BEFORE THE
ADMINISTRATIVE HEARING COMMISSION
STATE OF MISSOURI

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

RESPONDENT'S SUGGESTIONS IN OPPOSITION TO MOTION FOR STAY

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INTRODUCTION

This case concerns whether a regulated health care facility may refuse to cooperate in valid licensing investigation and still demand the renewal of its license. Petitioner Reproductive Health Services of Planned Parenthood of the St. Louis Region ("RHS") has refused to cooperate in an investigation conducted by Respondent Department of Health and Senior Services (the "Department"). The Department launched an investigation of several troubling instances of patient care at the facility, including one instance where a patient seeking a late-term abortion suffered a potentially life-threatening complication. For months, the Department has sought to interview several physicians who directly provided the patient care at issue—including three fully qualified physicians who remain affiliated with RHS and continue to provide services at RHS to this day. These physicians have refused to cooperate, and RHS has refused to take any step to induce its own physicians to cooperate. This situation is literally unprecedented—none of the hundreds of facilities regulated by the Department has refused to make its physicians available for interviews during a licensing inspection or investigation. In no other context would the Department renew a license in the face of ongoing non-cooperation by a license applicant.

RHS's stay motion should be denied. It is not arbitrary or capricious for the Department to request interviews with treating physicians in an investigation. It is not arbitrary or capricious for the Department to insist that regulated facilities make their own medical staff available for interviews. And it is not arbitrary or capricious for the Department to infer from the non-cooperation of RHS and its physicians that they lack satisfactory explanations for their conduct. There is no "irreparable injury" to RHS, because any injury to RHS is entirely of its own making. The public interest weighs against granting a stay that would effectively grant a license renewal to a regulated entity that continues to defy an ordinary licensing investigation.

FACTUAL BACKGROUND

A. The Department's History of Licensing Inspections and Investigations of Regulated Health-Care Facilities, Including RHS's St. Louis Facility.

Under Missouri law, the Department is charged with licensing, inspecting, and investigating complaints regarding patient care at ambulatory surgical centers and abortion facilities. § 197.200-.240, RSMo. In conducting such inspections and investigations, the Department routinely reviews medical records and conducts interviews of physicians, nurses, and other medical staff to ensure regulatory compliance. *See* Affidavit of William Koebel, ¶ 8 (attached as Exhibit A) ("Koebel Aff."). "Conducting interviews of physicians and others who provide care at healthcare facilities licensed by the Department is a routine part of an investigation and part of standard practice across other licensed facilities at the Department." *Id.* "[I]nterviews of care providers during investigations is a component of the Department's standard practice." *Id.* Indeed, "[i]t would be completely outside the norm and generally unacceptable to complete an investigation into potentially deficient patient care at one of the Department's licensed facilities without interviewing the person who actually and directly provided the care at issue." *Id.* ¶ 12.

Consistent with this standard practice, physicians and other health care professionals routinely cooperate with such investigations and agree to be interviewed. *Id.* ¶ 36. This has been the norm both at RHS and at virtually all other facilities regulated by the Department—which includes many hundreds of facilities. *Id.* It is "unprecedented" for physicians to refuse to participate in interviews with the Department regarding health care that they personally have provided. *Id.* Under Department policy, "it is the duty and responsibility of [the regulated] facility to cooperate and ensure that all physicians who provide patient care at [the] facility are available for interviews during the Department's investigation." *Id.* Ex. N, at 2. Accordingly, the "refusal

to cooperate in interviews is unprecedented and departs from longstanding practice at [RHS's] facility and virtually every other regulated facility." *Id.*

B. The Department Commences an Investigation of Troubling Instances of Patient Care at RHS's St. Louis Facility.

On March 11, 12, and 13, 2019, the Department conducted a routine licensing inspection of the St. Louis facility. Koebel Aff., ¶ 2. As a result of that inspection, on March 27, 2019, the Department issued a Statement of Deficiencies to RHS, identifying ten deficiencies to be corrected prior to relicensing. *Id.* ¶ 3 & Ex. A. RHS subsequently submitted a Plan of Correction for this Statement of Deficiencies, and after extensive back-and-forth between the parties, all issues in the initial Statement of Deficiencies from the licensing inspection that did not depend on physician interviews were resolved.

On April 2, 2019, the Department initiated a related investigation of RHS relating to a several specific instances of patient care that came to light during the March licensing inspection. *See* Koebel Aff. ¶¶ 5-7; *see also* § 197.230.1, RSMo (authorizing the Department to "make, or cause to be made, such inspections and investigations as it deems necessary"). The investigation reviewed several troubling instances in which RHS's medical records reflected serious concerns regarding patient safety, deviations from standard care, and statutory and regulatory compliance.

For example, the investigation considered one instance in which a patient ("Patient 1") suffered two failed abortion attempts after receiving care from an inadequately supervised resident physician. *See* June 13, 2019 Statement of Deficiencies Cover Letter, at 2 (attached as Exhibit B). The resident performed a pelvic exam before a first-trimester surgical abortion that failed to detect that the uterus was severely retroflexed. *Id.* A physician fellow then attempted a surgical abortion, which failed. *Id.* RHS then attempted a medication abortion on the same patient, which also failed. *Id.* A fully qualified physician then performed a second attempted surgical abortion, which

succeeded. *Id.* The Department never received a mandatory complication report for either of the failed abortions, as required by § 188.052.2, RSMo, and RHS admits that it never prepared one for the first failed abortion. *Id.* This incident raised a series of grave concerns, including: (1) the adequacy of supervision of inexperienced physicians, (2) failure to comply with the statutory complication-plan requirement, (3) failure to comply with the statutory same-physician requirement, and (4) the recurrence of two failed surgical abortions by the same physician fellow in a close time frame. *Id.* Both the resident physician and the fellow—who is still affiliated with RHS and provides abortions there—refused to be interviewed regarding this incident. *Id.*

