particular order. Nor can I think of a situation where DHSS has ever requested to speak with a resident or fellow about care they provided under an attending physician's supervision."); *id.* ¶ 12 ("In the instances . . . where DHSS asked for follow-up information on patient care following an ambulance transfer (a very rare occurrence), to the best of my knowledge DHSS has always been satisfied with the information that I, as Medical Director, provided. More often than not, these cases were ones where I was not directly involved in the care of the patient, but reviewed the care in my role as medical director and discussed my findings and their concerns. I am not aware of any instance where they asked to speak with the physician who treated that patient.").

co-Medical Director and incoming Chief Medical Officer. DHSS can articulate no reason why it need demand to question individual physicians (nor, indeed, why it can penalize Planned Parenthood for these physicians' refusal to be questioned).

Moreover, DHSS exploits the complications experienced by four patients (out of thousands treated) in a failed attempt to paint Planned Parenthood as a sub-standard provider. As is clear from Planned Parenthood's various Plans of Corrections, including the June 18, 2019 Plan of Corrections, and from the Declaration of Dr. Colleen McNicholas, Planned Parenthood's incoming Chief Medical Officer and a board-certified obstetrician-gynecologist and Associate Professor in the Department of Obstetrics and Gynecology at the Washington University School of Medicine, there is no basis in fact or medical science for such allegations, and it is wholly unclear what "corrections" DHSS believes Planned Parenthood could make other than to somehow ensure its patients do not experience complications—a standard to which no medical provider can be held. McNicolas Decl. ¶¶ 11, 12, 21, 25.

For example, DHSS cites to two instances in which a patient had an ongoing pregnancy following a failed abortion—a rare but known complication that occurs some 1% of the time. Maureen Paul et al., *Is Pathology Examination Useful After Early Surgical Abortion?*, 99 Obstetrics & Gynecology 567 (2002); *see also* McNicholas Decl. ¶¶ 39–43; *see also id.* ¶¶ 40–41. There is no reason to believe that these occurrences are anything but rare medical complications happening at a rate well within the norm—indeed, in both cases the findings of the physician providing care was independently verified by a pathologist. *Id.* ¶¶ 36–42.

Another of the four instances of patient care relied upon by DHSS involves simple mischaracterizations of facts. The patient in question was referred to Planned Parenthood after a team of physicians at the Washington University School of Medicine determined that it would be

the best course of treatment for her. *Id.* ¶ 46. As soon as it was apparent that she might be experiencing a complication, physicians at Planned Parenthood transferred her to the hospital for further treatment. *Id.* ¶ 48. Contrary to DHSS's mischaracterizations, she did not hemorrhage or become critically ill at Planned Parenthood or as a result of the care provided by any physicians. *Id.* ¶¶ 49–50.

Similarly, DHSS inexplicably accuses Planned Parenthood of "inadequate[] supervi[sion]" of a physician resident from the Washington University School of Medicine, because the resident found the uterus of Patient #1 to be anteverted and did not note a finding of retroflexion, and later pelvic exams by different physicians found the patient's uterus to be retroverted and retroflexed (a uterus's "version" and "flexion" refer to its position relative to the body). *See* 6/18 POC at 5–7; McNicholas Decl. ¶ 26–27. However, as any student of basic female anatomy would know, a woman's uterus does not have a fixed position. *See* McNicholas Decl. ¶ 25. Rather, it can change position based on how the patient is lying on the exam table, not to mention due to a progression in pregnancy and the taking of medication for a medication abortion, both of which were relevant in this instance. Mot. for Stay ¶ 49; McNicholas Decl. ¶¶ 26–27.[5] Yet again, DHSS relies on nothing more than its "gut feeling" to accuse Planned Parenthood of wrongdoing and deprive the women of Missouri of access to abortion care anywhere in the state. *See Mo. Nat'l Educ. Ass'n v. Mo. State Bd. of Educ.*, 34 S.W.3d 266, 281 (Mo. Ct. App. 2000) (relying on gut feeling is arbitrary and capricious).

[5] As Planned Parenthood pointed out to DHSS, "The uterus may naturally lie in different positions such as anteverted/retroverted, anteflexed/retroflexed, or midline, and it may be rotated (especially during pregnancy). The uterus most commonly lies in an anteflexed and anteverted position in 50% of women." 6/18 POC at 6 (quoting Jessica N. Sosa-Stanley & Diana C. Peterson, *Anatomy, Abdomen and Pelvis, Uterus* (last updated Feb. 1, 2019), https://www.ncbi.nlm.nih.gov/books/NBK470297/).

Planned Parenthood has gone to great lengths to explain exactly what complications each patient experienced in its multiple plans of correction. *See* 6/18 POC. Rather than applying medical knowledge to make considered licensing decisions, DHSS is, at best, relying on a "gut feeling" (and at worst a political bias) to argue in essence that, because Petitioner provides abortion care and abortion can include complications—at an extremely low rate compared to other medical procedures—Planned Parenthood must be doing something wrong. *See* Resp't's Suggestions in Opp'n to Mot. for Stay at 15 (noting that "to avoid being arbitrary, unreasonable, or capricious, an agency's decision must be made using some kind of objective data rather than mere surmise, guesswork, or 'gut feeling'" (quoting *Mo. Nat'l Educ. Ass'n*, 34 S.W.3d at 281 (Mo. Ct. App. 2000))).[6]

If every medical facility were forced to undergo this level of scrutiny every time a patient experienced a complication, it is hard to imagine that any facility would be granted a license renewal. That's what makes DHS demand so unreasonable. The reality, however, is that no medical practice is expected to have a zero percent patient complications rate—indeed there is no population of patients that can be expected to experience no medical complications. And indeed, when dealing with facilities outside the context of abortion, it appears DHSS—appropriately—takes the extreme step of license revocation only very rarely, and certainly not where, as here, there is simply no reason to believe the licensee is providing anything other than high-quality medical care. *See Planned Parenthood of Kan. & Mid-Mo. v. Lyskowski*, No. 2:15-CV-04273-NKL, 2016 WL 2745873, at *1, *7 (W.D. Mo. May 11, 2016) (issuing injunctive relief based on a determination the plaintiff was likely to succeed on its claim that it was being singled out by

[6] Were it the case that DHSS believed Planned Parenthood posed any serious risk to its patients, it would have suspended its license immediately, as it is authorized to do by law. § 197.293 RSMo. DHSS does not claim this and could not credibly do so.

DHSS and treated differently from non-abortion providers, in part because the "evidence shows that revocation of an ASC license is an extremely rare event" and that "DHSS has in ***only two instances*** sought to revoke ASC licenses: in this case, and in the case of the Surgical Center of Creve Coeur . . . [and] unlike the situation at SCCC where patient health and safety were at risk, there are no similar risks present here" (emphasis added)).

For all the reasons set forth above and in Petitioner's Complaint and Verified Petition before the Circuit Court (incorporated into the Complaint by reference), Petitioner is likely to succeed on the merits that DHSS's denial of its license renewal was arbitrary, capricious, unreasonable and unlawful, and that Planned Parenthood is entitled to have its abortion facility license renewed.

II. PETITIONER, ITS PHYSICIANS, AND THE PEOPLE OF MISSOURI WILL BE IRREPARABLY HARMED IN THE ABSENCE OF A STAY

There is no dispute that, without a stay, Planned Parenthood will have to stop providing an important service to patients. Respondent contends that any harm is of Petitioner's own making. But DHSS's briefing makes clear the only reason Petitioner is facing the irreparable harm of a license revocation is because of DHSS's actions. Planned Parenthood has taken no action to impede the investigation—*DHSS* is demanding non-employee physicians sit down for interviews, and *those physicians* have, through independent counsel, declined to do so. There is no accusation that Planned Parenthood has interfered with DHSS's request nor that Petitioner requested these physicians not speak with DHSS. Indeed, DHSS even admits that Planned Parenthood has been exceedingly cooperative and "in this very case, [Planned Parenthood] and the Department have managed to resolve every deficiency for which the non-cooperation of [Planned Parenthood] and its physicians did not obstruct its resolution." Resp't's Suggestions in Opp'n to Mot. for Stay at 25. Planned Parenthood has done all that it can do and this harm is not of its own making.

Without a stay, Petitioner, and its patients will all be irreparably harmed, as will the 1.1 million Missouri women of reproductive age who, despite their constitutional right to obtain a pre-viability abortion, will no longer have access to abortion care anywhere in the state. *See* Suggestions in Supp. of Mot. for TRO and Prelim. Inj. at 23–24, *Planned Parenthood v. Parson*, attached hereto as Exhibit C. Because part of Planned Parenthood's mission is to provide high-quality comprehensive reproductive health care and education to medically underserved populations and patients with low incomes, who often cannot rearrange work or childcare to make the time to travel out-of-state to obtain abortion services elsewhere. Mot. for Stay ¶ 79.

Indeed, the Circuit Court of St. Louis has *twice* found that irreparable injury would ensue if Petitioner's license were allowed to expire. *See* Compl. Ex. C (*Planned Parenthood v. Parson*, May 31, 2019 Order) at 3; Compl. Ex. D (*Planned Parenthood v. Parson*, June 10, 2019 Order) at 5–6.[7]

Petitioner will also be irreparably harmed if a stay is not issued. Petitioner's provision of abortion care is a core component of its central mission to provide a full range of high-quality, evidence-based, and non-judgmental reproductive health care to the people of Missouri, particularly to medically underserved populations and patients with low incomes. Mot. for Stay ¶ 83. Without a stay, Planned Parethood's highly trained and qualified physicians will not be able to continue providing the comprehensive reproductive care, including abortion care, to which they

[7] Given the intense media attention this case has received, if a stay is not granted, the general public will be aware that Planned Parenthood has had to suspend abortion services (even if only pending the outcome of proceedings before the Commission). Mot. for Stay ¶ 81. This interruption in service means that even if Planned Parenthood's license is ultimately renewed, patients will be confused as to whether they can come to Planned Parenthood for the care they need, forcing them to either forgo care entirely or travel out-of-state to obtain it. *Id.* ¶ 82. Thus, even a brief interruption in Planned Parenthood's ability to provide services will do real and lasting harm to Missouri women.

have dedicated their lives. *Id.* ¶ 84. Similarly, the residents and fellows who train at Planned Parenthood will not be able to receive the high-quality training that was promised to them and, as a result, will be irreparably harmed. *Id.* ¶¶ 85–89.

III. THE BALANCE OF HARMS WEIGHS IN FAVOR OF A STAY

Planned Parenthood has been providing reproductive health care in St. Louis for over twenty years. DHSS does not allege that allowing Planned Parenthood to continue providing safe, legal abortions would in any way harm patients—nor could it. Given that Petitioner is the last remaining abortion provider in the state, and that the women of Missouri have a constitutional right to access abortion care, the public interest weighs heavily in favor of a stay. *See, e.g., Mo. State Med. Ass'n v. State*, No. 07AC-CC00567, 2007 WL 6346841 (Mo. Cir. July 3, 2007) ("[B]alancing of the harms favors immediate injunctive relief, because a restraining order will not harm the State of Missouri and will actually further its interests in ensuring the health and safety of its citizens.").

Thus, the balance of harms weighs in favor of allowing Planned Parenthnood to continue providing care, preventing Missouri from becoming the first state in the country without an abortion provider, until this Commission has an opportunity to hear the full case on the merits.

CONCLUSION

For the foregoing reasons, Petitioner respectfully requests that the Commission stay Respondent's decision denying Petitioner its license renewal application pending the Administrative Hearing Commission's review of Respondent's decision and any subsequent appeals, and grant any other relief deemed just and proper. This will maintain the status quo as it has been for over two decades, with Planned Parenthood providing high-quality patient-centered reproductive health care to the people of Missouri.

Respectfully submitted,

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**Pro hac vice motion to be filed*

EXHIBIT A

IN THE CIRCUIT COURT OF ST. LOUIS CITY
STATE OF MISSOURI

REPRODUCTIVE HEALTH SERVICES OF PLANNED PARENTHOOD OF THE ST. LOUIS REGION,	)	
Plaintiff,	)	Cause No. 1922-CC02395
v.	)	Division No. 6
RANDALL WILLIAMS, M.D., et al.	)	
Defendants.	)	

MEMORANDUM OF LAW IN SUPPORT OF MOTION TO QUASH SUBPOENA AND FOR PROTECTIVE ORDER

COME NOW Non-Party Resident Physicians, identified as "Staff F" and "Staff G" in the State's pleadings (collectively referred to herein as "the Residents"), by and through their undersigned counsel, and file this Memorandum of Law in support of their Motion to Quash Plaintiff's Subpoena and for Protective Order, stating in support:

I. INTRODUCTION

Before the Court is the question of whether the defendants (collectively referred to as "the State") improperly withheld renewal of licensure for Reproductive Health Services of Planned Parenthood of the St. Louis Region ("Planned Parenthood"). The State protests that its precursor investigation is incomplete and is now trying to expand its investigation by using the Court's subpoena power, a power denied to the State investigators by the legislature. The subpoenas served on the Residents should be quashed because 1) the testimony sought has no relevance to the issue before this Court, 2) utilization of the Court's subpoena power to expand the State's investigative power is improper, 3) compelling testimony in the face of criminal

penalties threatens the Residents' civil rights, and 4) compliance with the subpoenas creates an undue burden on the Residents.

II. LEGAL STANDARD

The power to quash a subpoena falls within the Trial Court's discretion to exclude evidence. *Wilkins v. Office of the Missouri Attorney General, et al.*, 464 S.W.3d 271, 275 (Mo. App. E.D. 2015). "A trial court has broad discretion to admit or exclude evidence, and we presume that a ruling within the trial court's discretion is correct." *Coyle v. St. Louis*, 408 S.W. 281, 289 (Mo. App. E.D. 2013).

Although there is no explicit rule governing use (or abuse) of trial subpoenas, the Courts have analyzed the proper scope of trial subpoenas under the rules governing subpoenas issued during discovery. *Wilkins*, 464 S.W.3d at 277, ftnote 3. Specifically, Supreme Court Rule 57.09(c) requires that "a party or attorney responsible for the issuance and service of a subpoena shall take reasonable steps to avoid imposing undue burden or expense on a non-party subject to the subpoena." Further, pursuant to Rule 56.01(c), a Trial Court may issue an order restricting the use of subpoena power to protect a non-party from annoyance, embarrassment, oppression, undue burden or expense. *See also, generally, State ex. Rel. Ford Motor Company v. Messina*, 71 S.W.3d 602 (Mo. en banc 2002). Thus, this Court must evaluate whether the State is unreasonably and unduly burdening the Residents. The Court is further empowered to protect them as non-parties from the annoyance, embarrassment, oppression, and undue burdens described below.

III. THIS LITIGATION IS NOT A VEHICLE FOR STATE INVESTIGATIONS

The State's issuance of subpoenas to the Residents is a gross misuse of this court proceeding. The State cannot take advantage of the Court's subpoena power to compel

testimony the State had no power to obtain during its investigation, especially when such testimony is not relevant to issues the Court must decide. This Court is not a proper forum for the State to develop new evidence in support of its licensure determination.

Missouri courts have strictly required administrative agencies to comply with the subpoena power granted to them by statute to effectuate the legislature's intent. *See State Bd. of Registration for Healing Arts v. Vandivort*, 23 S.W.3d 725, 729 (Mo. App. W.D. 2000). "[A]gencies possess no inherent authority to issue a subpoena." *Angoff v. M & M Management Corp.*, 897 S.W.2d 649, 652 (Mo. App. W.D. 1995). Here, the DHSS has no authority to issue subpoenas as part of its investigative process, though the legislature could clearly have granted that authority had it wished to do so. (*See generally*, RSMo § 334.127, authorizing subpoena power to the State Board of Registration for the Healing Arts.) Instead, the State is seeking to use this Court's subpoena power to augment the DHSS' authority beyond RSMo § 197.220 *et seq*. This litigation is not a vehicle for DHSS investigations.

