**IN THE UNITED STATES DISTRICT COURT**
**WESTERN DISTRICT OF MISSOURI**
**CENTRAL DIVISION**

| | | |
|---|---|---|
| COMPREHENSIVE HEALTH OF PLANNED PARENTHOOD GREAT PLAINS, et al. | ) | |
| Plaintiffs, | ) | Case No. 2:16-cv-04313-HFS |
| v. | ) | |
| DR. RANDALL WILLIAMS, et al., | ) | |
| Defendants. | ) | |

**THE STATE DEFENDANTS' POST-HEARING SUPPLEMENTAL BRIEF IN OPPOSITION TO PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION**

Defendants Hawley and Williams (the "State Defendants") respectfully submit this Post-Hearing Supplemental Brief in Opposition to Plaintiffs' Motion for Preliminary Injunction.

**A. The Court Should Not Enjoin Defendants from Enforcing Critical, Non-Controversial Health and Safety Regulations of Abortion Facilities.**

Plaintiffs seek a sweeping injunction that would prevent the State from enforcing virtually any health-and-safety oversight of abortion facilities. Because Plaintiffs seek an injunction against ***all*** of 19 CSR § 30-30.060, they seek to block the State from (1) requiring basic infection-control procedures at abortion facilities, (2) mandating abortion facilities to adopt quality-assurance programs, (3) performing safety inspections of abortion facilities, and (4) investigating complaints regarding patient care at abortion facilities—among many others. *See* 19 CSR §§ 30-30.060(1)(A)(5), 30-30.060(1)(B)(8), 30-30.060(3)(J), 30-30.060(5). Such an injunction would impose a regulatory blackout on abortion facilities, shielding *all* abortion providers from oversight—including those whom Plaintiffs' expert Dr. Henshaw describes as "the shoddiest operators" and "the worst providers." *See* Megan Twohey, *State Abortion Records Full of Gaps*, CHICAGO TRIBUNE, at 5 (June 16, 2011) (attached as Exhibit 1).

Nothing in *Whole Woman's Health v. Hellerstedt* mandates this regulatory blackout. In *Hellerstedt*, the Supreme Court emphasized that its facial invalidation of Texas's ASC and hospital-privileges requirements would leave in place a large number of ***preexisting*** statutes and regulations that authorized Texas to engage in robust health-and-safety oversight of abortion facilities. *See* 136 S. Ct. 2292, 2314 (2016). The Court observed:

> Prior to enactment of the new requirement, Texas law required abortion facilities to meet a host of health and safety requirements. Under those ***pre-existing*** laws, facilities were subject to annual reporting and recordkeeping requirements, see Tex. Admin. Code, tit. 25, §§ 139.4, 139.5, 139.55, 139.58; ***a quality assurance program***, see § 139.8; personnel policies and staffing requirements, see §§ 139.43, 139.46; physical and environmental requirements, see § 139.48; ***infection control standards***, see § 139.49; disclosure requirements, see § 139.50; patient-rights standards, see § 139.51; and medical- and clinical-services standards, see § 139.53, including anesthesia standards, see § 139.59. These requirements are policed by ***random and announced inspections, at least annually***, see §§ 139.23, 139.31; Tex. Health & Safety Code Ann. § 245.006(a) (West 2010), as well as administrative penalties, injunctions, civil penalties, and criminal penalties for certain violations, see Tex. Admin. Code, tit. 25, § 139.33; Tex. Health & Safety Code Ann. § 245.011 (criminal penalties for certain reporting violations).