In addition, the investigation considered two similar instances in which both RHS and its pathology lab erroneously concluded that a surgical abortion had succeeded after examining the fetal tissue. Both patients ("Patient 2" and "Patient 3") later discovered they had continuing pregnancies and were forced to undergo second abortion attempts about five weeks later. *Id.* at 2-3. In the first instance, the physician who performed the abortion noted that he or she had observed fetal parts to confirm the success of the abortion, and the pathology lab did so as well. *Id.* at 2. Yet the patient contacted RHS three weeks later, reporting a continuing pregnancy, and the second abortion attempt was not scheduled for another two weeks. *Id.* Before the second abortion attempt, RHS did not provide the informed consent required by § 188.027, RSMo, even though both the risks of the procedure and the fetal development had materially changed, due to the advanced gestational age. *Id.* RHS's quality assurance process claimed that the failed abortion must have been the result of a "twin," even though no twin had been detected in a pre-abortion ultrasound. *Id.* Two days after the second abortion attempt, the patient was admitted to the hospital via the Emergency Department and became septic because of complications from the second abortion. *Id.* at 3. RHS had no communication with the pathology lab following either failed abortion attempt,

and did not comply with the informed-consent statute before the second abortion attempt for either patient. *Id.* These two incidents raised a series of grave questions, including: (1) the accuracy of fetal-tissue examinations by RHS, (2) the accuracy of fetal-tissue examinations by the pathology lab, (3) the adequacy of RHS's communication with the pathology lab, (4) RHS's non-compliance with Missouri's informed-consent statute, and (5) the adequacy of RHS's quality-assurance review of these incidents. *Id.* at 2-3. The RHS physicians who were directly involved in these incidents—including two fully qualified physicians who continue to be affiliated with RHS—refused to be interviewed. *Id.*

The Department's investigation also considered a deeply troubling incident where a patient with placenta previa and history of C-section ("Patient 12") underwent a late second-trimester abortion attempt at RHS's facility instead of a hospital. *Id.* at 3-4. Because of the risk of life-threatening hemorrhage, a recent ACOG Practice Bulletin states that a second trimester abortion on such a patient should be performed at a facility with blood products and the capacity for interventional radiology and/or hysterectomy.[1] *Id.* RHS's medical director admitted in an interview that RHS's facility lacks all three. *Id.*

Patient 12 was first examined at the hospital by an RHS-affiliated physician, but for unexplained reasons, RHS's physician referred the patient to RHS's facility for the abortion at a

[1] "Women with prior cesarean deliveries are at an increased risk of placenta accreta and warrant special attention, particularly if ultrasonography indicates a low-lying placenta or placenta previa [this was true of Patient 12]. When there is a suspicion of abnormal placentation, D&E is the preferred abortion method, and preparations should be made for possible hemorrhage by *ensuring the procedure is performed at an appropriate facility with accessibility to blood products, interventional radiology, and the capability to perform a hysterectomy if necessary*." Am. Coll. of Obstetricians and Gynecologists, Practice Bulletin No. 135 (June 2013), at 4-5 (emphasis added), *available at* https://www.acog.org/-/media/Practice-Bulletins/Committee-on-Practice-Bulletins----Gynecology/Public/pb135.pdf?dmc=1&ts=20190530T1037529034. RHS's medical director admitted that RHS's facility has none of these three.

gestational age of nearly 22 weeks. *Id.* The abortion attempt at RHS was broken off, as the patient began to experience uncontrolled bleeding. *Id.* The patient underwent an emergency transfer back to the hospital, where she experienced massive bleeding and received a uterine artery embolization while in critical condition. *Id.* This incident raised grave concerns about patient safety and compliance with the standard of care, as the decision to attempt the late-term abortion at RHS's facility needlessly placed the patient in a potentially life-threatening situation. *Id.* at 4. The RHS physician who treated this patient—a fully qualified physician who is performing abortions at RHS to this day, and who alone has first-hand knowledge of the incident—refused to be interviewed regarding the incident. *Id.*

C. RHS and Its Physicians Refuse to Cooperate in the Department's Investigation.

On April 11, 2019, the Department requested that RHS make available for interviews seven physicians who had directly participated in the incidents of patient care under investigation. *Id.* ¶ 11. The Department requested a response regarding their availability by April 16. *Id.* On April 12, in a phone call with RHS's attorney, the Department advised RHS of the general topic of the interviews with the requested physicians—*i.e.*, that they would relate to the medical records that RHS has examined at the facility on April 2 and 3. *Id.* ¶ 13.

On April 16, an attorney for RHS sent the Department a letter requesting an additional two days to respond to that request, to which the Department agreed. *Id.* ¶ 14 & Ex. D. In the April 16 letter, RHS's attorney contended that "we can find nothing in the law that obligates licensees" like RHS to cooperate in Department investigations and make their physicians available for interview with regulators. *Id.* Ex. D, at 1. RHS's attorney contended that "nothing in sections 197.200 to 197.240, RSMo requires personnel to be made available for interviews or even requires the cooperation RHS has already been giving." *Id.*

The Department responded on April 22, identifying its authority to initiate investigations and impose penalties for non-compliance under §§ 197.220, 197.230, 197.240, 197.293, RSMo, and 19 CSR § 30-30.060(7)(C). Koebel Aff. ¶ 17 & Ex. E. Under Missouri law, "[t]he department of health and senior services shall make, or cause to be made, such inspections and investigations as it deems necessary"—without any further qualification. § 197.230.1, RSMo. This broad authority includes the authority to conduct "witness interviews deemed necessary by the Department to determine whether statutory and regulatory requirements applicable to abortion facilities were being met." Koebel Aff. Ex. E, at 1.