The State's efforts in issuing these subpoenas is tantamount to seeking judicial approval of an unauthorized administrative subpoena. "When the power of the circuit court is invoked to enforce an administrative subpoena, the court must guard against the abusive use of its process. Enforcement of an administrative subpoena, which the agency in question has no authority to issue, is clearly an abuse of process." *Brooks v. Pool-Leffler*, 636 S.W.2d 113, 119 (Mo. App. E.D. 1982) (internal citation omitted). Moreover, a Court should not imply an agency's subpoena power "simply because that power would facilitate the accomplishment of an end the court deems beneficial." *Id.* The subpoena power must be authorized by statute. *Id.*

Here, the State investigated to the limits of its statutory authority. It should not be permitted to exceed the bounds of that authority by utilizing the Court's subpoena power,

particularly against third parties whose role in the investigation remains unclear. For this reason, the subpoenas should be quashed.

IV. THE EVIDENCE SOUGHT BY SUBPOENA LACKS RELEVANCE

Beyond the propriety of issuing the subpoenas, the Court should consider the utility of enforcing them, particularly whether any admissible evidence would result. The principal criterion for the admission of evidence is relevancy. *Mengwasser v. Anthony Kempker Trucking, Inc.* 312 S.W.3d 368, 372 (Mo. App. W.D. 2010), *citing Porter v. Toys 'R' Us-Del., Inc.* 152 S.W.3d 310, 318 (Mo. App. W.D. 2004). The party seeking to present evidence bears the burden of establishing both its logical and its legal relevance. *Nolte v. Ford Motor Company*, 458 S.W.3d 368, 382 (Mo. App. W.D. 2014)

A. The State Cannot Establish Logical Relevance for the Subpoenaed Testimony.

"Logical relevance refers to the tendency of evidence 'to make the existence of any fact that is of consequence to the determination of the action more probably or less probably than it would be without the evidence.'" *Westerman v. Shogren*, 392 S.W.3d 465, 474 (Mo. App. W.D. 2012), *citing Secrist v. Treadstone, LLC,* 356 S.W.3d 276, 281 (Mo. App. W.D. 2011). Here, the State's own evidence, in the form of Mr. William Koebel's affidavit, strongly suggests there is no value in the testimony it seeks to compel.

In paragraphs 32 and 33 of his affidavit, Mr. Koebel explains that the dispute between the parties in this case rests solely on the **legal interpretation** of Section 188.027.6 RSMo., that is whether the same physician must provide informed consent and perform / induce the abortion. All other disputes seem to have been resolved through Plan of Correction. Yet in paragraph 35 of the affidavit, Mr. Koebel attests that the **facts** involved in the case are not in dispute. According to Mr. Koebel, "Dr. McNicholas admitted that she was not always physically present

in the procedure room during an abortion procedure performed by a resident or fellow she supervises" and "she further confirmed that she provided informed consent to multiple patients, knowing that she may not later perform the actual abortion." (State's Exhibit A, ¶ 35). Therefore, the State asserts it already has testimony that it believes establishes a violation of Section 188.027.6 RSMo. The testimony of the Residents to establish this violation would be cumulative and unnecessary. The State cannot establish logical relevance because the testimony would not make a fact more probable or less probable than it would be without the testimony. Per the State, the fact has already been established.

B. The State Cannot Establish Legal Relevance for the Subpoenaed Testimony.

Without logical relevance, the Court need not consider legal relevance. Legal relevance requires that the Trial Court "weigh the probative value, or usefulness, of the evidence against its costs, specifically the dangers of unfair prejudice, confusion of the issues, undue delay, misleading the jury, waste of time, or needless presentation of cumulative evidence." *Nolte*, 458 S.W.3d at 382 (citations omitted).

First, there is no probative value. The DHSS performs a licensing function, and the issue before this Court is prospective in nature: should the license for Planned Parenthood be renewed? Based on its survey findings, DHSS issued a Statement of Deficiencies, and Planned Parenthood responded with a Plan of Correction. That Plan of Correction, among other things, proscribed the further involvement of resident physicians in performing abortions at Planned Parenthood. The Residents are not currently rendering patient care at Planned Parenthood, nor will they do so in the future. They are simply irrelevant to the question of whether Planned Parenthood meets its prospective licensing requirements.

Second, any probative value would be outweighed by the costs of enforcing the subpoenas. The State's own evidence suggests it is merely seeking cumulative evidence from doctors who no longer see patients at Planned Parenthood. Against that "value," the Court must guard against unnecessary cumulative evidence. Further, the Court should consider the prejudice to the Residents of being compelled to participate in a hearing that will necessarily involve unwanted attention. Compelling their testimony will forever link the Residents' names and careers with a brief aspect of their training, simply because that training was tangential to one of the most politically charged topics of the day. The Court risks attaching a stigma to the Residents, the burden of which outweighs the usefulness of any testimony.

Because the State bears the burden of establishing relevance, and has not established either logical or legal relevance, the testimony sought by these subpoenas is inadmissible. The subpoenas should be quashed.

V. THE RESIDENTS HAVE A RIGHT TO EFFECTIVE COUNSEL

Although it is clear there can be criminal liability for not complying with Missouri's abortion laws, it remains unclear whether the State has pivoted from investigation to accusation against the Residents, which would trigger the right to criminal counsel. *U.S. v. Edelmann*, 458 F.3d 791, 804 (8th Cir. 2006) (quoting *Moran v. Burbine*, 475 U.S. 412, 430 (1986)). Obviously, this Court is not conducting a criminal proceeding on June 4, 2019, but the witnesses have a right to adequate assistance of counsel in preparing for the proceeding and protecting their rights.

"[T]he privilege against self-incrimination can be asserted 'in any proceeding, civil or criminal, administrative or judicial, investigatory or adjudicatory.'" *Maness v. Meyers*, 419 U.S. 449, 465 (1975). Moreover, it is irrelevant that a witness asserts the privilege in a statutory inquiry and not as a defendant in a criminal prosecution. *Lefkowitz v. Turley*, 414 U.S. 70, 77

(1973). The privilege "insure[s] (sic) that a person should not be compelled, when acting as a witness in any investigation, to give testimony which might show that he himself had committed a crime." *Id.* (quoting *Counselman v. Hitchcock*, 142 U.S. 547, 562 (1892)). Additionally, the Missouri privilege contained in Article 1, section 19 of the Missouri Constitution, has been treated as an identical corollary to the Federal privilege. *See State ex rel. Munn v. McKelvey*, 733 S.W.2d 765, 767 (Mo. banc 1987) ("[t]he provisions to be followed applying these two provisions are consistent.").

Here, the State has purposefully remained circumspect about the need to interview the Residents, despite an apparent months-long dialogue with Planned Parenthood about specifically defined concerns. It bears repeating that the Residents are not employed by Planned Parenthood or even affiliated in a way that carries any legal significance. They are not privy to the patient charts created at Planned Parenthood, and until the State put them before this Court, they had no access to the various Statements of Deficiencies or Plans of Correction resulting from the State's investigation. When asked repeatedly for information regarding the nature of the investigation, the State demurred, offering no substantive information about the inquiry. To be clear, it was the State's chosen strategy that prevented interviews with the Residents. (See generally, Exhibit G to The Affidavit of William Koebel.) That choice does not justify discarding the Residents' civil rights.

The State, via Mr. Koebel's affidavit, argues that physician interviews are standard for any licensing investigation, but this situation is hardly analogous to other license renewals. Clearly, the unique criminal penalties associated with abortion laws distinguish this investigation from a licensure application submitted by an ambulatory care center. It is disingenuous for the State to pretend that calculation has no relevance here. The State should not be permitted to

bully participation by the Residents through the use of this Court's subpoena power, jeopardizing the Residents' civil rights. For this additional reason, the subpoenas should be quashed.

VI. THE STATE'S ACTIONS WARRANT A PROTECTIVE ORDER

The Trial Court's inherent power includes those described in Rule 56.01(c) governing discovery. A Trial Court may issue an order restricting the use of subpoena power to protect a non-party from annoyance, embarrassment, oppression, undue burden or expense.

At all relevant times, the Residents were trainees in the Obstetrics and Gynecology residency program at Barnes-Jewish Hospital, which is accredited through the Accreditation Council for Graduate Medical Education (ACGME). As mandated by the ACGME, the program must offer training in family planning and contraception, including the management of abortion complications. Such experience prepares obstetricians to recognize and treat medical emergencies that threaten patients' lives. To further their education, the Residents spent approximately twelve (12) days each at Planned Parenthood, across a period of four (4) years, learning the clinical and surgical skills required of licensed physicians in their chosen field.

Each Resident is now in the final year of training, with the increased level of responsibility that entails. Each is preparing for Board exams in June. Each is scheduled to participate in the treatment of numerous patients on June 4, the date of the hearing. The Resident identified as "Staff F" is scheduled to serve as the Chief Resident in the High Risk Obstetrics Clinic, helping to supervise three junior residents in the care of approximately thirty (30) "high risk" patients. These are patients with complicated pregnancies requiring frequent and sophisticated care. The Resident identified as "Staff G" is serving as the Chief Resident on the Gynecological Oncology service, managing approximately twenty (20) admitted patients while assisting with multiple surgical procedures throughout the day. These subpoenas, served less

than two business days before the date of appearance, unnecessarily inconvenience, and potentially put at risk, dozens of women.

In evaluating the need for a Protective Order, the Court should also consider the personal cost to the doctors of compelling a trial appearance. If ever there was justification for a Court order to protect a third party from annoyance, embarrassment, oppression, or undue burden, this case provides it.

Rather than demonstrating reasonable steps to avoid an undue burden on these third parties, the State's actions show a complete disregard for economy and consequence. And while the State is sure to respond that this could have been avoided if the Residents had submitted to interviews, it was the State's refusal to share available information that prevented that occurrence. The Court should enter a Protective Order to prevent further annoyance, embarrassment, and undue burdens.

VII. CONCLUSION

In this matter, the Court will determine the future of Planned Parenthood in Missouri. The Residents' have no testimony that will assist the Court in its important task. Testimony about their past actions while caring for Planned Parenthood patients is not relevant to any issue the Court will decide, and would be cumulative to statements the State has already received from physicians who supervised the Residents. The Residents cannot testify about the current disputes between the State and Planned Parenthood, nor the attempts to resolve them, as the Residents have not cared for Planned Parenthood patients for many months, and will not in the future.

The issues before the Court are weighty ones. The future of Planned Parenthood's ability to provide reproductive health care services to Missouri women is at stake. This litigation, and the politically charged issues surrounding it, have garnered daily, national media attention. The

Residents – young OB/GYNs still in training – appreciate the significance of the issues at bar. What we ask the Court in this Motion, however, is not to lose sight of the Residents' futures. Their medical services to Planned Parenthood patients were required by their training program and done under the supervision of attending physicians who have already provided statements. The Residents' testimony is neither central nor relevant to the Court's determination of the issues before it. Requiring it with less than two business days' notice, with no access to the patient records, and under the specter of criminal prosecution, is wholly unreasonable, harassing, unduly burdensome, and a threat to their civil rights.

The Residents are not central witnesses to what surely will be a legally and politically divisive decision. Drawing the Residents into this proceeding, with any personal-affecting results that might follow, is unnecessary and inappropriate.

The subpoenas should be quashed.

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Certificate of Service

I hereby certify that on 3rd day of June, 2019, the foregoing was filed electronically with the Clerk of the Court to be served by operation of the Court's electronic filing system upon the following:

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EXHIBIT B

BEFORE THE
ADMINISTRATIVE HEARING COMMISSION
STATE OF MISSOURI

REPRODUCTIVE HEALTH SERVICES OF PLANNED PARENTHOOD OF THE ST. LOUIS REGION, Petitioner, v. MISSOURI DEPARTMENT OF HEALTH AND SENIOR SERVICES, Respondent.	AHC No. 19-0879

DECLARATION OF COLLEEN P. McNICHOLAS, DO, MSCI, FACOG, IN SUPPORT OF PETITIONER'S SUGGESTIONS IN FURTHER SUPPORT OF MOTION FOR STAY

Colleen P. McNicholas, DO, MSCI, FACOG, declares as follows:

1. I am a board-certified obstetrician-gynecologist ("OB/GYN") physician licensed in the state of Missouri. I received a degree in osteopathic medicine degree in 2007 and a Masters of Science in Clinical Investigation in 2013. I completed a four-year residency in obstetrics and gynecology in 2011 and two-year fellowship in family planning in 2013.

2. I am currently an Associate Professor in the Department of Obstetrics and Gynecology at the Washington University School of Medicine, and one of four faculty members within the Department's Division of Family Planning. The Washington University School of Medicine is consistently rated among the top medical schools in the country (#10 in 2019 rankings) and is the top medical school in Missouri. The School's Department of Obstetrics and Gynecology

is also among the top ten obstetrics and gynecology programs in the nation.[1]

3. I am also an Attending Physician at Barnes-Jewish Hospital, which is a teaching hospital affiliated with the Washington University School of Medicine. Like the School, Barnes-Jewish is ranked among the top hospitals in the nation (#11) and best in Missouri. Its gynecology program is also nationally ranked (#12).[2]

4. Through these appointments, I have served as Director of the Ryan Residency Training Program (which provides enhanced training to OB/GYN residents in family planning, including abortion care), Assistant Director of the Family Planning Fellowship (which is a two-year post-residency program that focuses on research, teaching, and clinical practice to develop future leaders with expertise in family planning, including abortion care), and member of the Obstetrics and Gynecology Performance Evaluation Committee. I am also a member of Missouri's Section of the American College of Obstetricians and Gynecologists ("ACOG") and its incoming secretary and treasurer.

5. I am also a member (known as a fellow) of ACOG, and I serve on ACOG's Committee on Healthcare for Underserved Women.

6. I have authored or co-authored more than twenty-five peer-reviewed articles on obstetrics and gynecology, specifically on family planning, including an editorial in the *Journal of*

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[1] *E.g.*, U.S. News & World Report, *Best Medical Schools: Research (2019),* https://www.usnews.com/best-graduate-schools/top-medical-schools/washington-university-in-st-louis-04060 (last accessed June 27, 2019); Wash. Univ. Sch. of Med., *Education*, https://medicine.wustl.edu/education/ (last accessed June 27, 2019).

[2] *E.g.*, U.S. News & World Report, *2018–19 Best Hospitals Honor Roll and Medical Specialties Rankings*, https://health.usnews.com/health-care/best-hospitals/articles/best-hospitals-honor-roll-and-overview (last accessed June 27, 2019), U.S. News & World Report, *Best Hospitals for Gynecology*, https://health.usnews.com/best-hospitals/rankings/gynecology (last accessed June 27, 2019); Barnes-Jewish Hospital, *Awards & Honors*, https://www.barnesjewish.org/About-Us/Awards-Honors (last accessed June 27, 2019).

the American Medical Association (JAMA), entitled *Is It Time to Abandon the Routine Pelvic Examination in Asymptomatic Nonpregnant Women?*[3] I am also a peer reviewer of many publications, including the *American Journal of Obstetrics and Gynecology*, *Obstetrics and Gynecology*, and the journal *Contraception*.