*Hellerstedt*, 136 S. Ct. at 2314 (emphases added). Thus, it was central to *Hellerstedt*'s reasoning that "[p]re-existing Texas law already contained numerous detailed regulations covering abortion facilities, including a requirement that facilities be inspected at least annually." *Id.*

By contrast, such "preexisting law" is largely absent in Missouri. Virtually all such noncontroversial oversight will immediately cease in Missouri if Plaintiffs receive their requested relief. Unlike Texas, Missouri imposes such commonsense regulations through the ASC regulatory code, subchapter 30-30.060 of title 19 of the Code of State Regulations, which Plaintiffs seek to enjoin in its entirety. Numerous regulations that remained effective in Texas after *Hellerstedt*—*e.g.*, "annual reporting and recordkeeping requirements," "a quality assurance program," "personnel policies and staffing requirements," "infection control standards," and "random and announced inspections," *id.*—would become defunct in Missouri under Plaintiffs' proposed injunction. *See* Demonstrative Summary Exhibit of Regulations Plaintiffs Seek to

Enjoin (attached as Exhibit 2); *see also* 19 CSR § 30-30.060 (complete copy of 19 CSR § 30-30, attached as Exhibit 3). None of these provisions imposes any undue burden on abortion access.

Further, Plaintiffs seek to enjoin the enforcement of provisions of 19 CSR § 30-30.060 that are plainly constitutional and *independently authorized by other Missouri statutes that Plaintiffs do not challenge*—simply because those provisions happen to be housed in the same subchapter of the Code of State Regulations as the hospital-privileges requirement. These include (1) the requirement that abortion facilities report suspected child abuse, § 30-30.060(1)(B)(2), authorized by Mo. Rev. Stat. § 188.023, which Plaintiffs do not challenge; (2) the requirement that abortions be performed by a physician, § 30-30.060(3)(B), authorized by Mo. Rev. Stat. §§ 188.020, 188.230, 334.245, which Plaintiffs do not challenge; and (3) the requirement that abortion providers seek informed consent before performing abortions, § 30-30.060(3)(H), authorized by Mo. Rev. Stat. § 188.027, of which Plaintiffs challenge only one small subpart, § 188.027.1(1)(e). *See* Ex. 2, at 3. There is no simply basis to enjoin regulations authorized by statutes that Plaintiffs have not even challenged.

Therefore, even if the Court were to accept *all* of Plaintiffs' arguments on the merits, the Court should enjoin the State from enforcing, ***at most***, the physical-plant requirements of § 30-30.070 and the hospital-privileges requirement of 19 CSR § 30-30.060(1)(C)(4). ***The rest of § 30-30.060 consists of entirely non-controversial regulations of abortion facilities that plainly advance women's health and safety, and Plaintiffs have offered no evidence or argument that these regulations are invalid.*** *Hellerstedt* manifestly does not require these other provisions of § 30-30.060 to be enjoined, and this Court should not enjoin them. To do so would immediately empower "the shoddiest operators" and "worst providers" in Missouri to perform abortions entirely free of State oversight. Ex. 1, at 5.

Further, Plaintiffs repeatedly insist that the Court's undue-burden analysis should focus on women who live near the clinics they seek to open, in Springfield, Joplin, Columbia, and Kansas City. *See, e.g.,* Doc. 70, at 3-4. But they request *statewide* relief, including relief as to women who already live within close proximity of the St. Louis facility—for whom the regulations impose no conceivable burden on clinic access—and future unforeseen abortion facilities that are not before this Court. This position is self-contradictory, and the Court should not grant relief so broadly. Injunctive relief—if any—should extend only to these Plaintiffs and these specific facilities at issue in this litigation. Further, because the Kansas City and Columbia facilities are independently governed by the 2010 Settlement Agreement, any injunctive relief should extend, at most, only to the Springfield and Joplin facilities. *See* Doc. 28-1, at 17-36 (2010 Settlement Agreement).