On April 22, RHS's attorney notified the Department that "we have not been able to find a time for interviews that would work for us and each of" the requested physicians. RHS notified the Department that "[e]ach of the [physicians] is represented by their own counsel," and invited the Department to reach out to the physicians' personal counsel to attempt to schedule interviews. The Department then proceeded—also on April 22—to contact the three attorneys representing the seven physicians whose interviews were requested. Koebel Aff. ¶ 16. These physicians included two medical residents, three fully qualified physicians with ongoing affiliation with RHS who continue to provide abortions at its facility, and two supervising physicians with senior roles at RHS's St. Louis facility.

On May 3, 2019, the attorney for the two resident physicians notified the Department that those residents declined to be interviewed. On May 7, the attorney for one fully qualified RHS physician notified the Department that that physician refused to participate in an interview. On May 14, the attorney for the other two fully qualified RHS physicians notified the Department that they refused to participate in interviews. Koebel Aff. ¶ 28. Only the two supervising physicians

with senior roles at RHS's St. Louis facility offered to participate in interviews, and they did not offer to do so until May 14. *Id.*

In litigation before the Twenty-Second Judicial Circuit, RHS's counsel admitted that RHS has not taken any steps to ensure the cooperation of its own physicians—including those who are affiliated with RHS and performing abortions there to this day—and contended instead that RHS should not have to cooperate. Ex. B, at 1. RHS's counsel has made clear that "RHS has taken, and will take, ***no*** affirmative steps to request, encourage, induce, pressure, or otherwise procure the cooperation of the non-cooperating physicians." *Id.* "As RHS's counsel stated in open court, RHS has not taken any steps to ensure the cooperation of its own physicians, and it does not believe that it has any obligation to encourage those doctors to cooperate." *Id.* To this day, RHS has never alleged that it has taken any steps to induce the cooperation of its physicians. And RHS refuses to explain the nature of its contractual relationship with these physicians, or reveal whether it has the authority to induce them to cooperate.

D. RHS Demands a License Despite Its Refusal to Cooperate in the Investigation.

On May 16, 2019—two days after its physicians refused to participate in interviews—RHS submitted an application for a license renewal. Koebel Aff. ¶ 29. Also on May 16, counsel for RHS emailed the Department and demanded action on its pending Plan of Correction from the relicensing inspection. Koebel Aff. ¶ 29 & Ex. J. RHS's counsel reiterated their position that "the physicians are not RHS employees, and therefore, we are unable to compel them to sit for an interview." *Id.* Ex. J, at 2. RHS's counsel demanded a response to its Plan of Correction "by Noon CT on Monday, May 20, 2019." *Id.*

On May 20, per RHS's request, the Department responded to RHS's Plan of Correction from the licensing inspection. Koebel Aff. ¶ 30 & Ex. L. The Department reiterated that, in the

pending complaint investigation, "RHS has been unable to produce some physician abortion providers . . . for interview with Department Inspectors." *Id.* The Department noted that it "cannot complete our investigation as required until we interview the physicians involved in the care provided in the potential deficient practices." *Id.* The Department reminded RHS that "[h]istorically, RHS has always provided physicians for interview. This is also the standard practice across all regulated provider types." *Id.*

On May 22, RHS offered to make available for interview only Dr. Eisenberg and Dr. McNicholas, who serve as supervisory physicians at RHS. Koebel Aff. ¶ 32 & Ex. M. On May 23, the Department agreed to interview Dr. Eisenberg and Dr. McNicholas immediately, and offered to conduct the interviews as soon as the next business day. Koebel Aff. ¶ 33 & Ex. N. In making this agreement, the Department noted that it was conferring a benefit on RHS by departing from ordinary investigative practices: "[I]nterviewing the attending or supervising physicians before interviewing the physicians who actually provided patient care contradicts well-established investigative standards that we apply in all investigations." *Id.* at 2.

On Friday, May 24, 2019, RHS notified the Department that Dr. Eisenberg and Dr. McNicholas would be available for interviews on Tuesday, May 28. Koebel Aff. Ex. O. On Tuesday afternoon, the Department interviewed Dr. McNicholas and Dr. Eisenberg. Koebel Aff. ¶ 35. These interviews lasted about 45 minutes and 30 minutes, respectively. *Id.* During the interviews, Dr. McNicholas confirmed that she had frequently not been present for abortion procedures for which she had performed the informed-consent process, thus violating the same-physician requirement—even though she had made repeated entries in the medical records incorrectly implying that she had been personally present for these procedures. *Id.*

E. Proceedings in the St. Louis City Circuit Court.

On May 28, 2019, RHS filed a lawsuit in St. Louis City Circuit Court and sought both a temporary restraining order and preliminary injunction to compel the renewal of its license. On June 10, 2019, the Circuit Court issued a limited preliminary injunction that directed the Department to make a final decision on RHS's application for license renewal by June 21, 2019. Order in *Reproductive Health Services v. Parson*, No. 1922-CC02395 (St. Louis City Cir. Ct. June 10, 2019), at 8.

On June 13, 2019, the Department issued to RHS a 62-page Statement of Deficiencies regarding the problems identified in its ongoing investigation. *See* June 13, 2019 Cover Letter (attached as Exhibit B); *see also* June 13, 2019 Statement of Deficiencies (submitted for *in camera* inspection). This Statement of Deficiencies provided lengthy, detailed, and specific recitation of the concerns identified in the investigation—including those with regard to Patients 1, 2, 3, and 12, discussed above. The Department advised RHS that the fundamental obstruction to a meaningful resolution of the investigation was RHS's and its physicians' unprecedented failure to cooperate: "RHS and its physicians have made two things abundantly clear: (1) there is no reasonable prospect that the five non-cooperating doctors will agree to participate in interviews in the foreseeable future; and (2) RHS has taken, and will take, ***no*** affirmative steps to request, encourage, induce, pressure or otherwise procure the cooperation of the non-cooperating physicians." Ex. B, at 1. "RHS's non-cooperation on this point is unprecedented and unacceptable." *Id.* Because RHS and its physicians had not cooperated, the Department's Statement of Deficiencies inferred that they had no satisfactory explanation for the conduct under investigation: "Due to this ongoing non-cooperation, . . . we are forced to infer that each physician who declined to participate in an interview has no satisfactory explanation for the conduct under

investigation, and we are forced to apply the same presumption to RHS." *Id.* The Department also emphasized that this systemic refusal to cooperate itself constituted a critical deficiency: "In addition to these deficiencies in patient care, it is ***imperative*** that your Plan of Correction must address the failure of RHS and its physicians to cooperate in this investigation, which is unprecedented and unacceptable." *Id.* at 4.