7. As explained in the Declaration of Cathy Williams in Support of Petitioner's Motion for Stay, the arrangement between Washington University School of Medicine and Planned Parenthood ensures OB/GYN residents at Barnes-Jewish can access abortion training, as required by the American Council for Graduate Medical Education and the Council on Resident Education in Obstetrics and Gynecology. The arrangement also allows fellows in the highly competitive Family Planning Fellowship to receive advanced training in abortion and contraceptive care. Planned Parenthood is the only generally available abortion provider in Missouri. As part of my faculty appointment at Washington University School of Medicine, I (along with my colleagues in the family planning division) provide family planning services, including abortion, at Reproductive Health Services of Planned Parenthood of the St. Louis Region ("Planned Parenthood"). I have provided high-quality abortion care at Planned Parenthood since at least 2008. Beginning in July, I will be Planned Parenthood's Chief Medical Officer. At Planned Parenthood, we provide the same high-quality care provided at Washington University School of Medicine and Barnes-Jewish Hospital. In fact, all attending physicians at Planned Parenthood are either current or previous faculty members or graduated fellows of the program at Washington University School of Medicine. All care provided at Planned Parenthood, including abortion care, is pursuant to nationally recognized, evidence-based standards and guidelines.

[3] Colleen McNicholas & Jeffrey A. Peipert, *Is It Time to Abandon the Routine Pelvic Examination in Asymptomatic Nonpregnant Women?*, 317 JAMA 910 (2017).

8. I attach a copy of my curriculum vitae as Exhibit 1.

Statement of Deficiencies

9. I have reviewed the Missouri Department of Health and Senior Services ("DHSS") June 13 statement of deficiencies ("SOD") sent to Planned Parenthood, including the attached cover letter. I have also reviewed Planned Parenthood's June 18 plan of correction ("POC") in response to the June 13 SOD.

10. The June 13 SOD focuses almost exclusively on the care provided to four patients: Patients #1, #2, #3, and #12. I am familiar with the care provided to each of these patients because either I was the attending physician involved or have reviewed the patient's medical records.

11. At the outset, it is important to note that DHSS has focused on a rare but known complication of abortion in which the pregnancy remains ongoing despite a reasonable belief that the intervention would terminate the pregnancy—also known as a failed abortion. Complications in medicine, though unfortunate, are not entirely preventable despite our best efforts.

12. In medical literature, the rate of failed surgical abortion ranges from 0.05% to 0.2%, up to 2.3%.[4] Planned Parenthood's rate is well within the published range: in 2018, of the approximately 2,500 surgical abortions provided, less than five patients were known to have had a failed abortion. For these reasons, the concerns DHSS espouses about these patients' care are unfounded.

Pelvic Exams

13. Before turning to the care received by those specific patients, it is necessary to address DHSS's allegation that Planned Parenthood's long practice of performing a pelvic exam

[4] Luu Doan Ireland et al., *Medical Compared with Surgical Abortion for Effective Pregnancy Termination in the First Trimester*, 126 Obstetrics & Gynecology 22 (2015); Maureen E. Paul et al., *Early Surgical Abortion: Efficacy and Safety*, 187 Am. J. Obstetrics & Gynecology 407 (2002).

on the day of the procedure—and not also at least three days before—is a deficiency. It is my understanding DHSS now considers any deficiencies related to the timing of the pelvic exam to be resolved, although I also understand that DHSS's opposition brief continues to raise this issue.

14. Except for approximately four weeks in late May and June of this year, Planned Parenthood has performed a pelvic exam immediately before the surgical abortion is done for approximately twenty years without issue, and DHSS has never raised any concerns on this topic in its annual inspections. But in May (and again in the June SOD), DHSS claimed that—although the regulation requiring a pelvic exam had not substantively changed in two decades—the regulation in fact required a pelvic exam on the same day the patient is required to receive certain state-mandated information, which must be at least 72 hours before the abortion. As Planned Parenthood advised DHSS, this change would require surgical-abortion patients to receive two pelvic exams—the first of which would be medically unnecessary.

15. A pelvic examination is an invasive exam that includes inspection of the external genitalia, insertion of a speculum into the vagina to inspect the vagina and cervix, and a bimanual palpation of the uterus. As we explained to DHSS, a pelvic exam is relevant immediately before the abortion because it helps inform the procedural approach by giving the physician information on the patient's uterine size and position. Conversely, a pelvic exam at least three days prior is medically unnecessary because the information gained could be stale by the time of the procedure, since the patient's uterus may have shifted.

16. Indeed, ACOG recently said: "While pelvic exams may be appropriate for patients with certain conditions, routine multiple pelvic exams for women seeking abortion care are

unwarranted, invasive, and not supported by evidence."[5]

17. Despite this, and after explaining the medicine to DHSS multiple times and urging without success for it to change its position, Planned Parenthood acceded to DHSS's new interpretation in its May 22 POC in order to maintain its license.

18. Since then, and after public outrage over these medically unnecessary pelvic exams, DHSS abruptly reversed course and recognized that (as Planned Parenthood had already told it) the additional pelvic exam was medically unnecessary. DHSS issued an amendment to the regulation allowing us to continue to perform only one exam—on the day of the procedure. As reported in the media, DHSS Director Williams reversed course on the new additional pelvic exam requirement because he was "sensitive" to the fact that we, as the patients' physicians, "think that causes a burden for patients to do (the pelvic exam) twice."[6]

Patient #1

19. DHSS alleges Planned Parenthood failed to file a post-abortion care report (also called a complication report) for Patient #1 after a failed medication abortion; failed to complete and file a post-abortion care report after I made the clinical decision, in consultation with the patient, to change from a surgical to a medication abortion;[7] and failed to ensure a pelvic exam

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[5] ACOG Stands With Clinicians Who Provide Reproductive Health Care (May 28, 2019), https://www.acog.org/About-ACOG/News-Room/Statements/2019/ACOG-Stands-with-Clinicians-Who-Provide-Reproductive-Health-Care.

[6] Chris Mills Rodrigo, *Missouri Will no Longer Require Pelvic Exam Before Abortion*, The Hill, June 22, 2019, https://thehill.com/homenews/state-watch/449861-missouri-will-no-longer-require-pelvic-exam-before-abortion; *see also*

[7] There are two types of abortion: surgical abortion and medication abortion. Surgical abortion is not what is commonly understood to be "surgery;" it involves no incision and no need for general anesthesia. Surgical abortion involves the use of suction and/or instruments to remove the contents of the uterus. Medication abortion is a U.S. Food & Drug Administration ("FDA")-approved, safe, and effective method of terminating an early pregnancy non-surgically by taking medication by mouth that end the pregnancy in a process similar to a miscarriage.

was done on the counseling day and in a manner to accurately document the size and orientation of the patient's uterus. None of this is correct.

20. As explained in our POC, the patient's pelvic exam was performed on the day of the patient's procedure, by a fourth-year OB/GYN resident under the supervision of a board-eligible physician fellow who has completed her OB/GYN residency. The pelvic exam reflected no reason to believe the procedure would be difficult, and indeed, the pelvic exam would not have revealed the level of discomfort the patient could tolerate. Although this patient's uterine direction as assessed by pelvic exam could globally be described as anteverted, or tilting to the front of her body, the uterine cavity, the space in which the pregnancy exists, was found to be flexed toward the back. Because of the patient's unique uterine shape and orientation, which we could not know until we attempted the procedure, the surgical abortion attempt proved to be unusually uncomfortable for the patient, and because the safe and non-invasive option of medication abortion was available, the care team (including me) in consultation with the patient opted to stop attempting a surgical abortion and change the treatment plan to a medication abortion. Continuous reassessment of an evolving clinical picture is always the most appropriate and best approach to care.

21. Unfortunately, this patient's medication abortion failed, as occurs in 0.7% of medication abortions.[8] Such failures have to do with the medications not having the desired effect, and are in no way indicative of any sort of error or lack of skill by the clinician providing the medication abortion; and indeed, given that medication abortion at Planned Parenthood is provided by oral medications according to the FDA-approved regimen, and given there is no dispute as to

[8] U.S. Food & Drug Admin., Highlights of Prescribing Information: Mifeprex (rev. Mar. 2016), https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf.

the gestational age, it is difficult to conceive what user error or variation in skill could possibly occur. Thus, to the degree DHSS is attempting to suggest the medication abortion would have been more likely to be successful had a resident or fellow not been involved in the patient's care, this suggestion is misplaced.

22. Following her failed medication abortion, I provided the patient's surgical aspiration. This second procedure was uneventful. This is unsurprising; the known effect that mifepristone and misoprostol have on the cervix, uterus, and location of the pregnancy, undoubtedly changed the clinical situation, making it easier. Additionally, my personal attempt of her first aspiration afforded our care team the opportunity to discuss additional interventions to manage discomfort, specifically the use of intravenous sedation (which she accepted). Neither the use of adjunctive medication to alter the anatomy or use of the IV sedation to better manage discomfort were part of the patient's first surgical abortion attempt.

23. As explained in the POC, DHSS's allegation that I failed to file a post-abortion report after the medication abortion failed is false. Indeed, the SOD acknowledges that DHSS has a copy of the report, the report is contained within the patient's medical record (which DHSS has), DHSS has proof that Planned Parenthood mailed the report to DHSS, and DHSS has confirmation that it received the report. SOD at 60. Because the report was mailed to DHSS (as required) and DHSS received it (as it acknowledges), Planned Parenthood asked DHSS for clarification on this alleged deficiency, which DHSS has not provided. Absent this clarification, it is unclear how we could correct this issue when the report was timely sent and received as required.

24. DHSS alleges we failed to perform an additional, unnecessary pelvic exam at least 72 hours before the abortion. As explained above at paragraphs 14–16, consistent with our long-term prior practice that DHSS never previously took issue with and with the language of the

regulation, as well as with best medical practices and ethics, we provided the patient's pelvic exam on the day of the procedure and not three days earlier, which DHSS now agrees is not a deficiency. And to be clear, had we performed a pelvic exam at least three days before the patient's abortion, it would not have not influenced the method of abortion; there is absolutely nothing we would have done differently.

25. DHSS's contention that an inaccurate pelvic exam contributed to the change of treatment plan for Patient #1 is also false. In fact, documentation throughout the chart by both the fellow and attending physicians were consistent in documenting the pelvic exam. There is simply no basis to conclude the pelvic exam was not accurately performed. As we explained in the POC, DHSS's suggestion to the contrary reflects a lack of understanding of medicine and basic female anatomy.

26. The uterus is shaped like an upside-down pear and sits within the pelvis. "The uterus may naturally lie in different positions such as anteverted/retroverted, anteflexed/retroflexed, or midline, and it may be rotated (especially during pregnancy)."[9] Version refers to the tilt of the bottom part of the uterus, or the cervix; and flexion refers to the tilt of the top part of the uterus, or the fundus. Most patients with a uterus have an anteverted and anteflexed uterus, meaning both the fundus and the cervix are oriented toward the front of the patient's body.[10] Patient #1 has an anteverted and acutely retroflexed uterus. The resident physician did ***not*** find the patient had an *anteflexed* uterus, as DHSS suggests; she correctly documented anteversion in the patient's record, which is not inconsistent with my finding of retroflexion.

[9] Jessica N. Sosa-Stanley & Diana C. Peterson, Anatomy, Abdomen and Pelvis, Uterus (last updated Feb. 1, 2019), https://www.ncbi.nlm.nih.gov/books/NBK470297/.
[10] *Id.*

27. After the patient returned following the failed medication abortion, I found the patient's uterus had shifted; it was retroverted and retroflexed. As we explained in the POC, this was likely due to a variety of factors, including the change in gestational age, the medications and sedation received, and patient comfort. The medications patients receive with a medication abortion have a substantial impact on both the cervix and uterus, including changing uterine orientation.[11]

28. DHSS also alleges the clinical decision to change from a surgical abortion to a medication abortion is tantamount to a failed abortion, which would require me to file a post-abortion care report. It is my understanding Missouri law requires such a report only when "post-abortion care" has been provided. A failed abortion occurs when there is an ongoing pregnancy after it was expected the pregnancy had been terminated. This understanding is consistent with my clinical practice, as well as the article DHSS relies on, which defined failed abortion as occurring where the patient "has been subjected to an operative procedure for abortion only to be found at some later date still to be pregnant."[12]

29. DHSS now suggests this commonly understood and accepted understanding of failed abortion is implausible and "contradicts [Planned Parenthood]'s own practice of filing complication reports for failed medication abortions, where the patient also knows that the abortion has failed." This is false. In the case of a surgical abortion, a failed abortion is understood to occur after the procedure has been completed and the patient has left the facility believing the procedure

[11] As part of the standard medication abortion protocol, the patient receives both mifepristone and misoprostol. Mifepristone is a progesterone receptor antagonist that initiates the breakdown of the endometrium and implanted embryo. Misoprostol is a prostaglandin, which causes uterine contractions and cervical ripening.

[12] Waldo Fielding et al., *Continued Pregnancy After Failed First Trimester Abortion*, 52 Obstetrics & Gynecology 56 (1978).

was successful, when in fact the patient remains pregnant. In the case of medication abortion, a failed abortion is understood to occur only after the patient has completed the prescribed regimen and allowed sufficient time for the medications to work. In either case, if the patient returns to Planned Parenthood with an ongoing pregnancy, and is treated for the ongoing pregnancy, a post-abortion report is completed. Because there was no expectation the first surgical abortion attempt had terminated Patient #1's pregnancy, because we made a clinical decision not to continue the surgical abortion attempt in light of the patient's discomfort and the option of a non-invasive medication abortion, there was no complication (or treatment of it) requiring the filing of a post-abortion care report.

30. I cannot conceive what additional material information DHSS believes it could gain by interviewing the resident and fellow physicians, given that DHSS has the patient records and I sat for an interview and discussed this patient's care with DHSS, including my supervision of the trainee physicians. Nor is it clear how further interviews could have resolved (1) DHSS misplacing or losing the post-abortion report after the failed medication abortion; (2) the alleged failure to complete a post-abortion report after the change of procedure by the attending physician (in this case, me); or (3) the inaccurate pelvic exam allegation, despite that the record does not support the allegation.

Patients #2 and #3

31. Regarding Patients #2 and #3, DHSS alleges that after these patients' failed surgical abortions (two among the less than five known instances out of approximately 2,500 surgical abortions in 2018), Planned Parenthood—as well as its contracted, independent pathology lab—failed to ensure the accuracy of gross tissue examination. And DHSS also claims that Planned Parenthood failed to adequately re-consent these patients, or to promptly follow up with Patient

#2.[13] As with the allegations pertaining to Patient #1 these allegations are factually unsupported, as we outlined in our POC.

32. At Patient #2's first surgical abortion attempt, an attending physician identified some fetal parts, membranes/sac, and villi through the tissue exam, which indicated the abortion was successful. The independent pathology lab confirmed these findings.

33. Shortly after the procedure, Patient #2 called expressing concerns she still might be pregnant. Her call was promptly returned—within twenty minutes, which DHSS does not acknowledge in the SOD. After evaluation of her symptoms, we encouraged her to return for a follow-up appointment to confirm whether the abortion was complete. She was offered another appointment, but did not return. The patient did return later for a follow-up appointment, and at that point, was diagnosed with an ongoing pregnancy. Thus, it simply is not true that Planned Parenthood failed to appropriately follow up with this patient. Our patients' lives are complex and unfortunately it is not unusual for a patient not to come for a scheduled appointment or to be unable to arrange for an appointment when we suggest one; this can happen for any of a number of reasons including difficulty making work or childcare arrangements or travel arrangements—all of which are outside of our control.

34. DHSS suggests that Planned Parenthood failed to obtain Patient #2's informed consent before proceeding with the second surgical abortion attempt but this is flatly untrue; this consent is in the patient's record, copies of which DHSS has but discussion of which DHSS omitted in its SOD.

[13] DHSS also alleged we failed to communicate with the pathology lab after the failed abortions. Although this deficiency is not based on any legal requirement, we agreed to notify the contracted pathology lab each time we discover a failed abortion, even though the pathology report showed membrane/sac and/or fetal parts. DHSS accepted this corrective plan resolving this issue.