**B. Plaintiffs Understate and Underreport the Physical Risks of Abortion.**

Plaintiffs' experts significantly understate the physical risks of abortion procedures. The "record evidence" in this case, 136 S. Ct. at 2311, demonstrates that there are at least four types of physical complications about which the State is validly concerned. These include: (1) the actual reported complications, produced by RHS's St. Louis facility in discovery, which indicate that abortion in Missouri is significantly riskier than Plaintiffs' experts predict, *see* Doc. 65, at 1-4; (2) the complications known to abortion providers in Missouri that have nevertheless gone unrecorded or unreported, *see infra*; (3) complications that the abortion providers never find out about because the patients seek health care elsewhere, *see* Coleman Declaration, Doc. 56-1, at 6, 10-11; and (4) the complications and injuries from abortion procedures that currently do not occur in Missouri because Missouri ensures that abortions are performed under the safest

possible conditions, but will occur if Plaintiffs receive the overbroad relief they are requesting. Plaintiffs erroneously discount or understate *all* of these risks.

For example, regarding the second risk category, Plaintiffs' counsel stated at oral argument on March 21 that "there is no evidence" of underreporting of abortion complications in the State. Tr. 61. This is plainly incorrect. It appears that Plaintiffs themselves have persistently disregarded their statutory obligation to report abortion complications to the State for the last fifteen years at least. Section 188.052 of the Missouri Revised Statutes requires the filing of two kinds of abortion-related reports: (1) an abortion report for each abortion performed must be filed by the attending physician; and (2) separately, "an individual complication report for any post-abortion care performed upon a woman shall be completed by the physician providing such post-abortion care," in any case where any "abortion complication" is "diagnosed or treated." Mo. Rev. Stat. §§ 188.052.1, 188.052.2. DHSS regulations define the term "complication" broadly—"complication" "includes, but is not limited to, hemorrhage, infection, uterine perforation, cervical lacerations and ***retained products***." 19 CSR § 30-30.050(1)(D) (emphasis added).

Evidence produced in discovery indicates that Plaintiff RHS has diagnosed and treated hundreds of cases of such post-abortion complications at the St. Louis facility in the past five years alone. *See* Doc. 74-1, Exhibit 1 (filed under seal). Accordingly, one would expect that RHS has filed hundreds of post-abortion complication reports with the State. But DHSS records contain no post-abortion complication reports filed by RHS for post-abortion care at the St. Louis facility since 2002. *See* Declaration of Harold C. Kirbey, ¶¶ 6-7 (attached as Exhibit 4). RHS has filed many abortion reports—without providing complication information—over the past 15 years pursuant to the very same statute, but not a single abortion *complication* report. *Id.*

Plaintiffs' disregard of their statutory obligation to report abortion complication closely tracks underreporting problems in other States. For example, a study of similar Illinois records found that Illinois was missing "between 7,000 and 17,000" abortion reports per year, and that "nearly 4,000 reports of abortion complications involving Illinois residents in 2009 were missing the required description" of the nature of the complication. Ex. 1, at 2. Ironically, Plaintiff's expert, Dr. Henshaw, attributed such underreporting to the "shoddiest operators" and "the worst providers." *Id.* at 5. Here, Plaintiffs themselves have engaged in such underreporting.

Further, the problem of underreporting is illustrated by the ambulance records procured by third-party subpoena. The ambulance records enable the State to cross-check Plaintiffs' reports of emergency complications with third-party records. These records are likely underinclusive, because RHS directs its staff not to notify emergency responders that complications resulted from abortion procedures, so ambulance records frequently do not reflect the nature of the complication. But even the limited records procured indicate significant problems of underreporting. For example, in their discovery responses, Plaintiffs reported only two emergency transfers of abortion patients in all of 2012. *See* Doc. 74, Exhibit 1 (filed under seal). But records of ambulance providers, including the City of St. Louis Fire Department and Abbott Ambulance Inc., show at least four emergency transfers of abortion patients in 2012. *See* Excerpts of Abbott Records, attached as Exhibit 5 (to be filed under seal); Excerpts of City of St. Louis Fire Department Records, attached as Exhibit 6 (to be filed under seal).