On June 18, 2019, RHS responded to this Statement of Deficiencies with a defiant Plan of Correction. *See* Exhibit C (June 18, 2019 Plan of Correction Cover Letter), at 1-4; *see also* June 18, 2019 Plan of Correction (submitted for *in camera* review). The Plan of Correction did not address the ongoing refusal to cooperate by both RHS and its physicians, instead contending that RHS had no responsibility to cooperate in the Department's investigations. *See* Ex. C, at 1-4. The Plan of Correction also wholly ignored the Department's inference that the non-cooperating physicians and RHS had no satisfactory explanation for the troubling instances of patient care. *Id.* Instead, the Plan of Correction repeatedly denied that anything untoward had taken place, and offered a series of self-justifying explanations for the instances under review—explanations which the Department cannot verify, because of the ongoing refusal to cooperate. *Id.* Many of these self-justifying explanations, moreover, were facially implausible. *Id.*

On June 21, 2019, consistent with the Circuit Court's order, the Department issued a letter to RHS denying its application for license renewal. Exhibit D (June 21, 2019 Letter to RHS). The Department accepted RHS's proposed correction plan regarding improving communications with the pathology lab, complying the same-physician requirement, and ensuring the accuracy of medical records. *Id.* at 1-2. "For the remaining deficiencies," however, "RHS proposed no corrective actions." *Id.* at 2. "These deficiencies are serious and extensive," *id.*, including the failure of both RHS and its physicians to cooperate in the investigation. *Id.* at 2-3. The Department

also highlighted the ongoing concerns regarding various aspects of treatment of Patients 1, 2, 3, and 12, discussed above. *Id.* at 3-4. The Department noted that RHS's denials and self-justifying explanations were not plausible, and could not be verified in any event due to the ongoing non-cooperation. *Id.* "Summarily, except for those deficiencies noted at the outset of this letter, RHS fails to identify any corrective measures it will implement or any systemic changes it will make to ensure that the deficiencies will not recur—because RHS maintains there were no such deficiencies." *Id.* at 4. "[G]iven RHS's outright refusal to implement corrective actions with regard to such serious, extensive deficiencies," the Department concluded that further attempts at resolution would be futile. Under Section 197.220, RSMo, the Department found that "there has been a substantial failure to comply with the requirements" of the licensing statutes, and the Department "therefore denie[d] RHS's application for a licenses renewal." *Id.*

ARGUMENT

The Administrative Hearing Commission "may stay or suspend any action of an administrative agency pending the commission's findings and determination in the cause." § 621.035, RSMo. Four traditional factors govern the decision whether to grant a stay: "(1) the likelihood that the party seeking the stay will prevail on the merits; (2) the likelihood that the moving party will be irreparably harmed absent a stay; (3) the prospect that others will be harmed if the court grants the stay; and (4) the public interest in granting the stay." *State ex rel. Dir. of Revenue v. Gabbert*, 925 S.W.2d 838, 839-40 (Mo. banc 1996) (quoting *Ohio ex rel. Celebrezze v. Nuclear Regulatory Comm'n*, 812 F.2d 288, 290 (6th Cir. 1987)); *see also* Stay Mot. at 5 (agreeing that the *Gabbert* factors apply here). Here, these factors weigh against entering a stay.

I. RHS Is Not Likely to Succeed on the Merits Because RHS's Refusal to Cooperate in a Valid Investigation Caused the Non-Renewal of its License.

The first *Gabbert* factor considers "the likelihood that the party seeking the stay will prevail on the merits." *Gabbert*, 925 S.W.2d at 839. RHS has shown no likelihood of success here.

A. The Department's request to interview the physicians who directly provided the patient care under review is not arbitrary or capricious.

RHS's principal contention is that the Department is acting arbitrarily and capriciously by seeking to interview the physicians who directly participated in and performed the troubling aspects of patient care discussed above. Stay Mot. at 14-16. This argument has no merit.

The Department's request during a licensing investigation to interview physicians who directly participated in troubling aspects of patient care is not arbitrary and capricious. "Whether an action is arbitrary focuses on whether an agency had a rational basis for its decision." *Bd. of Educ. of City of St. Louis v. Missouri State Bd. of Educ.*, 271 S.W.3d 1, 11 (Mo. banc 2008). "Capriciousness concerns whether the agency's action was whimsical, impulsive, or unpredictable." *Missouri Nat'l Educ. Ass'n v. Missouri State Bd. of Educ.*, 34 S.W.3d 266, 281 (Mo. Ct. App. 2000). "To meet basic standards of due process and 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.' An agency must not act in a totally subjective manner without any guidelines or criteria." *Id.* (citation omitted). The Department's investigation plainly satisfies these criteria.

The Department's request to interview these physicians is part of routine, universal practice that is rooted in standard investigative techniques. The Department's uncontradicted evidence demonstrates: "Conducting interviews of physicians and others who provide care and healthcare facilities licensed by the Department is a routine part of an investigation and part of standard practice across other licensed facilities at the Department." Koebel Aff. ¶ 8. "It also makes the most sense that—when the focus of the investigation is the care provided by the physician—that

the investigation include interviews of the physician." *Id.* "This is why such interviews of care providers during investigations is a component of the Department's standard practice." *Id.*

Moreover, seeking to interview the providers who were directly involved in providing care—rather than supervisors who lack first-hand knowledge of the events in question—is also standard practice. "It is standard investigative practice to first interview the person who directly provided the care when the care is the issue being investigated." *Id.* ¶ 12. Relying only on such second-hand information would contradict ordinary investigative practices: "It would be completely outside the norm and generally unacceptable to complete an investigation into potentially deficient patient care at one of the Department's licensed facilities without interviewing the person who actually and directly provided the care at issue." *Id.* In fact, in the Circuit Court proceedings, Judge Stelzer asked RHS's counsel whether it was arbitrary and capricious for the Department to seek to interview the physicians who had provided care in the course of a licensing investigation, and she admitted that it was not.