35. DHSS appears to suggest that Planned Parenthood should have forced this patient to wait an additional 72 hours before having a second procedure, despite that the patient had already received the state-mandated information and then waited the required 72 hours before the first abortion attempt. But as with all patients, the information this patient was given 72 hours before the first abortion consent included the risks and benefits of the procedure, including infection, hemorrhage, cervical tear or uterine perforation, harm to subsequent pregnancies or the ability to carry a subsequent child to term, and possible adverse psychological effects associated with the abortion, as required by Missouri law. The complications a patient is at risk for from surgical abortion are the same regardless of gestational age, though the degree of risk increases with gestational age. And we specifically advise patients that the risk of each complication increases in degree with each week of pregnancy. Also as required by Missouri law, we provide the patient with DHSS's informed consent booklet,[14] which lists complications related to surgical abortion and states: "The later in pregnancy the abortion is done, the more complex the procedure and the higher the risk." All of this information is provided at least 72 hours before the abortion procedure. For these reasons, the physician fully complied with the 72-hour mandatory delay law.

36. As with Patient #2, following Patient #3's first surgical abortion attempt, a fellow physician found membranes/sac and villi on the tissue exam, which the pathology lab confirmed. The patient returned a few weeks later with an ongoing pregnancy, and had an uncomplicated second surgical abortion.

37. As with Patient #2, Patient #3 signed appropriate informed consent documentation a second time before the follow-up procedure, as reflected in her record (which DHSS has). And

[14] Mo. Dep't of Health & Senior Servs., Missouri Informed Consent Booklet 12, https://health.mo.gov/living/families/womenshealth/pregnancyassistance/pdf/InformedConsentBooklet.pdf (last updated Oct. 2017).

as with Patient #2, Patient #3 received all required information at least 72 hours before her abortion. *See* ¶ 36 above.

38. As to both Patients #2, and #3, DHSS's primary complaint appears to be that it does not credit that a patient could have a failed abortion if an adequate tissue examination was done. But this is simply wrong.[15]

39. After a surgical abortion, the physician performs a visual exam of the tissue that has been evacuated from the uterus, known as a gross tissue examination. Amongst the main purposes of the tissue exam is to rule out an ectopic pregnancy or a pregnancy outside the uterus as well as to help to ensure a completed abortion. As required by Missouri law, the tissue is then sent to a pathologist to confirm what tissue was removed, as well as identify other concerns, such as possible uterine infection.

40. As we explained in our POC, and as I stated in my interview, gross tissue exams are imperfect and even highly trained physicians and pathologists are not always able to accurately confirm a completed abortion from a gross tissue exam, particularly at earlier gestations. Presence of the gestational sac on the initial gross exam and final pathological exam does not necessarily ensure a complete abortion; rather, all that can be verified is that some tissue was evacuated. For instance, in one study, 1% of pregnancies were ongoing even though both the abortion provider and a pathologist found products of conception in the aspirates.[16]

41. DHSS nevertheless accuses three licensed, board-certified, and fellowship-trained

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[15] With Patient #2, specifically, DHSS suggests but does not cite as a deficiency the fact that Patient #2 developed an infection from retained tissue. Incomplete abortion, like failed abortion, is a rare but known complication. In the medical literature, rates of incomplete abortion range from <0.1% to 8%. Nat'l Acads. of Scis., Eng'g, and Med., Assessing the Safety and Quality of Abortion Care in the U.S. at 60 (2018).

[16] Maureen Paul et al., *Is Pathology Examination Useful After Early Surgical Abortion?*, 99 Obstetrics & Gynecology 567 (2002).

physicians of failing to perform an accurate tissue exam. DHSS offers no medical evidence disputing the consistent examination and laboratory results.

42. Regarding Patient #2 specifically, because of the gestational age, fetal parts should be observed in the tissue exams,[17] and for this patient, the tissue exams after the first procedure found some fetal parts and the exams after the second procedure found all fetal parts, Planned Parenthood's quality assurance team reasoned the patient likely had an undiagnosed twin pregnancy. That is because it is impossible to evacuate some fetal parts during the procedure yet leave the pregnancy undisturbed. DHSS found this explanation "insufficient" because in one study from 1978, of the 46 patients with failed surgical abortions, the authors did not note that any involved twin pregnancies.[18] But it is unclear how the article's authors could have known if there was an undiagnosed twin pregnancy. In any event, as should be obvious, whether any of the 46 patients in that study had a twin pregnancy or not does not tell us whether Patient #2 had a twin pregnancy.[19] In a systematic review of the literature on ultrasound in early pregnancy, the rate of undiagnosed multiple pregnancy despite routine ultrasound screening was found to be 1.3%, or 2 out of 153.[20]

43. DHSS also contends interviews with the physicians involved in the care of these patients would have shed light on the adequacy of supervision of trainee physicians and compliance with the same-physician law, as well as the reoccurrence of two failed abortions by

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[17] In early first-trimester abortions, fetal parts are not observable; instead, the physician and pathologist look for other evidence, including such as the gestational sac.
[18] Fielding, *supra* note 12.
[19] Twin pregnancies are common. According to the CDC, the twin birth rate in the U.S. is 33.3 twins per 1000 births. U.S. Ctrs. for Disease Control & Prevention, *Multiple Births*, https://www.cdc.gov/nchs/fastats/multiple.htm (last reviewed Jan. 18, 2014).
[20] Melissa Whitworth et al., *Ultrasound for Fetal Assessment in Early Pregnancy*, Cochrane Database of Systematic Revs., July 2015, at 14.

the fellow physician. But it is my understanding alleged deficiencies relating to the supervision of trainee physicians and compliance with the same-physician requirement have long been resolved—when DHSS accepted our May 28 POC, which stated in part: "If [Planned Parenthood] continues providing care through fellows and/or residents, it will ensure that the fellow or resident provides the information required by 188.027.6 RSMo, in the presence of the attending physician, and that both the fellow or resident and the attending physician document their participation in this process. In addition, as noted in our prior plan of correction, the attending physician and the fellow and/or resident will also both be present in the procedure room." Additionally, the fellow physician did not have two failed abortions; Patient #1 did not have a failed surgical abortion, as discussed above. And at any rate, I personally attempted the procedure and made the determination that given the patient's discomfort it was clinically preferable to stop the attempt and provide the patient with a medication abortion instead. Thus, the inability to complete the surgical attempt certainly did not indicate any failure, lack of training, or inadequate supervision.

44. As I explained in my interview, Washington University School of Medicine faculty provide some care through trainee physicians under our supervision, including through Washington University School of Medicine's and Barnes-Jewish Hospital's nationally recognized fellowship and residency programs. The manner in which we provide this care, through supervision of residents and fellows, is in accordance with national standards for medical education, and we do not alter the training, including supervision, depending on the setting (including whether we are training at Planned Parenthood).[21]

[21] DHSS takes issue with my note in the record stating that I was present during the procedure. As we stated in the POC, the timestamp on the note reflects the time of the patient's appointment, and we agreed that going forward the physician would manually annotate the current time. DHSS accepted this corrective plan. Nor is the note otherwise incorrect; I was present for the procedure. As discussed above, I personally attempted the aspiration for Patient #1. And as I stated in my

Patient #12

45. DHSS has made many factual misrepresentations about the care provided to Patient #12. To be clear, the patient did not have an abortion or an attempted evacuation at Planned Parenthood. Nor is it true the patient experienced "massive," "uncontrolled" bleeding.

46. As more fully explained in our POC, the patient sought an abortion for medical reasons. She was evaluated at Washington University School of Medicine after being referred from out of state because of limited access to care in her home state and with a condition known as placenta previa, in which the placenta was in the setting of a prior cesarean incision. A senior, experienced OB/GYN physician with a fellowship in ultrasonography diagnosed placenta previa but also specifically noted no concerning findings regarding placenta accreta spectrum. The Washington University School of Medicine Family Planning Division faculty, including myself, discussed this patient's condition, and determined her abortion could be safely managed in an outpatient setting and that this would be the most appropriate setting for her care.

47. For procedures later in pregnancy, the abortion must be done over two days (in addition to the state-mandated counseling day). On the first day, dilators are inserted into the cervix and the patient is sent home or to a nearby hotel overnight to allow the dilators to absorb moisture from the body and slowly expand. Dilation is necessary to ensure safe passage of surgical instruments into the uterus. The following day, the dilators are removed and the abortion procedure can begin.

48. DHSS attempts to blur the lines of these separate days. Patient #12 had dilators inserted at Planned Parenthood. During that process, the patient began to bleed a small amount. The bleeding was controlled and the patient remained stable and alert. After the bleeding began,

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interview, in all cases, I am always present on the surgical floor either in the procedure room or nearby, depending on the patient's needs and the trainee physician's skill.

the clinical team—comprising three physicians, including two Washington University School of Medicine faculty members—reassessed the situation and opted to complete the patient's care in the hospital setting. The patient was then transferred via EMS to Barnes-Jewish Hospital. Again, her bleeding was stopped and she was stable and alert upon arrival.

49. After she was admitted to Barnes-Jewish, physicians attempted the abortion. During that hospital-based procedure a uterine artery embolization was performed to control blood loss.

50. DHSS suggests the abortion should never have been planned for Planned Parenthood. But the basis for this suggestion is pure speculation that the patient had placenta accreta. But as discussed, there was no ultrasound evidence suggesting placenta accreta found by the ultrasound specialist, and because the patient did not require hysterectomy, there is no evidence to confirm such a diagnosis now. Given the available information it was completely appropriate for the care team at both Washington University School of Medicine and Planned Parenthood to determine that Planned Parenthood was the appropriate facility for the patient to receive care at.

51. ACOG Practice Bulletin 135 is not to the contrary.[22] The bulletin does not set or otherwise reflect the standard of care. Indeed, as the bulletin states: "The information is designed to aid practitioners in making decisions about appropriate obstetric and gynecologic care. These guidelines should not be construed as dictating an exclusive course of treatment or procedure. Variations in practice may be warranted based on the needs of the individual patient, resources, and limitations unique to the institution or type of practice."

52. I declare under penalty of perjury the foregoing is true and correct to the best of my knowledge.

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[22] Am. Coll. of Obstetricians & Gynecologists, Practice Bulletin No. 135: Second-Trimester Abortion 4–5, reaffirmed 2019, https://www.acog.org/-/media/Practice-Bulletins/Committee-on-Practice-Bulletins----Gynecology/Public/pb135.pdf?dmc=1&ts=20190530T1037529034.

Dated: June 27, 2019

Colleen P. McNicholas, DO, MSCI, FACOG

EXHIBIT 1

CURRICULUM VITAE
Colleen Patricia McNicholas, DO, MSCI, FACOG

Date: June 2019

Address:

Department of Obstetrics and Gynecology
Washington University in St. Louis
660 S Euclid Ave
Mailstop 8064-37-1005
St. Louis, Missouri 63110-1094

Present Position:

Associate Professor
Washington University School of Medicine in St. Louis
Department of Obstetrics and Gynecology
Division of Family Planning

Director- Ryan Residency Collaborative
Oklahoma University and Washington University School of Medicine

Assistant-Director- Fellowship in Family Planning
Washington University School of Medicine in St. Louis

Education:

Undergraduate:	1998-2003	Benedictine University Lisle, Illinois B.S. Forensic Chemistry
Graduate:	2003-2007	Kirksville College of Osteopathic Medicine Kirksville, Missouri Doctor of Osteopathy
	2011-2013	Washington University in St. Louis St. Louis, Missouri Masters of Science in Clinical Investigation
Internship:	2007-2008	Atlanta Medical Center Atlanta, Georgia Internship
Residency:	2008-2011	Washington University School of Medicine Residency in Obstetrics and Gynecology
Fellowship:	2011-2013	Washington University School of Medicine Clinical Instructor – Obstetrics and Gynecology Clinical Fellow – Family Planning

Academic Positions/Employment:

2018- 2019	Associate Professor Department of Obstetrics and Gynecology Washington University School of Medicine

2014-2018	Director, Ryan Residency Training Program Washington University School of Medicine
2013- 2018	Assistant Professor Department of Obstetrics and Gynecology Washington University School of Medicine
2012-2014	Missouri Baptist Medical Center, St Louis, MO Laborist

University and Hospital Appointments and Committees:

Appointments

2013-	Attending Physician Barnes Jewish Hospital St. Louis, MO
2014- 2019	Director, Ryan Residency Training Program Department of Obstetrics and Gynecology Washington University School of Medicine
2016- 2019	Co-Director, Fellowship in Family Planning Department of Obstetrics and Gynecology Washington University School of Medicine
2016-2019	Obstetrics and Gynecology Performance Evaluation Committee Washington University/Barnes Jewish OB/GYN Residency
2016-2019	Washington University School of Medicine Institutional Review Board Member
2018-2019	Washington University School of Medicine Committee on Admissions

Committees:

2014- 2017 2017-2020	American College of Obstetrics and Gynecology Committee on the Healthcare for Underserved Women Member
2015- 2017 2017-2020	American College of Obstetrics and Gynecology Underserved Liaison to Committee on Adolescent Health Care
2015-	International Federation of Gynecology and Obstetrics (FIGO) Women's Sexual and Reproductive Rights Committee Master Trainer, Integrating Human Rights in Health
2016-	Ibis Reproductive Healthcare Over the counter oral contraceptive working group Policy Subcommittee
2017-	MERCK Global Advisory Board on Contraception
2017-	Washington University School of Medicine OUT Med Advisory Board

Volunteer	2015-	Saturday Neighborhood Health Clinic Washington University School of Medicine Volunteer Attending Physician Faculty, Primary Care Volunteer Attending Physician Faculty, Americore Homeless

Medical Licensure and Board Certification:

Licensure

Missouri, Kansas, Oklahoma, Washington
Illinois Pending

Board Certification:

2014- current	American Board of Obstetrics and Gynecology General Obstetrics and Gynecology Diplomate

Honors and Awards:

2001	Gregory Snoke Memorial Scholarship
2001	American Chemical Society Analytical Achievement Award
2001	American Chemical Society Division of Analytical Chemistry 2001 Undergraduate Award
2002	PGG Industries Foundation J. Earl Burrell Scholarship
2003	Senior Academic Award: College of Arts and Science
2006	Presidents Award: Women in Medicine
2011	Kody Kunda Resident Teaching Award
2012	ACOG Health Policy Rotation, LARC Program January 2013
2012	Physicians for Reproductive Health and Choice (PRCH) Leadership Training Academy
2012	President's Award: St. Louis Gynecologic Society, best research presentation
2016	Fellowship in Family Planning, Warrior Award
2016	Physicians for Reproductive Health, Voices of Courage: A Benefit Celebrating Extraordinary Abortion Providers
2016	2015 Roy M. Pitkin Award, Obstetrics and Gynecology (The Green Journal)
2018	Massingill Family Scholarship, 2018 Robert C. Cefalo Leadership Institute
2018	ACOG District VII Mentor of the year award
2019	Arnold P. Gold, Gold Humanism Honor Society Inductee

Editorial Responsibilities:

2011-	*Reviewer*, Contraception
2011-	*Reviewer*, Journal of Family Planning and Reproductive Health Care
2012-	*Reviewer*, American Journal of Obstetrics and Gynecology
2012-	*Reviewer*, European Journal of Obstetrics and Gynecology and Reproductive Biology
2013-	*Reviewer*, Obstetrics and Gynecology

Professional Societies and Organizations:

2003-	Medical Students for Choice
2006-2011	Association of Reproductive Health Professionals
2006-	American Congress of Obstetricians and Gynecologists

Leadership Roles

- 2013: The American College of Obstetricians and Gynecologists/Bayer HealthCare Pharmaceuticals Research Fellowship in Contraceptive Counseling (Selection committee)