This problem of underreporting is exacerbated by Plaintiffs' own practices. As noted, Plaintiffs have failed to file mandatory complication reports with the State for fifteen years. Moreover, RHS has a policy of not notifying EMS services that a health emergency was caused by an abortion procedure. *See* RHS Emergency Response Protocol, at RHS000122 (attached as

Exhibit 7) (to be filed under seal). RHS directs its staff who contact emergency responders, "Do NOT give procedural information (i.e. had first trimester…)," to such emergency responders. *Id.* This policy makes it difficult to ascertain from third-party records whether abortion caused any particular health emergency.

### C. The Record Evidence Directly Contradicts Plaintiffs' Claim that the ASC and Hospital-Privileges Requirements Do Not Advance Patient Health and Safety.

At the March 21, 2017, hearing, the Court invited the State Defendants to supplement the record to address Plaintiffs' argument that abortion is similar to gynecological procedures that Plaintiffs claim are commonly provided in a doctor's-office setting. Tr. 44. Plaintiffs' expert Dr. Eisenberg has opined that gynecological procedures such as "surgical completion of miscarriage, diagnostic dilation and curettage, or hysteroscopy" are both "analogous" to abortion "in terms of risk" and "frequently . . . provided in a doctors' office setting." Corrected Eisenberg Decl., Doc. 63-1, ¶ 21. These statements are incorrect and misleading. Such gynecological procedures as D&C and hysteroscopy are typically performed in doctors' offices only in "selected cases," while "they are most commonly performed in a hospital-based operating suite or ambulatory surgical center." Supplemental Declaration of Dr. Andrew Steele, ¶ 2 (attached as Exhibit 8). "It is the common and routine practice to perform D&C's for miscarriage and gynecologic indications, as well as hysteroscopy, in hospitals or ASC's." *Id.* Moreover, based on empirical research, it is not correct that such gynecologic procedures "are equivalent in risk to D&C and D&E for pregnancy termination." *Id.* ¶ 3. Published literature indicates significantly lower complication rates from these procedures from even the dramatically understated figures for abortion complications reported by Plaintiffs. *Id.*

Moreover, this issue illustrates the deeper problems with Plaintiffs' erroneous argument that the ASC and hospital-privileges requirements provide ***no*** health benefits to patients. Outside

the politically charged and heavily litigated area of abortion, it is widely recognized that there are significant health benefits to having surgical procedures to be performed in an ASC by a physician with hospital privileges or a transfer agreement. *See, e.g.,* Steele Decl., Doc. 28-4, ¶¶ 5-7, 9-10, 11, 15, 20. This is especially true of procedures involving even moderate sedation, as abortion frequently does. *Id.* ¶¶ 5-6. In Missouri, procedures that Plaintiffs identify as relevant comparators to abortion—such as colonoscopy, endoscopy, liposuction, cataract surgery, etc.—are routinely provided in ASCs by doctors with hospital privileges, and this arrangement is mandatory if such surgeries form the majority of the facility's practice. This routine practice is evidenced by the fact that Missouri has no less than 120 registered ambulatory surgical centers. List of Missouri's Registered Ambulatory Surgical Centers (attached as Exhibit 9, and available at http://health.mo.gov/safety/asc/pdf/ListofASC2.pdf). Moreover, federal Medicaid regulations require ASCs providing Medicaid-covered services to have precisely the same kind of hospital relationship that Missouri requires of abortion providers. *See* 42 CFR § 416.41(b)(3). Thus, outside the politically charged context of abortion, it is simply not controversial that there are significant health benefits to having all manner of outpatient surgical procedures performed in ASCs by physicians with local hospital privileges and/or a transfer agreement with a local hospital.