The only thing arbitrary, capricious, or unreasonable about these requests for interviews is RHS's refusal to comply with them. As the Department's investigator attested, based on 25 years' of investigative experience: "It is unprecedented in my experience for physicians and other health care professionals to refuse to be interviewed regarding health care that they personally provided during a licensing inspection or investigation." *Id.* ¶ 36. "This is true regardless of whether these professionals are deemed 'employees' or 'independent contractors' by the facility." *Id.* Such non-cooperation is unprecedented even by RHS's own standards: "In the Department's prior inspections and investigations involving RHS, its physicians and health care professionals have always agreed to be interviewed." *Id.* Moreover, such cooperation is the universal norm across

all other licensed facilities: "[T]he same is true of virtually all facilities regulated by the Department, which includes many hundreds of facilities." *Id.*

RHS repeatedly contends that the non-cooperating physicians "are not Petitioner's employees," and that it lacks authority to force them to cooperate. Stay Mot. at 14; *see also id.* ¶¶ 9, 11, 25, 39, 42, 58, 61. This argument has no merit. RHS does not dispute that three of the five non-cooperating physicians are fully qualified physicians who continue to maintain their affiliation with RHS and continue to provide abortions there to this day. While RHS insists that these physicians are not "employees" of RHS, it refuses to disclose the nature of its contractual relationship with them. It refuses to explain whether its contracts with them (or with their employers) authorize RHS to insist on their cooperation with the Department. On the contrary, RHS concedes that it has taken *no* steps to encourage or induce them to cooperate, and it certainly has not threatened to terminate its affiliation with them if they do not cooperate. *See* Koebel Aff. ¶ 12. RHS's claim that it "has no power to compel [its physicians] to sit for interviews," misses the mark. RHS has not even *tried* to convince them to sit for interviews, and it refuses to do so.

RHS contends that the Department should be forced to rely solely on interviews of supervising physicians who lack first-hand knowledge of the treatment provided, urging that "[t]here is no reason to believe . . . that DHSS would learn anything new or relevant from interviewing these physicians." Stay Mot. at 15. On the contrary, the Department has presented uncontradicted evidence, based on decades of investigative experience, to show that the *best* information is acquired by interviews of the physicians who directly provided the patient care under review. "It makes the most sense that—when the focus of the investigation is the care provided by the physician—that the investigation include interviews of the physician." Koebel Aff. ¶ 8. "That is why interviews of care providers during investigations is a component of the

Department's standard practice." *Id.* In addition, "25 years of investigative experience" demonstrate that "the order of interviews can have a definite impact on the reliability of interviews, which are necessary for an investigation—a truth-seeking process—to most reliably ascertain the truth." *Id.* ¶ 12. For this reason, "[i]t is standard investigative practice to first interview *the person who directly provided the care* when the care is the issue being investigated, followed by the person (if necessary) who supervised that care." *Id.* (emphasis added). Interviewing the physician who directly provided the care is both essential and universal practice: "It would be completely outside the norm and generally unacceptable to complete an investigation into potentially deficient patient care at one of the Department's licensed facilities without interviewing *the person who actually and directly provided the care at issue.*" *Id.* (emphasis added). "It is unprecedented in my experience for physicians and other health care professionals to refuse to be interviewed regarding health care that they provided during a licensing inspection or investigation." *Id.* ¶ 36.

The Department has also explained the specific need for physician interviews as to the specific instances of patient care under investigation. In its June 21 letter, the Department noted that "RHS does not contend that the supervising physicians have first-hand knowledge of the events under investigation, and RHS's own medical records . . . underscore the fact that interviews are necessary because medical records do not always contain all accurate information regarding the care provided." Ex. D, at 2. Indeed, RHS does not dispute that its medical records contained misleading and inaccurate entries, including entries that "state that a supervising physician was 'present' for a procedure that did not occur until hours later, and regarding which a later interview revealed that 'present' meant that the physician was merely 'available in the surgical suite.'" *Id.* "The Department is charged with safeguarding the health of the people of Missouri. For those people who receive services from a licensed facility, the Department's ability to interview facility

staff and physicians who provide patient care to determine what occurred regarding that patient care and whether corrective actions are needed is indispensable to that duty." *Id.* at 2-3.

RHS contends that the Department insisted on "formal, deposition-style recorded interviews," Stay Mot. at 15, but this argument plainly mischaracterizes the facts. The Department's interviews of Dr. McNicholas and Dr. Eisenberg lasted approximately 45 minutes and less than 30 minutes, respectively. Koebel Aff. ¶ 35. The interviews were audio recorded because litigation was imminent at the time—in fact, RHS had already filed its lawsuit in Circuit Court when the interviews occurred.

In sum, there was nothing "arbitrary, capricious, or unreasonable" about the Department's attempts to interview RHS's physicians in its licensing investigation.

B. The Department has clear statutory and regulatory authority to interview medical staff during licensing investigations.