- 2012-2019: American Congress of Obstetrics and Gynecology Congressional Leadership Conference, participant
    - 2015: Presenter, Reproductive Health Legislation in the States
    - 2016: Presenter, Reproductive Health Legislation in the States

- 2014-2020: Committee on Health Care for Underserved Women
    - Author, CO-Healthcare for Women with Disabilities
    - Author, Policy statement- Marriage and Family Equality
    - ACOG Liaison, AAMC Family Building Webinar series
    - Author, CO- Trauma informed care

- 2015-current: Committee on Adolescent Health Care, Underserved Liaison

- 2015-current: Missouri ACOG Section Advisory Committee, Member
    - 2015- current: Member, Legislative Committee
    - 2019-current: Secretary/Treasurer

2006- Gay and Lesbian Medical Association
2006- Women in Medicine
Leadership Roles

- 2010-current Board Member
- 2016: Chair of annual conference, Aug 2016
- 2018-2020: Board Treasurer

2008-2011 St. Louis Obstetrics and Gynecology Society
Leadership Roles: resident board member
2011- Society of Family Planning

Invited Presentations:

2001 Cadmium's effect on Osteoclast Apoptosis
12th Annual Argonne Symposium for Undergraduates in Science, Engineering and Mathematics

2002 Cadmium's effect on Osteoclast Apoptosis
2002 Experimental Biology Conference

2012 Contraception for medically complicated women
Women in Medicine Annual meeting

2013 The troubling trend of legislative interference.
Washington University School of Medicine, OBGYN Grand Rounds.

2013 An update on abortion: Why lesbians and those who treat them should care
The Gay and Lesbian Medical Association

2013 Findings from the Contraceptive CHOICE Project. Are you meeting your patient's contraceptive needs?
Washington University School of Medicine Annual OB/GYN Symposium

2013 Legislative interference and the impact on public health.
Washington University Brown School of Social Work.

2014	Business of Medicine Medical Student Elective Course Legislating Medicine Washington University School of Medicine
2014	Practical tips for your first RCT, lessons learned Lecture in Randomized Control Trial course
2014	Uniting tomorrow's leaders of the RJ movement with providers of today National Abortion Federation Annual Meeting
2014	Systems based practice and advocating for your patients Washington University School of Medicine OB/GYN residency core lecture
2014	Abortion in sexual minority populations *National Abortion Federation*
2014	Complications of uterine evacuation St. Louis University OB/GYN Grand Rounds
2014	Medical contraindications in CHOICE Participants using combined hormonal contraception Over the Counter Oral Contraceptive Working Group
2015	Implementing immediate postpartum LARC Kansas University OB/GYN grand rounds
2015	The evidence for immediate Post-partum IUD insertion Kansas City Gynecologic Society
2105	Business of Medicine Medical Student Elective Course Legislating Medicine Washington University School of Medicine
2015	Getting Politics Out of the Exam Room: Combating Legislative Interference in the Patient-Provider Relationship National Abortion Federation Annual Meeting
2015	Are you meeting your patient's contraceptive needs? Tennessee Department of Health.
2015	Colorado Initiative to reduce unintended pregnancy (webinar): Reducing Unplanned Pregnancies in Colorado through Strategies to Promote Long-Acting Reversible Contraception Huffington Post, Live
2105	Method mix it up: Expanding options to meet the unique contraceptive needs of young people FIGO World Conference
2015	Getting to Yes-Interventions to Increase LARC Acceptance with a Focus on IUC Nurse Practitioners Women's Health Annual Symposium
2015	Put your megaphone where your mouth is: Getting your professional society to speak up

Forum on Family Planning

2015 When Politics Trumps Science- Why is Birth control at Center Stage?
Carbondale Illinois Grand Rounds

2016 Using research to effectively advocate
Physicians for Reproductive Health Leadership Training Academy

2016 Partial Participation and Abortion Training in Residency: A Structure for Optimizing Learning and Clinical Care
APGO/CREOG

2016 Are we meeting the needs of our teen and adolescent patients? Our role in preventing unintended pregnancy. Barnes Jewish Hospital/Washington University School of Medicine CME Outreach.

2016 The emerging role of physicians as advocates
St Louis OB/GYN Society

2016 Legislation and Advocacy
Washington University School of Medicine- Elective course
Gun violence as a public health issue

2016 Legislative advocacy and the impact on public health
Washington University, Brown School of Social Work

2017 GOV 101
Learning to advocate at the MO legislature

2017 Reevaluating the longevity of LARC
GrandRounds, BayState Medical Center

2018 Ryan Residency Program Annual Meeting
Patient and Community Advocacy in Residency Training

2018 Physician advocacy, the key to public health
Keynote Speaker
Washington University
Center for Community Health Partnership & Research (CCHPR)
Global Health Center Summer Research Program

2018 XXII World Congress of Gynecology and Obstetrics
Whether, when, and how many: a global movement toward reproductive freedom
Rio de Janeiro, Brazil

2018 Domestic and Global epidemiology of abortion
Washington University, Brown School of Social Work

Research Support:

3125-946435
Role: Principal Investigator
MERCK
Ovarian function with prolonged use of the implant
Award: January 2017-June2018
Award Amount: $279,126

U01DK106853 (Colditz, Sutcliffe)
Role: Co-investigator
NIH/NIDDK
LUTS prevention in adolescent girls and women across the lifespan
Award: 07/01/2015-06/31/2020

(Peipert, McNicholas)
Role: Co-Principal Investigator
Anonymous Donor
EPIC: Evaluating prolonged use of the IUD/implant for Contraception
Award: Sep8, 2014 – Aug 31, 2018
Award Amount: $ 1,000,000

National Institutes of Health- Loan Repayment Program
Role: Principal Investigator
EPIC: Evaluating prolonged use of the IUD/implant for Contraception
Aug 17, 2014- July 31, 2017
Award Amount: $70,000
Aug 1, 2016- July 31, 2018
Award Amount: $70,000
Aug 1, 2018- July 31, 2020

81615 (Peipert, McNicholas)
Role: Co-Principal Investigator
William and Flora Hewlett Foundation
LIFE: Levonorgestrel Intrauterine system For Emergency Contraception; a multicenter randomized trial
June1, 2014- May 31, 2015
Award Amount: $351,500

IRG-58-010-57 (McNicholas)
Role: Principal Investigator
American Cancer Society Institutional Research Grant (ACS-IRG)
Evaluating the impact of the IUD on HPV and cervical cancer risk
January 1, 2014-December 31, 2014
Award Amount: $30,000

SFPRF12-1 (McNicholas)
Role: Principal Investigator
Society of Family Planning Research Fund
Effectiveness of Prolonged use of IUD/Implant for Contraception (EPIC)
January 2012 – July 2014
Award Amount: $70,000

UL1 TR000448 (Evanoff)
Role: Postdoctoral MSCI Scholar

NIH-National Center for Research Resources (NCRR)
Washington University Institute of Clinical and Translational Sciences (ICTS)
July 1, 2011 – June 30, 2013

5T32HD055172-03 (Macones, Peipert)
Role: Clinical fellow, trainee
NIH T32 Research Training Grant
July 1, 2011 – June 30, 2013

Bibliography:

Peer-reviewed Publications:

1. Allsworth JE, Hladky KJ, Hotchkiss T, McNicholas C, Rohn A. Discussion: 'Douching and the risk for sexually transmitted disease' by Tsai et al. *Am J of Obstet and Gynecol* 2009;200(1):e11-4.

2. Stoddard A, McNicholas C, Peipert JF. Efficacy and safety of long-acting reversible contraception. *Drugs*. 2011 May 28;**71**(8): p. 969-80. PMID: 21668037

3. McNicholas C, Hotchkiss T, Madden T, Zhao Q, Allsworth J, Peipert JF. Immediate postabortion intrauterine device insertion: continuation and satisfaction. *Women Health Iss.* 2012 Jul-Aug; 22(4):e365-369. PMID: 22749197

4. McNicholas C, Peipert JF. Long-acting reversible contraception for adolescents. *Curr Opin Obstet Gyn.* 2012 Oct; 24(5):293-298. PMID: 22781078

5. McNicholas C, Peipert JF. Initiation of long-acting reversible contraceptive methods (IUDs and implant) at pregnancy termination reduces repeat abortion. *Evid Based Med.* 2013 Jun;18(3):e29. PMID: 23161505

6. McNicholas C, Madden T, Zhao Q, Secura G, Allsworth JE, Peipert JF. Cervical lidocaine for IUD insertional pain: a randomized controlled trial. *Am J Obstet Gynecol. 2012* Nov;207(5):384 e381-386. PMID: 23107081

7. McNicholas C, Zhao Q, Secura G, Allsworth J, Madden T, Peipert J. Contraceptive failures in overweight and obese combined hormonal contraceptive users. *Obstet Gynecol*. 2013 March; 121(3):585-92. PMID: 23635622

8. McNicholas C. Transcending politics to promote women's health. *Obstet Gynecol.* 2013 Jul;122(1):151-3. PMID: 23743460

9. Eisenberg D, McNicholas C, Peipert JF. Cost as a barrier to long-acting reversible contraceptive (LARC) use in adolescents. *J Adolescent Health*. 2013 Apr;52(4 Suppl):S59-63. PMID: 23535059

10. Grentzer J, McNicholas C, Peipert J. Use of the etonorgestrel-releasing implant. *Expert Rev. of Obstet and Gynecol.* 8 (4), 337-344. 2013

11. Secura G, McNicholas C. Long-acting reversible contraceptive use among teens prevents unintended pregnancy: a look at the evidence. *Expert Rev. of Obstet Gynecol*. 8(4), 297-299. 2013

12. McNicholas C, Peipert JF, Madipati R, Madden T, Allsworth, J Secura G. Sexually transmitted infection prevalence in a population seeking no-cost contraception. *Sex Transm Dis.* 2013 July;40(7):546-51. PMID: 23965768

13. Sehn JK, Kuroki LM, Hopeman MM, Longman RE, McNicholas CP, Huettner PC. Ovarian complete hydatidiform mole: case study with molecular analysis and review of the literature. *Hum Pathol*. 2013 Dec;44(12):2861-4. PMID: 24134929

14. Madden T, McNicholas C, Zhao Q, Secura G, Eisenberg D, Peipert JF. Association of Age and Parity with IUD Expulsion. *Obstet Gynecol.* 2013 Oct; 124 (4): 718-26. PMID: 4172535

15. Secura G, Madden T, McNicholas C, Mullersman J, Buckel C, Zhao Q, Peipert JF. No-Cost Contraception Reduces Teen Pregnancy, Birth, and Abortion. *New Engl J Med.* 2104 Oct; 371(14); 1316-23. PMCID: 4230891

16. McNicholas C, Madden T, Secura G, Peipert JF. The Contraceptive CHOICE Project Round Up: What we did and what we learned. *Clin Obstet Gynecol.* 2014 Dec; 57(4); 635-43. PMCID: 4216614

17. McNicholas C, Maddipati R, Swor E, Zhao Q, Peipert JF. Use of the Etonogestrel Implant and Levonorgestrel Intrauterine Device Beyond the U.S. Food and Drug Administration-Approved Duration. *Obstet Gynecol,* 2015 Mar; 125(3):599-604.

18. Grentzer J, Peipert J, Zhao Q, McNicholas C, Secura G, Madden T. Risk-based screening for Chlamydia trachomatis and Neisseria gonorrhoeae prior to intrauterine device insertion. *Contraception* 2015 Jun; S0010-7824(15)00250-4. PMID:26093189

19. Mejia M, McNicholas C, Madden T, Peipert J. Association of Baseline Bleeding Pattern on Amenorrhea with Levonorgestrel Intrauterine System Use. *Contraception.* 2016 Nov;94(5):556-560. PMID: 27364099

20. Hou M, McNicholas C, Creinin M. Combined Oral Contraceptive Treatment for Bleeding Complaints with the Etonogestrel Contraceptive Implant: A Randomized Controlled Trial. *Eur J Contracept Reprod Health Care.* 2016 Oct;21(5):361-6. PMID: 27419258

21. Zigler RE, Peipert JF, Zhao Q, Maddipati R, McNicholas C. Long-acting reversible contraception use among residents in obstetrics/gynecology training programs. *Open Access J of Contracept*. 2017 Jan; 2017(8) 1—7. PMID: 29386949

22. Zigler RE, McNicholas C. Unscheduled vaginal bleeding with progestin-only contraceptive use. *Am J of Obstet and Gynecol*. 2017 May;216(5):443-450. PMID: 27988268

23. McNicholas C, Swor E, Wan L, Peipert JF. Prolonged use of the etonogestrel implant and levonorgestrel intrauterine device: 2 years beyond Food and Drug Administration-approved duration. *Am J Obstet Gynecol*. 2017 Jan 29. PMID:28147241

24. McNicholas C, Peripert JF. Is it time to abandon the routine pelvic exam in asymptomatic nonpregnant women? *JAMA* 2017 Mar 7;317(9):910-911. PMID:28267835

25. McNicholas C, Madden T. Meeting the Contraceptive Needs of a Community: Increasing Access to Long-Acting Reversible Contraception. *MO Med*. 2017 May-Jun; 114(3):163-167. PMID:30228573

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27. McNicholas C, Klugman J, Zhao Q, Peipert J. Condom Use and Incident Sexually Transmitted Infection after Initiation of Long-Acting Reversible Contraception. *Am J of Obstet and Gynecol.* 2017 Dec;217(6):672.e1-672.e6. PMID: 28919400

28. Zigler RE, Madden T, Ashby C, Wan L, McNicholas C. Ulipristal Acetate for Unscheduled Bleeding in Etonogestrel Implant Users: A Randomized Controlled Trial. *Obstet Gynecol*. 2018 Oct;132(4):888-894. PMID: 30130151

Non-Peer Reviewed Invited Publications:

1. McNicholas C. Rev. of Recent advances in obstetrics and gynecology, *Royal Society of Medicine Press*, 2008.

2. McNicholas C, Levy B. The original minimally invasive hysterectomy; no hospitalization required. *Expert Rev. of Obstet and Gynecol*. 8(2), 1-3. 2013

Chapters:

1. Gross G, McNicholas C. Rev. of Shoulder dystocia and birth injury: prevention and treatment, by James A. O'Leary 3rd Ed
2. McNicholas C, Peipert JP. Pelvic inflammatory disease. *Practical Pediatric and Adolescent Gynecology*. Oxford. Wiley-Blackwell. ISBN: 978-0-470-67387-4.
3. McNicholas C, Madden T*., 2015 Contraceptive counseling for obese women.* In E. Jungheim (Ed) Obesity and Fertility. Springer, New York. ISBN 978-1-4939-2611-4

Abstracts:

1. McNicholas C, Maddipati R, Secura G, Peipert J. Use of the contraceptive implant beyond the FDA-approved duration. Poster Presentation. North American Forum on Family Planning. Miami, FL October 2014.

2. McNicholas C, Swor E, Peipert J, Secura G. Serum etonogestrel levels in women using the contraceptive implant beyond the FDA-approved duration*. Oral Presentation. North American Forum on Family Planning*. Seattle, WA October 2013.

3. McNicholas C, Zhao Q, Peipert J, Secura G. Condom use and incident sexually transmitted infection after initiation of long-acting reversible contraception. *Oral Presentation. 40th Annual Scientific Meeting of the Infectious Diseases Society for Obstetrics and Gynecology*. Sante Fe, NM Aug 2013.

4. McNicholas C, Madden T, Zhao Q, Secura G, Allsworth JE, Peipert JP. Cervical lidocaine for IUD insertional pain: a randomized controlled trial. *Poster Presentation*. *North American Forum on Family Planning*. Denver, CO. October 2012.

5. McNicholas C, Maddipati R, Allsworth J, Madden T, Peipert J, Secura G. Baseline sexually transmitted infection prevalence in a low risk urban population. *Oral Presentation*. *39th Annual Scientific Meeting of the Infectious Diseases Society for Obstetrics and Gynecology.* Whistler, BC Aug 2012.