**D. Defendants Respectfully Seek Leave to Supplement the Record With Copies of Published Studies Discussed by the Parties' Experts.**

As discussed at the March 21 hearing, Tr. 46, the State Defendants respectfully request leave of the Court to supplement the record with copies of various studies and journal articles discussed by the parties' experts. Though these articles are publicly available secondary sources, it may assist this Court and the reviewing Court to have them readily available for review. These are submitted through a separately filed Memorandum of Filing.

## CONCLUSION

For the reasons stated, the State Defendants respectfully request that this Court deny the Plaintiffs' Motion for Preliminary Injunction.

Respectfully submitted,

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I hereby certify that on the 31st day of March, 2017, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which sent notification to the following:

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# State abortion records full of gaps

## Thousands of procedures not reported to health department

June 16, 2011 | By Megan Twohey, Tribune reporter

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Health care providers are failing to detail abortion complications to the state as required by law, one of many gaps in a surveillance system viewed as crucial to protecting patients, a Tribune review has found.

The state's system for tracking abortions is so broken that regulators also may be missing more than 7,000 of the procedures per year.

The Illinois Department of Public Health must collect details about every abortion performed in the state, including whether the patient is injured or dies.

The mandatory reporting is essential for tracking trends in public health and can provide a window into quality of care. While abortion has proven to be a very safe procedure, heightened rates of complications or clusters of deaths could signal problems with particular providers.

"If people are looking at reports and seeing excessive complications, that might warrant another look or another inspection," said Vicki Saporta, president of the National Abortion Federation, an association of providers.

But there are significant holes in state monitoring of a procedure that affects tens of thousands of Illinois women each year. Nationally, current rates suggest that nearly 1 in 3 women will have an abortion, according to research published in the medical journal Obstetrics & Gynecology.

The Tribune found:

•State regulators have documented between 7,000 and 17,000 fewer abortions a year than a national research group found in Illinois.

•This reporting is the only tool Illinois authorities have to monitor some abortion providers, yet regulators may be allowing doctors and clinics to operate off the books. Regulators collect reports from 26 providers, but the abortion rights research group has identified 37 providers doing business in the state.

•Also unknown to officials are the types of abortion-related problems experienced by women. Nearly 4,000 reports of abortion complications involving Illinois residents in 2009 were missing the required description.

•Health care providers who intentionally fail to submit accurate and complete reports are committing a criminal act, and a failure to report abortion complications is grounds for revoking their licenses, but the Department of Public Health has never sought disciplinary action against a provider.

Kelly Jakubek, an agency spokeswoman, said in a written response that it was the responsibility of abortion doctors to ensure they comply with the mandatory reporting requirement.

Regulators don't respond to the reports in any way, she said, because they view the information as serving statistical purposes only.

"It's outrageous," declared Maurice Stevenson, whose wife died in 2002 from infection following an abortion at a Planned Parenthood clinic in Chicago. "These procedures, complications and deaths should be public record."

Critics contend that accurate government accounting is essential, especially with a politically charged issue such as abortion in which both sides push information to further their agendas.

A review of malpractice cases revealed other abortion-related complications in Illinois — with no way of knowing whether they were reported to the state.

For example, in 2002, after an area woman's uterus was torn in an abortion she began hemorrhaging, went into cardiac shock and was hospitalized for three weeks. Several years later, a mother of three experienced seizure symptoms and slipped into a coma following her abortion at a city clinic. And in 2009, a teenage girl suffered respiratory and cardiac arrest and died immediately following her abortion in a northern suburb, according to court records.

The state Legislature included mandatory reporting in the 1975 Illinois Abortion Law, a compilation of guidelines enacted after the U.S. Supreme Court decision in Roe v. Wade.

Abortion providers succeeded in stripping away many of the law's other requirements, but a 1993 legal settlement between providers and the state retained mandatory reporting "to better protect the health of women undergoing these procedures."

Why does the information matter?

The confidential reports are "very important from both a demographic and public health viewpoint," according to the federal Centers for Disease Control and Prevention, which surveys abortion data collected by the states.