RHS argues that the Department lacks statutory authority to "compel" physician interviews because the statute does not confer subpoena power on the Department during its investigations. Stay Mot. at 15-16. This argument is beside the point, because the Department did not seek to issue subpoenas during its investigation. Rather, the Department requested physician interviews, and ultimately it was forced to draw adverse inferences from the RHS's and its physicians' persistent failure to cooperate in the requested interviews. *See* Ex. B (noting that the Department is "forced to infer that each physician who declined to participate in an interview has no satisfactory explanation for the conduct under investigation, and we are forced to apply the same presumption to RHS"). The Department's authority to request physician interviews, and to draw reasonable conclusions from those interviews (or lack thereof) lies squarely within the Department's broad grant of statutory authority and discretion to conduct inspections and investigations of licensed facilities: "The department of health and senior services shall make, or

cause to be made, such inspections and investigations *as it deems necessary*." § 197.230.1, RSMo (emphasis added). This deliberately broad grant of authority plainly includes the authority to request access to medical records and interviews of health care providers "as [the Department] deems necessary." *Id.*

Requesting interviews of physicians, and drawing adverse inferences from their failure to cooperate, are also plainly authorized by Missouri regulations. The Department's regulations provide: "[n]o license shall be issued or renewed by the department until the department has inspected the facility and *determined that it is in compliance with all requirements of applicable statutes and regulations*." 19 CSR 30-30.050(2)(I) (emphasis added). The refusal of a regulated facility and its medical staff to cooperate in an investigation obstructs the Department's ability to "determine[] that [the facility] is in compliance with all requirements of applicable statutes and regulations," *id.*—as the facts of this case vividly demonstrate.

Moreover, RHS's cramped interpretation of the Department's statutory authority would lead to absurd conclusions. RHS contends that, because the statute does not expressly grant the Department subpoena power to compel testimony, it does not even permit the Department to request voluntary interviews in the course of an investigation, or draw inferences from refusal to cooperate. Stay Mot. at 15-16. But the same logic would apply to the Department's ability to request documents—such as medical records—which are routinely requested and reviewed during inspections and investigations of all licensed facilities. The statute does not explicitly grant the power to subpoena documents such as medical records, yet one cannot reasonably dispute that the Department has authority to request those during its investigations—and to draw adverse inferences if documents are withheld. If followed to its logical conclusion, RHS's argument would contend that the Department, in effect, has no investigative authority at all. This absurd

interpretation of § 197.230.1 should be rejected. *See, e.g.*, *State v. Fanning*, 557 S.W.3d 449, 451-52 (Mo. App. 2018).

The Department's policy—which applies to all regulated facilities, not just abortion facilities—places the "duty and responsibility" on the *regulated facility*, not the Department, to secure cooperation of its own physicians in Department investigations. Koebel Aff. Ex. N, at 2. The regulated facility must "cooperate and ensure that all physicians who provide patient care at [the] facility are available for interviews during the Department's investigation." *Id.* This policy is not arbitrary, capricious, or unreasonable. On the contrary, the opposite policy urged by RHS—which would place *no* duty on the regulated facility to ensure that its physicians cooperate in investigations—would be absurd and unreasonable. *Fanning*, 557 S.W.3d at 451-52.

C. The Department's 62-page, specific, detailed Statement of Deficiencies was not "vague" or "incomprehensible."

RHS also contends that the exhaustively detailed, 62-page Statement of Deficiencies that the Department sent on June 13 is too "vague" and "incomprehensible" to permit a meaningful response. Stay Mot. at 16. This argument is difficult to fathom. The supposed "vagueness" of the Statement of Deficiencies did not prevent RHS from submitting its own 60-plus-page Plan of Correction, addressing each alleged deficiency in detail. *See* June 18, 2019 Plan of Correction (submitted for *in camera* review). As RHS's Plan of Correction makes clear, RHS had no difficulty with the supposed "vagueness" of the deficiencies—rather, it insisted that none of them constituted deficiencies, and provided self-justifying explanations for all identified instances of troubling patient care. *See id.*

The Department, of course, has been deprived access to the physicians who actually provided this gravely concerning patient care, and so it is hampered in its ability to assess RHS's self-justifying explanations. But many of RHS's explanations are facially implausible. For

example, RHS contends that its physician provided responsible care to Patient 12, who suffered massive blood loss and became critically ill during a late-second trimester abortion. But RHS's Plan of Correction did not address the ACOG Practice Bulletin No. 135, which instructs that a late-term abortion on this patient with placenta previa and history of C-section should not be attempted outside a hospital, or explain why its physician disregarded this guidance. RHS's Plan of Correction, therefore, effectively conceded that RHS needlessly placed this patient in a life-threatening situation by planning the surgical abortion at its facility, which was not equipped to handle the possible complications.

Similarly, the Department cited RHS's failure to file a post-abortion complication report for the failed surgical abortion that was attempted on Patient 1. *See* § 188.052.2 (requiring the filing of post-abortion complication reports). RHS does not dispute that "failed abortion" is a complication that requires filing a report, and it admits that failed to file a report for that failed abortion. *See* Stay Mot. at 13, ¶ 51. Instead, in its Plan of Correction, "RHS contend[ed] that a failed abortion is not a failed abortion so long as the patient knows that the abortion has failed." Ex. D, at 3. "This explanation is not plausible and contradicts RHS's own practice of filing complication reports for failed medication abortions, where the patient also knows that the abortion has failed." *Id.*

RHS also accuses the Department of relying on "anti-abortion propaganda" in its Statement of Deficiencies. Stay Mot. at 11, ¶ 48. But here are the actual statements that RHS dismisses "anti-abortion propaganda," which address the consequences of failed abortion: "The woman who seeks abortion is often promised a relatively painless and simple procedure to eliminate a pregnancy that she does not wish to carry to term. Failed abortion may involve her in a number of unanticipated outcomes. If she changes her mind about 'medical' abortion and a child is born

with anomalies, maternal grief and guilt may be anticipated and counseling may be necessary. If a second procedure is successful at a late stage of fetal development, where the woman knows that procedures are chosen to ensure that an anticipated live birth cannot occur, grief and guilt may likewise ensue." Elizabeth Ring Cassidy et al., WOMEN'S HEALTH AFTER ABORTION: THE MEDICAL AND PSYCHOLOGICAL EVIDENCE (2002). It is not clear which of these non-controversial statements RHS rejects as mere "propaganda."