6. McNicholas C, Maddipati R, Allsworth J, Madden T, Peipert J, Secura G. An epidemiologic comparison of *Chlamydia Trachomatis* and *Trichomonas Vaginalis*: Information from the

Contraceptive CHOICE Project. *Poster Presentation*, *39th Annual Scientific Meeting of the Infectious Diseases Society for Obstetrics and Gynecology*. Whistler, BC Aug 2012.

7. McNicholas C, Madden T, Zhao Q, Secura G, Allsworth J, Peipert J. Cervical lidocaine for IUD insertional pain: a randomized control trial. *Oral Presentation. St. Louis Gynecologic Society*. April 2012.

8. Madden T, McNicholas CP, Secura GM, Allsworth JE, Zhao Q, Peipert JF. Rates of Expulsion and Continuation of Intrauterine Contraception at 12 months in Nulliparous and Adolescent Women. *Oral Presentation, Association of Reproductive Health Care Providers.* Sept 2010.

9. McNicholas CP, Madden T, Secura GM, Allsworth JE, Zhao Q, Peipert JF. Rates of Expulsion and Continuation of Intrauterine Contraception at 12 months in Nulliparous and Adolescent Women. *Oral Presentation, Rothman Resident Research Day.* April 2010.

10. McNicholas C. Acute Myelogenous Leukemia (AML) in an HIV Patient. A Diagnosis of exclusion and the implications of Cytogenetics. *Publication and Poster presentation Seaton Hall Research Colloquium.* May 2006.

EXHIBIT C

IN THE
CIRCUIT COURT OF ST. LOUIS, MISSOURI
22nd JUDICIAL CIRCUIT

REPRODUCTIVE HEALTH SERVICES OF PLANNED PARENTHOOD OF THE ST. LOUIS REGION Petitioner, v. MICHAEL L. PARSON, et al. Respondents.	Case No. 1922-CC02395

PETITIONER'S SUGGESTIONS IN SUPPORT OF MOTION FOR TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION

Petitioner Reproductive Health Services of Planned Parenthood of the St. Louis Region ("Planned Parenthood") seeks to enjoin Respondents Missouri Department of Health and Senior Services ("DHSS") and its Director, Randall Williams, from continuing to abuse its regulatory authority by refusing to grant Petitioner's application for license renewal and from allowing Petitioner's license to expire. In support of its motion, Planned Parenthood submits these suggestions demonstrating that a temporary restraining order and preliminary injunction should issue.

I. INTRODUCTION & FACTUAL BACKGROUND

Respondents are seeking to do by abuse of the licensing process what they may not do overtly—deprive the women of Missouri of their constitutional right to access safe and legal abortion services. Indeed, only four days ago, Governor Parson signed a blatantly unconstitutional bill criminalizing all previability abortions from eight weeks of pregnancy, with no exceptions for

rape or incest. Due to its clear unconstitutionality, the abortion ban (which does not take effect until late August) will likely face substantial legal hurdles. In the meantime, Respondents are abusing their administrative powers and violating their licensing obligations in an effort to deprive women of their constitutional right to access abortions at the last remaining abortion clinic in the state.

For over twenty years, Planned Parenthood has provided safe, legal abortions in St. Louis. Verified Petition for Declaratory and Injunctive Relief ("Pet.") ¶ 1. And for decades the State has sought to shut down abortion access by imposing a series of onerous and medically irrelevant restrictions on doctors and clinics providing abortions. Pet. ¶¶ 2–3, 20–48. In recent years, Respondents have intensified these efforts by abusing their administrative authority, harassing providers and their patients with changing and ever-stricter interpretations of these restrictions. *See, e.g.*, Pet. ¶¶ 37–48, 56–85.

As a result of these sustained efforts, two high-quality Missouri health centers have been forced to stop providing abortions over the last few years, and two others have been unable to obtain licenses, leaving Planned Parenthood's St. Louis health center as the *sole* remaining generally available abortion provider in the state of Missouri. Pet. ¶ 3. Not content with reducing abortion access in Missouri to an "ALL-TIME low," as Governor Parson recently tweeted, Respondents now seek to reduce it to zero. Pet. ¶ 5.

Planned Parenthood's license to provide abortions expires this Friday, May 31, 2019. This past March, DHSS conducted what appeared to be a routine inspection prior to a license renewal, followed by citations for relatively routine deficiencies (*e.g.*, not having all staff participate in a fire drill). Pet. ¶¶ 56–59; Pet. Ex. A. This inspection, however, rapidly spiraled into a far-reaching "investigation" supposedly based on a patient complaint—the full scope and subject matter of

which DHSS still refuses to reveal and which (as explained below) DHSS refuses to complete in a reasonable or lawful manner despite that Planned Parenthood has bent over backwards to fully cooperate. This "investigation" provides DHSS with pretext for refusing to act on and grant Petitioner's license renewal application, ensuring that without intervention by this Court, on June 1, 2019 Missouri will be the first state in the nation without access to abortion.

To the degree DHSS has told Planned Parenthood what the issues are, Planned Parenthood has been able to resolve most or all through the regulatory statement of deficiency/plan of correction process that is supposed to apply in the relicensing context. *See* § 197.293, RSMo. And it has managed to do so despite DHSS's shifting interpretations of its own regulations and imposition of requirements that interfere with good patient care, submitting multiple Plans of Correction to address DHSS's claimed concerns. For example, DHSS cited Planned Parenthood for providing a pelvic exam just before a surgical abortion instead of at least 72 hours prior[1]—despite that, the relevant regulation (19 CSR 30-30.060(2)(D)) does not state which day the pelvic exam must be done and that providing the pelvic exam on a previous day is medically unnecessary, invasive, and traumatic for some patients. Presumably for this reason, DHSS had never previously taken issue with Planned Parenthood's medically sound practices. But because DHSS refuses to resolve the deficiency in any other way, Planned Parenthood has submitted an amended plan of correction agreeing to start providing pelvic exams at least 72 hours in advance and DHSS has accepted this as resolving the "deficiency." Pet. ¶ 76; Pet. Ex. H.

And similarly, Respondents cited Planned Parenthood for violating DHSS's shifting interpretation of their obligations under Missouri's abortion-specific informed consent statute,

[1] As discussed below, Missouri statute requires patients to receive certain state-mandated information at least 72 hours before obtaining an abortion. § 188.027.6, RSMo.

which requires the physician who provides state-mandated information 72 hours prior to the abortion be the same physician who performs the abortion. § 188.027.6, RSMo.; Pet. ¶¶ 56, 59; Pet. Ex. A. As set forth more fully in the Petition, Pet. ¶¶ 77–79, DHSS had previously agreed (as had a Missouri Circuit Court) that in the context of a fellow or resident providing care under the supervision of an attending physician, this obligation was met if *either* physician provided the state-mandated information. DHSS now changed its interpretation, appearing to take the position that the attending physician—despite being responsible for the care provided by their trainee—can only provide the state-mandated information if they are physically involved in the procedure. Pet. ¶ 59, 77; Pet. Exs. A, I. This shift in position runs contrary to how residency and fellowship training are understood to work throughout the medical education system. Pet. ¶ 78. Nevertheless, in the interest of maintaining its license and being able to continue providing abortions to patients who have nowhere else in Missouri to go to obtain this care, Planned Parenthood has submitted a second amended plan of corrections resolving this issue by agreeing that if it continues providing training opportunities to fellows and/or residents it will ensure that the fellow or resident provides the state-mandated information at least 72 hours prior to the abortion, in the presence of the attending physician. Pet. ¶ 81; Pet. Ex. J.

Even though Planned Parenthood acceded to DHSS's shifting and unreasonable demands, Planned Parenthood and DHSS remain at an impasse. This is because DHSS is requiring that Planned Parenthood produce for interviews six physicians who are not Planned Parenthood employees and who have declined to be interviewed, including residents at Washington University School of Medicine in St. Louis and a fellow at its affiliated hospital being trained in the full range

of reproductive health care at Planned Parenthood's St. Louis health center.[2] DHSS has refused to provide the scope or topics to be covered during questioning, but has made clear that interviews may result in referrals for further licensing or even criminal inquiries. Pet. ¶¶ 69, 73. As a result of their well-founded fear of harassment, these young doctors have all, through outside counsel, declined to sit for interviews. However, the two most senior physicians DHSS requested to interview—Dr. Colleen McNicholas and Dr. David Eisenberg—have agreed to be interviewed. Together with a third physician DHSS has not requested to interview, these physicians supervise all care provided at the St. Louis health center and are the attending physicians for all care provided by fellows and residents, and thus any questions DHSS has could be explored with them.[3] Far from attempting to complete its investigation in a reasonable manner, until just days ago DHSS refused to even meet with these senior physicians, taking the position that the interviews must be done in a specified order (which required a Washington University fellow to be interviewed first). Pet. ¶¶ 72–73, 82. On Thursday, May 23, DHSS reversed this position and agreed to interview the senior doctors, and these interviews are scheduled to take place on Tuesday, May 28. Pet. ¶¶ 77, 82; Pet. Ex. I.

DHHS nevertheless continues to maintain that its "investigation"—concerning an unknown number of unspecified "potential" deficiencies—cannot conclude and the license be renewed based on the May 28 interviews and that the remaining doctors must sit for interviews. Pet. ¶¶ 74–75, 77; Pet. Exs. G, I. Given that these young physicians, who are outside of Planned

[2] Because physicians involved in abortion care are subjected to threats and harassment, including violence, and because their names and identities are irrelevant to the substance of this litigation, Petitioner has redacted their names from the exhibits attached to the Petition.

[3] In addition to being attending physicians to the trainees and faculty members at Washington University School of Medicine, Dr. McNicholas is Planned Parenthood's incoming Chief Medical Officer and Dr. Eisenberg is its Co-Medical Director.

Parenthood's control, understandably do not want to subject themselves to boundless interrogation, DHSS has created a situation where its investigation—and therefore, the license renewal—will *never* be concluded, despite that Planned Parenthood has cooperated in every way it can, agreeing to modify its patient care to meet DHSS's shifting and baseless demands, providing patient records, making its own staff available for interviews, and working with third-party counsel to make Drs. McNicholas and Eisenberg available for interviews. Pet. ¶¶ 68, 70, 72–75, 77; Pet. Ex. F.

It is important to note that there is no doubt that DHSS is authorized to prevent a licensed abortion provider from providing services if a deficiency presents an immediate and serious threat to patients' health and safety. In this circumstance, DHSS may immediately restrict access to the affected service until the facility has implemented a DHSS-approved plan of correction. § 197.293.2, RSMo. DHSS does not claim any such threat here, and could not credibly do so. What DHSS *cannot* do is hold Planned Parenthood's routine license renewal hostage to the outcome of an abusive investigation DHSS has made it impossible to complete.

As detailed below, DHSS has promulgated invalid regulations (upon which they rely in refusing to act on Planned Parenthood's license renewal); are engaging in an investigation whose scope and methods are arbitrary, capricious, unreasonable, and unlawful and violate Missouri constitutional prohibition on unreasonable searches; and have engaged in arbitrary, capricious and non-reviewable decision-making. Through all of these actions, Respondents seek to place an unconstitutional burden on Missouri women's ability to access abortion services. Respondents' weaponization of the administrative state to reach nakedly political ends is unlawful and unconstitutional, aimed as it is at making Missouri the first state in the nation where patients have no in-state option to obtain an abortion.

II. ARGUMENT

PETITIONER IS ENTITLED TO A TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION

When considering a motion for a temporary injunction, a trial court "weigh[s] the movant's probability of success on the merits, the threat of irreparable harm to the movant absent the injunction, the balance between this harm and the injury that the injunction's issuance would inflict on other interested parties, and the public interest." *State ex rel. Dir. of Revenue, State of Mo. v. Gabbert*, 925 S.W.2d 838, 839 (Mo. 1996) (internal quotation marks omitted); *see also Minana v. Monroe*, 467 S.W.3d 901, 907 (Mo. Ct. App. 2015). Though a "petitioner must make some showing of probability of success on the merits before a preliminary injunction will be issued," *Gabbert*, 925 S.W.2d at 839, the "inquiry should not be rigid or 'wooden' and cannot be accomplished with 'mathematical precision,'" *id*. at 840 (quoting *Dataphase Systems, Inc. v. C L Systems, Inc*., 640 F.2d 109, 113 (8th Cir. 1981) (en banc)). "The equitable nature of the proceeding mandates that the court's approach be flexible enough to encompass the particular circumstances of each case." *Id*. (quoting *Dataphase*, 640 F.2d at 113).

A. PETITIONER IS LIKELY TO SUCCEED ON THE MERITS

Under the Declaratory Judgment Act, §§ 527.010–.130, RSMo., and the Administrative Procedure Act, §§ 536.010–.328, RSMo., this Court has the "power to declare rights, status, and other legal relations whether or not further relief is or could be claimed," § 527.010 RSMo., and such power "extend[s] to declaratory judgments respecting the validity of rules, or of threatened applications thereof," § 536.050.1, RSMo. Courts administer the declaratory judgment statutes to "terminate the controversy or remove an uncertainty." *Mo. Ass'n of Nurse Anesthetists, Inc. v. State Bd. of Registration for Healing Arts*, 343 S.W.3d 348, 353 (Mo. 2011) (internal quotation marks omitted); Rule 87.02(d). Without a declaration that DHSS's actions are invalid and

unlawful, DHSS will, as it has threatened to, refuse to grant Planned Parenthood's license renewal application, fulfilling its goal of shutting down the last provider in the state where patients can obtain an abortion.

Section 536.150, RSMo. authorizes judicial review of an agency decision that "determin[es] the legal rights, duties or privileges of any person" where such decision "is not subject to administrative review" and "there is no other provision for judicial inquiry into or review of such decision." § 536.150.1, RSMo. In such a proceeding, the court's review of the agency decision is *de novo*, and the court may determine the facts and decide whether, in view of those facts, the agency decision is "unconstitutional, unlawful, unreasonable, arbitrary, or capricious or involves an abuse of discretion." § 536.150.1, RSMo.; *Mo. Nat'l Educ. Ass'n v. Mo, State Bd. of Educ.*, 34 S.W.3d 266, 274 (Mo. Ct. App. 2000); *Ard v. Shannon County Com'n*, 424 S.W.3d 468, 475 (Mo. Ct. App. 2014) (where no hearing required before Commission acted and no other means for review provided, petition for judicial review is an appropriate action under section 536.150, RSMo.).

Planned Parenthood is likely to succeed on the merits of its claims because DHSS has promulgated and interpreted its regulations in a way that is contrary to Missouri statutes, to the regulations themselves, and to Missourians' constitutional rights. An agency's regulation is invalid where there is an absence of statutory authority for the rule, the rule is in conflict with state law, or the rule is "so arbitrary and capricious as to create such substantial inequity as to be unreasonably burdensome on persons affected." § 536.014, RSMo.; *see Union Elec. Co. v. Dir. of Revenue*, 425 S.W.3d 118, 124–25 (Mo. 2014) ("[T]he rules or regulations of a state agency are invalid if they are beyond the scope of authority conferred upon the agency, or if they attempt to expand or modify statutes." (citation and internal quotation marks omitted)); *see also Parmley v.*

Mo. Dental Bd., 719 S.W.2d 745, 755 (Mo. 1986) ("When there is a direct conflict or inconsistency between a statute and a regulation, the statute which represents the true legislative intent must necessarily prevail.").