In addition to illuminating trends in unplanned pregnancies and documenting access to abortion, the reports have helped to reveal that certain procedures carry higher risks of complications and that dangers increase exponentially as the pregnancy progresses.

In Illinois, reporting also provides an opportunity to monitor all doctors who perform abortions. Not all abortion providers are licensed as such. The Department of Public Health has licensed 14 providers as ambulatory surgical treatment or pregnancy termination specialty centers.

# State abortion records full of gaps

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But licensing is different in other settings where abortions are performed, including at clinics where surgeries account for less than 50 percent of their business and at private physicians offices.

It is unclear which providers are making reports.

The New York-based Guttmacher Institute, an abortion rights research organization, conducts its own accounting across the country. Its information is widely viewed as more accurate than what is collected by state regulators because the organization makes extensive efforts to identify abortion doctors and follow up with them.

It was Guttmacher that located 37 providers in Illinois in 2008, and it is Guttmacher that has consistently counted thousands more abortions per year than the number recorded by state regulators.

A Tribune examination of the reporting data collected by the state revealed missing information.

Providers often did not specify, as required, whether a complication

was a tear of the uterus or another specific problem.

In certain medical malpractice cases reviewed by the Tribune, women said they were never informed by their provider that the abortion was unsuccessful and later underwent challenging pregnancies, painful deliveries and other complications.

Others suffered anesthesia-related problems, hemorrhaging and infections, according to the suits.

The federal government also identified gaps in Illinois' abortion surveillance system, saying that more than 15 percent of reports in 2007 did not specify how far along pregnancies were and what type of procedure was used.

Jakubek said the numbers of abortion providers documented by Illinois regulators and Guttmacher are different because they use different counting methods. The research organization's tally includes hospitals, clinics and physicians' offices. Jakubek said the 26 providers identified by state regulators "only includes facilities," but declined to elaborate on her definition of facility.

The problem of underreporting isn't limited to abortion, said John Lumpkin, who left the Department of Public Health in 2003 after serving as director for 12 years. But the agency lacks the funds to address it, he said.

"Whether it's flu, food poisoning or pregnancy termination, we knew there was underreporting going on," said Lumpkin, who now directs the Robert Wood Johnson Foundation's Health Care Group. "The health department doesn't have the resources to follow up with every doctor's office that is reporting food poisoning or flu, nor did it have resources to follow up with every provider of pregnancy termination."

Stanley Henshaw, a Guttmacher researcher, has explored abortion reporting problems and "lax enforcement" across the country.

Some providers feared that reports would fall into the hands of anti-abortion protesters or competitors, even though breaches of confidentiality are rare.

Today, Henshaw theorizes it is the shoddiest operators who are not reporting the abortions they perform. Either they refuse to comply or are so off the radar they are unaware of the requirement.

"I think it's only a problem with the worst providers," said Henshaw, who has recommended audits of state abortion reports, a process that would involve verifying who all the providers are.

As safe as abortion is, dangerous providers do exist, made evident by the murder charges filed this year against a Philadelphia abortion doctor whom prosecutors accused of operating a "house of horrors."

Some providers identified by the Tribune refused to discuss reporting.

Others, such as Planned Parenthood and Family Planning Associates, said they were diligent about complying and concerned if others were not.

"It is useful public health information. ... We'd hope all providers would comply," said Carole Brite, president of Planned Parenthood of Illinois.

At the same time, Planned Parenthood could not confirm for the Tribune whether it had reported the 2002 death of Stevenson's wife, only that it had reported the 2008 death of another patient. The organization said it had no reason to believe the 2002 death was not reported but that the records were in storage.

And Family Planning Associates said it could not confirm whether it had reported three deaths, in 1998, 1999 and 2000.

A woman who identified herself as a manager of the Women's Aid Clinic of Lincolnwood would not comment on a 2009 death.

The Tribune identified these deaths as part of its review of malpractice suits.