D. RHS, not the Department, has engaged in shifting positions and gamesmanship during the regulatory process.

RHS also contends that the Department supposedly "shifted the goalpost" during the regulatory process, citing two examples—the pelvic-exam requirement and the same-physician requirement. Stay Mot. at 6. But RHS concedes that both of these issues have been resolved, *see* Stay Mot. at 8-9, ¶¶ 32, 37, and so this argument is entirely beside the point. In any event, RHS's argument that the Department engaged in shifting positions cannot withstand scrutiny.

As to the pelvic-exam requirement, the relevant regulation states that, prior to an abortion, "[a] health assessment including a pelvic examination shall be performed," and that "[t]his information shall be used in determining the duration of gestation, identifying preexisting medical or other complications, and detecting any factors *which could influence the choice of the procedure, anesthesia, or preoperative and postoperative management*." 19 CSR § 30-30.060(2)(D), *available at* https://www.sos.mo.gov/cmsimages/adrules/csr/current/19csr/19c30-30.pdf (emphasis added). Plainly, the phrase "this information" in the regulation refers to the results of the pelvic exam, which "shall be used" to detect "any factors which could influence the choice of procedure." *Id.* In fact, the case of "Patient 1," discussed above, vividly illustrates the utility of performing the pelvic exam in advance of the procedure.

During the licensing inspection, the Department discovered that RHS's practice was to perform the pelvic exam immediately before the surgical abortion, as the last step before the surgical "time out," when it was clearly too late to influence the choice of procedure. RHS, not the Department, then took "shifting positions" on this issue. At first, RHS repeatedly insisted that it would not perform the pelvic exam any earlier than immediately before the surgical abortion. Then, on May 28, 2019, RHS agreed to comply with the regulation. Then, on June 18, 2019, RHS shifted back to refusing to comply with the regulation, in its June 18 Plan of Correction. Ex. C. In a good-faith effort to resolve this dispute, the Department then issued an emergency regulation that created an exception permitting the physician to perform the pelvic exam immediately before the procedure if he or she determined that an earlier pelvic exam was not medically indicated for the patient. Ex. D, at 2. Thus, RHS, not the Department, has been guilty of "moving the goalpost" on this issue.

Likewise, the Department has consistently interpreted the same-physician requirement throughout these proceedings. The informed-consent statute provides that "[t]he physician who is to *perform or induce* the abortion shall, at least seventy-two hours prior to such procedure, inform the woman" of the immediate and long-term medical risks of the procedure. § 188.027.5, RSMo (emphasis added). In other words, the same physician who is to "perform or induce" the abortion must also perform the medical informed-consent process. *Id.* In prior litigation, the Department took the position that, where two physicians both "perform or induce" the abortion together, either one of them may perform the medical informed-consent process. During the recent licensing inspection, however, the Department came to realize that RHS was frequently allowing residents and fellows to perform abortions where the attending physician who had done the medical informed-consent *was not even present in the room during the procedure*. *See* Koebel Aff. ¶ 7

(noting that RHS's medical records reflected "a systematic disregard for the requirement"). Obviously, a physician who is not even present when the procedure occurs does not "perform or induce" the abortion in any possible sense of the statute, and the Department has never contended otherwise. It became clear that RHS was repeatedly violating the statute, as Dr. McNicholas has since effectively conceded.[2] Therefore, RHS engaged in gamesmanship on this issue by seeking to evade the statutory requirement by engaging in a plainly unreasonable, undisclosed interpretation of the statute, after the Jackson County Circuit Court rejected its constitutional challenge to the interpretation. In any event, RHS has now conceded this point by agreeing to comply with the same-physician requirement in the future. Stay Mot. ¶ 37.

II. RHS Has Failed to Establish Irreparable Injury Because Its Alleged Injury Is Entirely of RHS's Own Making.

The second *Gabbert* factor directs the Commission to consider "the likelihood that the moving party will be irreparably harmed absent a stay." *Gabbert*, 925 S.W.2d at 839-40. RHS contends that both it and Missouri women will suffer irreparable injury if its facility license is allowed to expire. Stay Mot. at 17-22. This argument has no merit, because any injury from the non-renewal of its license is entirely of RHS's own making.

The troubling incidents of patient care under review in this case, while serious, are the sorts of incidents that can and should be addressed through the regulatory process without resulting in a non-renewal. Indeed, in this very case, RHS and the Department have managed to resolve every deficiency for which the non-cooperation of RHS and its physicians did not obstruct its resolution.

[2] In her May 28 interview, Dr. McNicholas admitted that she was frequently not present during abortions performed by medical residents or fellows, even though she herself had done the medical informed consent. She attempted to justify this practice by stating that she considered all the abortions performed by physicians whom she supervised to be "performed" by her. *See* Koebel Aff. ¶ 35.

The non-cooperation of RHS and its physicians thus presents the final, critical obstacle preventing the renewal of RHS's license.

The removal of this obstacle lies entirely within RHS's power. As RHS has admitted, it has taken no steps to procure the cooperation of its physicians—including the three fully qualified physicians who remain affiliated with RHS to this day. RHS has not asked, encouraged, or urged them to cooperate. It has not invoked any provision of its affiliation contracts with them or their employers to induce them to cooperate. It has not threatened to terminate its affiliation with them if they do not cooperate. And it has not in fact terminated its affiliation with them, despite their non-cooperation. *See* Ex. A, Koebel Aff. ¶ 12.

RHS has never alleged otherwise. On the contrary, RHS's counsel advised Judge Stelzer that RHS does not believe that it has any duty to cooperate or to encourage its physicians to cooperate in the Department's investigation. RHS's non-cooperation is entirely of its own making.