Planned Parenthood is further likely to succeed on the merits of its claims because DHSS's conduct with respect to inspecting and investigating Planned Parenthood in connection with its licensing renewal application is arbitrary, capricious, unlawful, unconstitutional and outside the scope of its agency authority. DHSS has continually changed its positions and interpretations of relevant regulations in an effort to prevent Planned Parenthood's continued operation, and now seeks to stonewall its license renewal application by conducting an investigation of indefinite length and scope. Not only is such conduct well outside DHSS's statutory authority, DHSS is construing its investigation so broadly as to constitute an unconstitutional warrantless administrative search. These actions combine to violate Missouri women's right to access to abortion by shutting down the operations of the last abortion clinic in the state.

1. The Regulation on Which DHSS Relies Is Likely Invalid and Conflicts with the Relevant Statute

DHSS has made clear that it will not grant Planned Parenthood's application for license renewal while its "investigation" remains pending, on the grounds that 19 CSR 30-30.050(2)(I) ("Nonrenewal Regulation") purportedly prevents the state from renewing a license while any investigation is ongoing, since the existence of an investigation prevents it from "determin[ing] that the facility is in compliance with all statutory and regulatory requirements." Pet. ¶¶ 66–67, 74–75, 77; Pet. Exs. E, G, I.

The Nonrenewal Regulation is invalid because it conflicts with the Licensing Law (§§ 197.200–197.240, RSMo.), which states that, upon receipt of a renewal application, the State "*shall* . . . renew the license" unless "the department finds that there has been a substantial failure

to comply with the requirements of section 197.200 to 197.240." §§ 197.220; 197.215.2, RSMo. (emphasis added). In order to deny a license even for substantial noncompliance, however, the State must engage in a series of progressive steps: first it must notify the facility of deficiencies in meeting regulatory standards and provide the facility with an opportunity to correct such deficiencies; should that fail to correct the problem the State may restrict new outpatient entrants; should the problem persist, the State may then suspend the facility's operations. §§ 197.293.1(1)–(5), RSMo. *Only then* may the State deny a facility's license renewal application. *See Planned Parenthood of Kansas v. Lyskowski*, No. 2:15-CV-04273-NKL, 2016 WL 2745873, at *7 (W.D. Mo. May 11, 2016) (preliminarily enjoining DHSS attempt to revoke Planned Parenthood license, because "[t]his statute contemplates that when DHSS identifies deficiencies in an ASC the ASC will be given an opportunity to submit a plan of correction and time to implement this plan . . . . If the initial plan of correction is not successful in correcting the deficiency, the statute sets out steps DHSS may take, increasing in severity as corrective action fails to solve the deficiency."). In fact, the Licensing Law includes an exception to the progressive discipline policies where a deficiency "presents an immediate and serious threat to the patients' health and safety"—an exception that would be superfluous if Respondents had the power to simply refuse to accept a license renewal application whenever they deemed a facility out of compliance without following the required corrective steps. § 197.293.2, RSMo.

The Nonrenewal Regulation, in stark contrast, prohibits the State from renewing an abortion facility's license "until the department has inspected the facility and *determined that it is in compliance with all requirements of applicable regulations and statutes*." 19 CSR 30-30.050(2)(I) (emphasis added). The Nonrenewal Regulation (at least as DHSS interprets it) thus

inverts the process outlined in the Licensing Law, requiring the State to force a licensed abortion facility to close unless and until the State makes an affirmative finding of complete compliance.

This inversion is completely at odds with the Licensing Law's clear requirements that a license "shall" be renewed and may not be denied unless there has been a finding of "substantial failure to comply."[4] §§ 197.220; 197.215, RSMo. The requirement to renew the license is thus mandatory in the absence of a finding of substantial noncompliance after the aforementioned progressive steps have been taken by the State. *See State ex rel. Wolfe v. Mo. Dental Bd.*, 289 Mo. 520, 233 S.W. 390, 394 (1921) (where licensing law provides that license "shall" be renewed upon payment of fee, there is no discretion; the renewed license must issue if the statutory prerequisites are met); *see also State ex rel. Am. Inst. of Mktg. Sys., Inc. v. Mo. Real Estate Comm'n*, 461 S.W.2d 902, 906–07 (Mo. App. 1970) (absent "established reasons," and not mere allegations, to refuse a license, the real estate commission was required to renew the license); *cf. State ex rel. Robison v. Lindley-Myers*, 551 S.W.3d 468, 474 (Mo. 2018) (bail bond agent licensing statute expressly authorized department to "refuse to issue or renew any license").

Not only does the Nonrenewal Regulation conflict with the text of the statute, it conflicts with its purpose. A regulation that is "in conflict with the sense and meaning of [a] statute" is

[4] Notably the Licensing Law draws no distinction in how the State should enforce the licensing statutes and regulations for abortion facilities and for other types of ASCs. *See* § 197.293.1, RSMo. ("the department of health and senior services shall use the following standards for enforcing hospital, ambulatory surgical center, and abortion facility licensure regulations"). Nevertheless, the State has adopted different license renewal regulations for abortion facilities. For other ASCs, which perform procedures far more risky than abortion, the State's regulation provides that a license will be renewed if the ASC is found to be "in substantial compliance with the requirements" of the ASC regulations. 19 CSR 30-30.010(2)(D); *cf.* § 197.220, RSMo. (providing that the State may deny an ASC or abortion facility license only where it finds "substantial failure" to comply). This is not true for abortion facilities, which must demonstrate "compliance with *all* requirements of applicable regulations and statutes." 19 CSR 30-30.050(2)(I) (emphasis added).

invalid. *State ex rel. River Corp. v. State Tax Comm'n*, 492 S.W.2d 821, 825 (Mo. 1973), *overruled on other grounds by Int'l Travel Advisors, Inc. v. State Tax Comm'n*, 567 S.W.2d 650 (Mo. 1978); *see also Osage Outdoor Advert., Inc. v. State Highway Comm'n of Mo.*, 624 S.W.2d 535, 537 (Mo. Ct. App. 1981) (invalidating regulation not contemplated by statutory scheme). The Licensing Law presumes compliance in the absence of a finding of noncompliance, and it requires the State to notify the licensed entity of any deficiency and afford it an opportunity to correct the deficiency before the State can impose a series of increasingly serious corrective measures, culminating in license denial only if those measures fail. *See* § 197.293.1, RSMo. The Nonrenewal Regulation presumes the opposite: noncompliance until the State makes an affirmative determination of perfect compliance.[5] As a result, the regulation (at least as DHSS construes it) mandates a license refusal or denial even where, as here, the State has made no findings of substantial noncompliance. Consequently, the Nonrenewal Regulation conflicts with the basic and "fundamental requirement of due process" embodied in the Licensing Law. *Jamison v. State, Dep't of Soc. Servs., Div. of Family Servs.*, 218 S.W.3d 399, 405 (Mo. 2007) (citation and internal quotation marks omitted).

[5] Indeed, the Nonrenewal Regulation could appear to require DHSS to affirmatively show compliance with statutes and regulations entirely unrelated to DHSS's mission or to patient care or safety, as the regulation's mandate that DHSS "determine [a facility] is in compliance with *all* requirements of applicable regulations and statutes" could apply to virtually anything, including, say, tax regulations.

2. The Scope and Manner of DHSS's Investigation Is Likely Arbitrary, Capricious, Unreasonable, and Outside the Scope of the Agency's Authority

(a) DHSS Is Conditioning the Conclusion of Its Investigation—and Thus Acceptance of Petitioner's License Renewal Application—on the Impossible

Here, as detailed above and in the Petition, DHSS has decided to condition the completion of its investigation (and thus has conditioned action on Petitioner's license renewal application) on Petitioner producing third parties for questioning,[6] which Petitioners cannot do.[7]

Petitioner has done what is in its power—offered for interviews its incoming Chief Medical Officer and current Co-Medical Director, both of whom are faculty members at Washington University School of Medicine (and not Planned Parenthood employees), and who supervise the more junior physicians DHSS seeks to interview. Planned Parenthood has also provided its own staff for interviews, as well as providing the patient records and other documentation DHSS has requested.

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[6] Moreover, Respondents lack the statutory authority to compel Planned Parenthood to produce testimony from third parties. While Section 197.230.1, RSMo grants general authority to the State to "make, or cause to be made, such inspections and investigations as it deems necessary," it has not given Respondents the power to compel witness testimony. Had the General Assembly intended to confer such authority, it would have done so by statute. *See Bodenhausen v. Mo. Bd. of Registration for Healing Arts*, 900 S.W.2d 621, 622 (Mo. 1995) (state agencies "possess only those powers expressly conferred or necessarily implied by statute"); *cf. Angoff v. M & M Mgmt. Corp.*, 897 S.W.2d 649, 653 (Mo. Ct. App. 1995). Where the Legislature means to provide agencies with such power, it does so clearly and unequivocally. *See, e.g.,* §§ 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, RSMo. (board of nursing, same); §§ 340.264.2(4)(*l*)–(m) and 340.280, RSMo. (veterinary medical board, same). Because the "legislature has elsewhere been fully capable of clearly articulating" this authority, it cannot be implied that the State possesses the power to compel interviews absent statutory language. *State v. Reprod. Health Servs. of Planned Parenthood of St. Louis Region, Inc.*, 97 S.W.3d 54, 61 (Mo. Ct. App. 2002); *see also Wolff Shoe Co. v. Dir. of Revenue,* 762 S.W.2d 29, 32 (Mo. 1988) ("rule of statutory construction that 'the express mention of one thing implies the exclusion of another'").

[7] The agency has made clear that this decision is final. Pet. ¶ 77; Pet. Ex. I. This decision, moreover, is not subject to any administrative hearing, necessitating that Petitioner seek judicial review before this Court. § 536.150, RSMo.

DHSS's insistence on holding Planned Parenthood's license renewal hostage to the outcome of its abusive investigation when DHSS has access to information that is more than adequate for any legitimate investigation is unreasonable, arbitrary, and capricious under Missouri law, including because it disregards the reality that Planned Parenthood cannot compel individuals who are not in its employ to sit for interviews. *See Ard*, 424 S.W.3d at 480 ("'Arbitrary and capricious' has been defined as 'willful and unreasoning action, without consideration of and in disregard of the facts and circumstances.'" (quoting *Beverly Enterprises-Missouri Inc. v. Dept. of Social Services, Div. of Medical Services*, 349 S.W.3d 337, 345 (Mo. Ct. App. 2008))); *Beverly Enterprises-Missouri*, 349 S.W.3d at 345 ("[A]n agency that completely fails to consider an important aspect or factor of the issue before it may be found to have acted arbitrarily and capriciously." (quoting *Barry Serv. Agency Co. v. Manning*, 891 S.W.2d 882, 892 (Mo. Ct. App. 1995))).

As the Supreme Court of Missouri has recognized, there is a "need for judicial resolution when plaintiffs are faced with the dilemma physicians now face: comply or 'take a potentially more costly alternative of risking serious penalties by continuing and waiting for the ax of Agency prosecution to fall.'" *Mo. Ass'n of Nurse Anesthetists,* 343 S.W.3d at 355. Planned Parenthood is currently faced with an even more intractable dilemma—produce witnesses for questioning over which it has no control, or count down the days until its license expires while its renewal application languishes at DHSS.

(b) DHSS's Demand for Questioning Itself Is Arbitrary, Capricious, Unlawful, and Outside the Scope of Agency Authority

As detailed above and in the Petition, DHSS has refused to provide the full scope or bases of its investigation and, further, refused to reveal even the basic topics on which it seeks to question the junior physicians, or indeed any of the individuals from whom it seeks testimony.

Neither Planned Parenthood nor the individuals DHSS seeks to question have been given notice of the grounds or scope of any such questioning, nor do they have any opportunity to seek precompliance review, except through this Court.

Moreover, as noted, DHSS has all the information it needs to conduct any legitimate inquiry, including patient files and medical records, and interviews with Planned Parenthood staff as well as Planned Parenthood's incoming Chief Medical Officer and current Co-Medical Director, who in turn supervise the junior physicians (including residents and a fellow) DHSS seeks to interview.

The indefinite and wide-ranging scope of the interviews DHSS seeks, as well as the methods by which it seeks to conduct its investigation, make the investigation itself arbitrary, capricious, and outside the agency's legitimate authority. Indeed, DHSS's opacity and the scope of its proposed questioning of young medical fellows and residents—particularly where DHSS has made clear that the results of such questioning may lead to further licensing or criminal inquiries—is so limitless and indefinite in scope as to likely violate the Missouri Constitution's prohibition on unreasonable searches.[8] *See Zorich v. St. Louis County*, No. 4:17-CV-1522 PLC, 2018 WL 6621525 at *16 (E.D. Mo. December 18, 2018) ("the scope and execution of an administrative inspection must be reasonable in order to be constitutional" (internal quotations omitted)); *cf. Club Retro, L.L.C. v. Hilston*, 568 F.3d 181, 195 n.5 (5th Cir. 2009) (holding that owners and employees of a nightclub could raise the unconstitutionality of a search of their patrons where the "allegations [were] relevant to . . . whether defendants' conduct exceeded the scope of

[8] The Missouri Constitution's prohibition on unreasonable searches is at least coextensive with the federal constitution and, indeed, the Missouri Constitution "may be construed to provide more expansive protections than comparable federal constitutional provisions." *State v. Rushing*, 935 S.W.2d 30, 34 (Mo. 1996); *see Ashworth v. City of Moberly*, 53 S.W.3d 564, 579 (Mo. Ct. App. 2001).

a proper administrative search."); *Bruce v. Beary*, 498 F.3d 1232, 1244 n.22 (11th Cir. 2007) (holding that the constitutionality of a search of business's employees "is relevant to our determination of whether their conduct exceeded the scope of a proper administrative inspection" of the business itself).

For an administrative search or inspection to be constitutional, and thus even conceivably within the scope of legitimate agency authority, the subject of the search must be afforded an opportunity to obtain precompliance review before a neutral decision-maker, without which there exists "an intolerable risk that searches authorized by it will exceed statutory limits, or be used as a pretext to harass." *City of L. A., Calif. v. Patel*, 135 S. Ct. 2443, 2452–53 (2015).[9] Here, there is no neutral arbiter to which Planned Parenthood or the subjects of DHSS's demands for questioning may turn, other than this Court, to contest the scope of the inquiry or the demands for testimony, or to compel DHSS to reveal the scope or basis of its proposed questioning.

Indeed, the "intolerable risk" that DHSS's demand for information is a "pretext to harass" has come to pass, which is precisely why the trainee physicians have declined, through independent counsel, to be questioned. *See id.* DHSS refuses to provide even the *topics* on which it seeks to interview these individuals (Pet. ¶¶ 69, 82, 98, 100) claiming that it is investigating "a

[9] To pass constitutional muster, such administrative search must also be conducted pursuant to a statutory scheme where there are "special needs . . . that make the warrant and probable-cause requirement impracticable." *Patel*, 135 S. Ct. at 2452. No such "special needs" are present in the statutory scheme authorizing DHSS to conduct investigations. While administrative searches or certain highly regulated industries are subject to a more relaxed constitutional standard, Petitioner here is not in a highly regulated industry. *See Planned Parenthood of Sw. & Cent. Fla v. Philip*, 194 F. Supp. 3d 1213, 1221 (N.D. Fla. 2016), citing *Patel*, 135 S. Ct. 2443; *Tuscon Woman's Clinic v. Eden*, 379 F.3d 531 (9th Cir. 2004); *Margaret S. v. Edwards*, 488 F.Supp.181, 216 (E.D. La. 1980). Even were this a highly regulated industry, DHSS's investigation does not meet even that more relaxed standard, which requires that the authorizing statute "limit the discretion of the inspecting officers," and only authorize warrantless inspections that are "carefully limited in time, place, and scope" and which are "necessary to further the regulatory scheme." *New York v. Burger*, 482 U.S. 691, 702 (1987); *see also Matter of Hein*, 584 S.W.2d 631, 632 (Mo. Ct. App. 1979).

large number of potential deficient practices" (Pet. ¶¶ 77, 82; Pet. Ex. I) while at the same time making clear that the results of any interviews may well result in referrals for criminal or licensing inquiries (Pet. ¶¶ 69, 73). It seems DHSS is using the license renewal process for its own fishing expedition to try to end abortion access, or worse to punish young doctors at the beginning of their careers for having provided constitutionally protected abortion services.