Providers are required to report all abortion-related deaths to the state, not just those in which the death was directly caused by abortion or those involving wrongdoing on the part of health care workers.

In states with more complete reporting, officials have taken active steps to identify providers and follow up with them.

In Minnesota, doctors are informed of the reporting requirement when they are licensed. And state officials send annual reminders to every physician and press those who submit incomplete forms, said Carol Hajicek of the Minnesota Department of Health, which sends a lengthy report on abortion data to the Legislature each year.

"We think we're getting them all," Hajicek said.

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## Regulations that Plaintiffs Seek to Enjoin

Plaintiffs have provided argument and evidence only regarding the constitutionality of (i) the ASC physical-plant requirements; (ii) the hospital-privileges requirement; and (iii) the hospital-transfer-agreement requirement. But they seek to enjoin ***all*** provisions of Mo. Rev. Stat. §§ 188.027.1(1)(e), 188.080, 197.200, 197.215, and ***all*** provisions of 19 CSR § 30-30.010, 30-30.050, 30-30.060, 30-30.070. This overly broad injunction would reach the following regulations for which the Plaintiffs have offered neither argument nor evidence:

**Examples of Regulations That Plaintiffs Seek to Enjoin For Which There Is No Clear "Fall-Back" Authority to Regulate Under Missouri Law:**

| Regulation | Subject of Regulation | Whether Missouri Has "Fall-Back" Authority to Regulate | Whether Texas Continued to Regulate after *Hellerstedt* |
|---|---|---|---|
| 19 CSR 30-30.060(1)(B)(8)-(9) | Mandates infection control procedures | No clear authority. Overly broad injunction would block state's ability to enforce Mo. Rev. Stat. §§ 197.250, *et seq*., because only hospitals and ambulatory surgical centers are subject to infection control statutes. | Yes. *Hellerstedt* explicitly noted Texas could regulate this aspect. *Hellerstedt,* 136 S.Ct. at 2314 (allowing continued enforcement of "infection control standards"). |
| 19 CSR 30-30.060(1)(A)(5) | Annual inspections | None. Plaintiffs' overly broad injunction would prevent the state from enforcing this requirement, as there is no other governing authority. | Yes. *Hellerstedt* explicitly noted Texas could regulate this aspect. *Hellerstedt,* 136 S.Ct. at 2314 (allowing continued enforcement of "requirement that facilities be inspected at least annually"). |
| 19 CSR 30-30.060(5) | DHSS investigation of complaints | None. Overly broad injunction would prevent the state from enforcing this requirement, as there is no other governing authority. | Yes. *Hellerstedt* explicitly noted Texas could continue to engage in both "random and announced" inspections. 136 S. Ct. 2314. |
| 19 CSR 30-30.060(3)(J)-(K) | Quality assurance program to review complications and other events | None. Overly broad injunction would prevent the state from enforcing this requirement, as there is no other governing authority. | Yes. *Hellerstedt* explicitly noted Texas could regulate this aspect. *Hellerstedt,* 136 S.Ct. at 2314 (allowing continued enforcement of "quality assurance program" requirement). |