It is black-letter law that an injury of the movant's own making does not qualify as "irreparable injury." Case after case has acknowledged this principle. "[A]n injury of Petitioners' own making . . . cannot justify a finding of irreparable harm." *Allen v. Fitzgerald for Region Four*, 590 B.R. 352, 361 (W.D. Va. 2018); *see also, e.g., Long v. Robinson*, 432 F.2d 977, 981 (4th Cir. 1970) (denying a stay because "the principal irreparable injury which defendants claim that they will suffer if the order of the district court is not stayed is injury of their own making"); *Colón–Merrero v. Conty–Pérez*, 703 F.3d 134, 139 (1st Cir. 2012) (finding that a plaintiff's "claims of irreparable harm were undermined by the fact that their emergency was largely of their own making" (internal quotations omitted)); *United States v. Apple Inc.*, 992 F. Supp. 2d 263, 288 (S.D.N.Y. 2014), *aff'd*, 787 F.3d 131 (2d Cir. 2015) ("After all, an entity cannot claim irreparable harm because of increased expenses where its cooperation would have resulted in a more cost-

effective process."); *NML Capital, Ltd. v. Republic of Argentina*, 727 F.3d 230, 246 (2d Cir. 2013) (declining to find irreparable harm where the complained injury was "almost entirely of the Republic's own making"). The same logic applies here.

Further, as the Supreme Court has held, "[a]lthough government may not place obstacles in the path of a woman's exercise of her freedom of choice, it need not remove those obstacles not of its own creation." *Harris v. McRae*, 448 U.S. 297, 316 (1980); *see also Maher v. Roe*, 432 U.S. 464, 474 (1977). This principle was reaffirmed by the Jackson County Circuit Court when it denied a TRO to these same plaintiffs in their challenge to the same-physician requirement: "the issue of abortion provider scarcity is not one of the state's making and, therefore, should not be considered by this Court in consideration of the undue-burden analysis." See Judgment/Order Denying TRO, *Comprehensive Health of Planned Parenthood Great Plains, et al. v. Hawley*, No. 1716-CV24109 (Jackson Cty. Cir. Ct.) (Oct. 23, 2017), at 8. As the Fifth Circuit recently held, the "inaction" and "personal choice" of abortion providers "cannot be legally attributed to" the State. *June Medical Services LLC v. Gee*, 905 F.3d 787, 811 (5th Cir. 2018). Here, the refusal of RHS's physicians to cooperate in a health-and-safety investigation is due to the "personal choice" of those physicians, and it "cannot be legally attributed" to the State. *Id*.

III. The Balancing of Harms and the Public Interest Weigh Against Granting a Stay in this Case.

The third and fourth *Gabbert* factors call for consideration of: "(3) the prospect that others will be harmed if the court grants the stay; and (4) the public interest in granting the stay." *Gabbert*, 925 S.W.2d at 839-40. These factors also weigh against granting a stay.

As many courts have recognized, an order that prevents the State from enforcing its duly enacted laws and regulations is heavily disfavored and inflicts per se irreparable injury on the State. *See, e.g., 1-800-411-Pain Referral Service, LLC v. Otto*, 744 F.3d 1045, 1053-54 (8th Cir.

2014) (holding that, "because Plaintiffs seek to enjoin enforcement of a validly enacted statute," they must meet "a more rigorous threshold showing than th[e] ordinary preliminary injunction test"). "Any time a State is enjoined by a court from effectuating statutes enacted by representatives of its people, it suffers a form of irreparable injury." *Maryland v. King*, 567 U.S. 1301, 1303 (2012) (Roberts, C.J., in chambers) (citation omitted). "When a statute is enjoined, the State necessarily suffers the irreparable harm of denying the public interest in the enforcement of its law." *Planned Parenthood of Greater Texas Surgical Health Servs. v. Abbott*, 734 F.3d 406, 419 (5th Cir. 2013). Thus, "a state suffers irreparable injury whenever an enactment of its people or their representatives is enjoined." *Coalition for Economic Equity v. Wilson*, 122 F.3d 718, 719 (9th Cir. 1997)

Granting a stay to RHS here would create a troubling precedent with potential implications for all regulated facilities in Missouri. As noted above, the Department regulates hundreds of facilities of all kinds—including home health centers, hospitals, nursing homes, ambulatory surgical centers, and many others—pursuant to regulatory regimes similar to the one at issue here. Among all these regulated facilities, RHS is the first to take the literally "unprecedented" step of refusing to cooperate in an investigation by the Department, and yet demanding a license anyway. Affording RHS a license in the face of its non-cooperation would send a message to all facilities that—notwithstanding decades of consistent practice to the contrary across hundreds of facilities—a license is an entitlement and cooperation in Department investigations is not required to obtain a renewal. Such a precedent would threaten to undermine the very authority of the Department to regulate facilities to promote patient health and safety. That is the authority that RHS openly challenges here.

Like other health-care facilities, abortion facilities are not above the law. RHS is not immune from regulation because it is an abortion facility. "No authority exists to support a conclusion that abortion clinics or abortion providers have a fundamental liberty interest in performing abortions free from governmental regulation." *Greenville Women's Clinic v. Bryant*, 222 F.3d 157, 173 (4th Cir. 2000). By refusing to cooperate in the Department's legitimate investigation, RHS effectively claims a wholesale exemption from the State's valid licensing scheme. No such exemption exists for RHS or any other regulated facility, and this Commission should not acknowledge one. The public interest weighs strongly against RHS's stay request.

CONCLUSION

Respondent the Department of Health and Senior Services respectfully requests that the Commission deny Plaintiff's Motion for Stay. Pursuant to 1 CSR 15-3.320(3), the Department also respectfully requests a hearing to present oral argument on the Motion for Stay.

Dated: June 26, 2019

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that, on June 26, 2019, the foregoing was filed electronically through the Administrative Hearing Commission's electronic filing system, and a true and correct copy was served by electronic mail upon counsel for Petitioner.

/s/ D. John Sauer