Administrative searches "cannot be used as a pretext for what is, in reality, a purely criminal investigation" and such searches "should be considered a pretext, and thus deemed impermissible, if the inspection was performed solely to gather evidence of criminal activity." *Manning v. Mayes*, No. 5:09CV-001820-JHM, 2010 WL 2858455 at *3 (W.D. Ky. July 19, 2010); s*ee Riggs v. Gibbs*, No. 14–0676–CV–W–FJG, 2017 WL 4391778 at * 11 (W.D. Mo. September 29, 2017) ("An administrative search which is a mere subterfuge for a criminal investigation violates the Fourth Amendment.").

Thus, to the extent that DHSS hopes to compel testimony from third parties, not to further inquiry into some specific concern, but rather in the hopes of stumbling incidentally upon some indication of a statutory violation or other pretext to harass Petitioner or physicians engaged in the provision of abortion services in Missouri, its demands for interviews are entirely unlawful, arbitrary, capricious, unreasonable, unconstitutional, and beyond the scope of legitimate agency authority.

(c) DHSS's Rationales for Its Investigation, to the Extent DHSS Has Revealed Them, Are Shifting, Arbitrary, Capricious, and Unreasonable

Throughout the course of its investigation, DHSS has continually shifted the grounds on which it seeks to find Planned Parenthood deficient and upon which it purports to base its demand to interview third parties. As noted above, DHSS has thus far refused to reveal what, exactly, it seeks to investigate or determine through its interview requests. Rather, DHSS has simply insisted

that its "complaint investigation has identified a large number of potential deficient practices," without further elaboration. Pet. ¶ 77, 82; Pet. Ex. I. This refusal to provide even the rough outlines of the scope of the investigation in question is arbitrary and capricious (as well as unconstitutional).

However, where DHSS has provided grounds, such grounds have themselves been arbitrary and capricious and, no matter how hard Petitioner tries to comply with each and every unreasonable demand, DHSS nevertheless insists on holding Planned Parenthood's license renewal application hostage until Planned Parenthood produces third parties for questioning, which Petitioner has no power to do.

For example, at the outset of its investigation, as detailed in the Petition, DHSS cited Planned Parenthood for providing a pelvic exam just before the patient obtains an abortion, rather than three days beforehand, despite that the relevant regulation includes no such requirement and that providing a pelvic exam days before the procedure is medically unnecessary and invasive. Pet. ¶¶ 56, 58, 76(a); Pet. Ex. A. In fact, presumably for this reason, though DHSS was previously aware that this has been Planned Parenthood's practice, it had never previously taken issue with it. Pet. ¶¶ 58, 76(a). Despite this changing, arbitrary, and unreasonable interpretation of Missouri regulations, and despite that it is bad for patient care, Planned Parenthood reluctantly agreed to comply. Pet. ¶¶ 76(a), 77; Pet. Ex. H. While DHSS accepted this portion of Planned Parenthood's plan of correction, it continued to insist that Petitioner produce third parties for interviews before it would conclude its investigation and accept Planned Parenthood's license renewal application. Pet. ¶¶ 77, 82; Pet. Ex. I.

Similarly, despite that DHSS previously endorsed Planned Parenthood's practices, DHSS now appears to allege that having the attending physician supervising a resident or fellow provide

state-mandated information to a patient 72 hours prior to an abortion does not comply with Missouri law.[10] This interpretation is contrary to DHSS's previous position, as well as the accepted understanding in the larger medical community of the relationship between attending physicians and the fellows and residents they supervise, and simply constitutes another example of DHSS moving the ball in order to prolong its investigation and keep Planned Parenthood's license renewal application in limbo. Despite the arbitrary and unreasonable nature of DHSS's interpretation, Planned Parenthood has agreed to comply with DHSS's this new, more onerous interpretation of Missouri law as well. *See* Ex. J to Pet. This too is not enough; DHSS continues to insist on interviewing third parties outside of Planned Parenthood's control as a condition of accepting Planned Parenthood's routine license renewal application.

Thus, not only are the methods of DHSS's investigation unlawful, in making unreasonable demands that Petitioner has no power to meet, but the bases for such demands, to the extent DHSS has revealed them, have also been arbitrary, capricious, unreasonable, and unlawful, further evidencing the degree to which DHSS's actions exceed the scope of its legitimate authority.

[10] In previous litigation DHSS stated that, where "a medical resident [] works with a teaching physician to perform an abortion," and thus "there are two or more physicians who are substantially involved in performing or inducing an abortion, any one of those physicians may satisfy section 188.027.6 by providing informed consent." Defendants' Suggestions in Opposition to Plaintiffs' Motion for Temporary Restraining Order at 22, Circuit Court of Jackson County, Missouri, *Comprehensive Health of Planned Parenthood Great Plains v. Hawley*, Case No. 1716-CV24109, Circuit Court of Jackson County, Missouri, (Oct. 16, 2017). Thus, DHSS had previously made clear that for purposes of section 188.027.6, an attending physician who supervises a resident (or a fellow, presumably) in providing an abortion is sufficiently involved to be able to provide the state-mandated information required by section 188.027.6, RSMo.—a position it has now reversed. *See also* Judgement/Order Decision at 6, *Comprehensive Health of Planned Parenthood Great Plains v. Hawley*, Case No. 1716-CV24109, Circuit Court of Jackson County, Missouri, (Oct. 23, 2017) (noting that Respondents' position is a "reasonable interpretation" of the provision and that, "if [Respondents'] interpretation expansion is correct, it would also follow that when multiple doctors are involved in the continuum of care before, during, and after a procedure that any one of those physicians could provide the required information").

3. Respondents' Actions Likely Violate Petitioner's Patients' Due Process Rights Under the Missouri Constitution

DHSS's abuse of its licensing authority to hold Planned Parenthood's routine license renewal hostage to the outcome of an investigation DHSS has made it impossible to complete unconstitutionally deprives Missouri patients of access to abortion.

Under Missouri law, "[c]laimed violations of a right to personal privacy, to procreate, and similar rights not specifically set out in the constitution but inherent in the concept of ordered liberty are analyzed under substantive due process principles." *Doe v. Phillips*, 194 S.W.3d 833, 843 (Mo. 2006) (citing inter alia *Albright v. Oliver*, 510 U.S. 266, 272 (1994) (generally applied to "matters relating to marriage, family, procreation, and the right to bodily integrity") (citing *Planned Parenthood of Se. Pennsylvania v. Casey*, 505 U.S. 833, 850 (1992))). The Missouri Supreme Court has in prior cases applied the due process clause of the Missouri Constitution "consistently with [its] interpretation under federal law." *Phillips*, 194 S.W.3d at 841; *see also Reprod. Health Servs. of Planned Parenthood of St. Louis Region v. Nixon*, 185 S.W.3d 685, 691–92 (Mo. 2006) (rejecting a challenge under the Missouri Constitution to a 24-hour mandatory delay law (citing *Casey*, 505 U.S. at 877)); *cf. Kansas City Premier Apartments, Inc. v. Mo. Real Estate Comm'n*, 344 S.W.3d 160, 169 n.4 (Mo. 2011).[11]

As the Missouri Supreme Court has recognized, "[a] state may not impose an 'undue burden' on a woman's decision to have an abortion before fetal viability." *Planned Parenthood of Kan. v. Nixon*, 220 S.W.3d 732, 743 (Mo. 2007) (citing *Casey*, 505 U.S. at 876–77)). An undue burden exists if a state "place[s] a substantial obstacle in the path of a woman seeking an abortion."

[11] This Court need not reach the issue of whether the Missouri constitution confers greater liberty and privacy rights than the Federal Constitution, because under any standard DHSS's conduct violates these protections.

Id. In *Whole Woman's Health v. Hellerstedt*, the U.S. Supreme Court recently stressed that the undue burden standard requires a court to balance "the burdens a law [or state executive action] imposes on abortion access together with the benefits those laws confer." 136 S. Ct. 2292, 2309 (2016) (citing *Casey*, 505 U.S. at 887). Moreover, in assessing the benefits as well as the burdens, a court must consider the actual evidence and not merely defer to speculation regarding the benefits of a law or state executive action. *Whole Woman's Health*, 136 S. Ct. at 2309 (it "is wrong to equate the judicial review applicable to the regulation of a constitutionally protected personal liberty with the less strict review applicable where, for example, economic legislation is at issue").

Under these principles, Respondents' actions are blatantly unconstitutional as they provide no benefit to Planned Parenthood's patients, but impose an extreme burden—eliminating access to abortion entirely in the state of Missouri. Other courts have recognized that state actions that would eliminate all or nearly all access to abortion in a state, including by shutting down its last remaining abortion-providing health center, are unconstitutional. *See Jackson Women's Health Org. v. Currier*, 760 F.3d 448, 458 (5th Cir. 2014) (finding plaintiff abortion provider likely to succeed where law would "effectively clos[e] the one abortion clinic in the state."); *see also MKB Mgmt. Corp. v. Stenehjem*, 795 F.3d 768, 772–73 (8th Cir. 2015), cert. denied, 136 S. Ct. 981 (2016) (striking down ban on abortion after 6 weeks, effectively eliminating nearly all abortion in state); *Edwards v. Beck*, 786 F.3d 1113, 1117–19 (8th Cir. 2015), *cert. denied*, 136 S. Ct. 895 (2016) (striking down a ban on abortion after twelve weeks).

As detailed above and in the Petition, Planned Parenthood has gone to pains to correct each and every cited deficiency as quickly as reasonably possible, only to be confronted with changing demands and unspecified lists of unnamed "potential" deficiencies. Pet. ¶¶ 74–74, 77, 82; Pet. Exs. G, I. Rather than engaging Planned Parenthood as required by statute, DHSS has decided to

define its investigatory powers so as to indefinitely delay any conclusion of its purported investigation and avoid accepting Planned Parenthood's application for license renewal. If DHSS believed that any of Planned Parenthood's practices constituted an immediate or serious threat to patient health or safety, DHSS would have invoked their statutory authority pursuant to § 197.293.2, RSMo. But because no such concerns exist—indeed, Planned Parenthood has been safely providing abortion services to Missouri women for over two decades—Respondents have instead chosen to engage in administrative stonewalling, creating Kafkaesque mazes of shifting requirements and demands in an attempt to accomplish administratively what they cannot constitutionally accomplish openly: deprive Missouri women of their constitutional right to abortion.

But the result of Respondent's actions will be to *harm* patient health and safety. Pet. ¶¶ 86–89. It is well-established that decreased access to safe and legal abortion increases the risks of poor health outcomes for women. For this reason, national experts and major medical and public health organizations oppose state actions that impede women's access to abortion. *See* Brief for Amici Curiae American College of Obstetricians and Gynecologists, American Medical Association, American Academy of Family Physicians, American Osteopathic Association, and American Academy of Pediatrics in Support of Petitioners at *5, *Whole Woman's Health v. Hellerstedt*, 2016 WL 74948 (U.S.2016) (medically unnecessary restrictions on access to abortion "jeopardize women's health"); Pet. ¶ 15 (citing National Academies of Sciences, Engineering, and Medicine, *The Safety and Quality of Abortion Care in the United States* 162 (March 16, 2018), (explaining that state restrictions on abortion create barriers that decrease the quality of abortion care women receive)).

Petitioner is, therefore, likely to prove that DHSS's actions here in attempting to weaponize the administrative state for politically motivated ends are fundamentally at odds with the constitutional rights of Missouri patients. These actions provide no benefit while imposing the ultimate burden on Missouri patients.

B. THE REMAINING FACTORS ALL FAVOR PETITIONER

1. Planned Parenthood and Its Patients Face Irreparable Injury

Without immediate intervention from this Court, the license of Missouri's last remaining generally available abortion provider will lapse on May 31, 2019. The State will succeed in its unconstitutional efforts to end abortion in Missouri, and over 1.1 million women of reproductive age in Missouri will face a world we have not seen since *Roe v. Wade*, 410 U.S. 113 (1973), was decided. Pet. ¶ 6.

This unquestionably constitutes an irreparable injury for which there is no adequate remedy at law. *See, e.g.*, *Rebman v. Parson*, No. SC 97307, 2019 WL 1613630, at *5 (Mo. Apr. 16, 2019) ("[B]eing subject to an unconstitutional statute, 'for even minimal periods of time, unquestionably constitutes irreparable injury.'" (quoting *Elrod v. Burns*, 427 U.S. 347, 373 (1976))); *Mo. State Med. Ass'n v. State*, No. 07AC-CC00567, 2007 WL 6346841 (Mo. Cir. Ct. for Cole Cty., July 3, 2007) (granting temporary restraining order against law that restricted practice of midwifery and would impose irreparable injury on physicians and their pregnant patients); *Planned Parenthood of Kan. & Mid-Mo. v. Lyskowski*, No. 2:15-CV-04273-NKL, 2015 WL 9463198, at *4 (W.D. Mo. Dec. 28, 2015) (any period during which plaintiff could not perform abortions because of the loss of its license constitutes irreparable injury), *appeal dismissed* (May 12, 2016); *Minana*, 467 S.W.3d at 907 ("Irreparable harm is established if

monetary remedies cannot provide adequate compensation for improper conduct.") (internal quotation marks omitted).

2. Preliminarily Relief Will Not Harm Respondents and Will Serve the Public Interest

Finally, the balance of equities also weighs heavily in favor of Petitioner. As set forth above, Respondents will suffer no harm if Planned Parenthood's license continues uninterrupted. Indeed, DHSS would be free to do (and only do) those actions allowed by statute, including continuing to engage in an investigation (of lawful scope and content) and to engage with Planned Parenthood's proposed plans of correction, as it does with other medical providers throughout the state. Planned Parenthood and its patients, however, are at risk of losing access to abortion services in the state entirely. Pet. ¶ 6.

Moreover, the public interest will be served by injunctive relief which will protect women's health and limit unauthorized and unfettered administrative overreach. *See, e.g.*, *Mo. State Med. Ass'n*, No. 07AC-CC00567, 2007 WL 6346841, (Mo. Cir. July 3, 2007) ("[B]alancing of the harms favors immediate injunctive relief, because a restraining order will not harm the State of Missouri and will actually further its interests in ensuring the health and safety of its citizens."); *see also Kirkeby v. Furness*, 52 F.3d 772, 775 (8th Cir. 1995) (public interest favored injunction against unconstitutional ordinance).

III. BOND IN THIS CASE

Petitioner respectfully submits that bond be set at no more than the nominal amount of $100 because Respondents are not at risk of harm should they later prevail in this litigation. *See Planned Parenthood of Kan. and Mid-Mo. v. Nixon*, No. 0516-CV25949, 2005 WL 3116528, at *1, *2 (Mo. Cir. Ct. for Jackson Cty., Nov. 8, 2005) (maintaining $100 bond for TRO and

subsequent preliminary injunction in case challenging law creating civil cause of action related to minors' abortions).

CONCLUSION

For these reasons, the Court should grant Planned Parenthood's Motion for a Temporary Restraining Order and/or Preliminary Injunction and enjoin Respondents from refusing to accept Planned Parenthood's license renewal application and from allowing Planned Parenthood's license to expire.

Dated: May 28, 2019

Respectfully submitted,

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* *Pro hac vice motion forthcoming*

CERTIFICATE OF SERVICE

I hereby certify that the foregoing was filed via the Court's electronic filing system on May 28, 2019, and a copy was personally served upon:

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