EXHIBIT 2

| **Regulation** | **Subject of Regulation** | **Whether Missouri Has "Fall-Back" Authority to Regulate** | **Whether Texas Continued to Regulate after *Hellerstedt*** |
|---|---|---|---|
| 19 CSR 30-30.060(2) | Medical recordkeeping | None. Overly broad injunction would prevent the state from enforcing this requirement, as there is no other governing authority. | Yes. *Hellerstedt* explicitly noted Texas could regulate this aspect. *Hellerstedt,* 136 S.Ct. at 2314 (allowing continued enforcement of "recordkeeping requirements"). |
| 19 CSR 30-30.060(1)(C)(5) | Board certified staff member | None. Overly broad injunction would prevent the state from enforcing this requirement, as there is no other governing authority. | Yes. *Hellerstedt* explicitly noted Texas could regulate this aspect. *Hellerstedt,* 136 S.Ct. at 2314 (allowing continued enforcement of "personnel policies and staffing requirements"). |
| 19 CSR 30-30.060(3) | Staffing requirements | None. Overly broad injunction would prevent the state from enforcing this requirement, as there is no other governing authority. | Yes. *Hellerstedt* explicitly noted Texas could regulate this aspect. *Hellerstedt,* 136 S.Ct. at 2314 (allowing continued enforcement of "personnel policies and staffing requirements"). |
| 19 CSR 30-30.060(3)(I), (L) | Equipment for emergencies | None. Overly broad injunction would prevent the state from enforcing this requirement, as there is no other governing authority. | This was not addressed by *Hellerstedt*. |
| 19 CSR 30-30.060(3)(C) | Pre-abortion exam | None. Overly broad injunction would prevent the state from enforcing this requirement, as there is no other governing authority. | This was not addressed by *Hellerstedt*. |
| 19 CSR 30-30.060(1)(B)(1) | Security obligations | None. Overly broad injunction would prevent the state from enforcing this requirement, as there is no other governing authority. | This was not addressed by *Hellerstedt*. |

**Regulations That Plaintiffs Seek to Enjoin, Even Though They Are Authorized by Statutes that Plaintiffs Do Not Even Challenge:**

| **Regulation** | **Subject of Regulation** | **Whether Missouri Has "Fall-Back" Authority to Regulate** | **Whether Texas Continued to Regulate after *Hellerstedt*** |
|---|---|---|---|
| 19 CSR 30-30.010(2)(D) and 19 CSR 30-30.060(3)(H) | Requires procedures to disclose information to ensure informed consent | Overly broad injunction may impact state's ability to enforce Mo. Rev. Stat. § 188.027, which Plaintiffs have not challenged (except for § 188.027.1(1)(e)). | Yes. *Hellerstedt* explicitly noted Texas could regulate this aspect. *Hellerstedt,* 136 S.Ct. at 2314 (allowing continued enforcement of "disclosure requirements"). |
| 19 CSR 30-30.060(1)(B)(2) | Mandates reporting of suspected child abuse | Overly broad injunction may impact state's ability to enforce Mo. Rev. Stat. § 188.023, which Plaintiffs have not challenged. | Yes. *Hellerstedt* did not address this, but Texas's abuse reporting statute, Tex. Fam. Code Ann. § 33.008, was not enjoined. |
| 19 CSR 30-30.060(3)(B) | Limits individuals other than physicians from providing abortions. | Overly broad injunction may impact state's ability to enforce Mo. Rev. Stat. §§ 188.020, 188.230, and 334.245, which Plaintiffs have not challenged. | Yes. *Hellerstedt* did not address this, but Tex. Health & Safety Code Ann. § 171.003 (prohibiting non-physicians from performing abortions) was not enjoined. |

# Rules of
# Department of Health and Senior Services
## Division 30—Division of Regulation and Licensure
## Chapter 30—Ambulatory Surgical Centers



EXHIBIT 3



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# Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES
## Division 30—Division of Regulation and Licensure
## Chapter 30—Ambulatory Surgical Centers

### 19 CSR 30-30.010 Definitions and Procedures for Licensing Ambulatory Surgical Centers

*PURPOSE: The Division of Regulation and Licensure, Department of Health and Senior Services has the authority to establish rules for ambulatory surgical centers. This rule defines specific terms and presents procedures to follow in making application for a license.*

(1) Definitions.

(A) Administrator means a person who is delegated the responsibility of carrying out the policies and programs established by the governing body.

(B) Ambulatory surgical center. Any public or private establishment operated primarily for the purpose of performing surgical procedures or primarily for the purpose of delivering newborns, and which does not provide services or other accommodations for patients to stay more than twelve (12) hours within the establishment. However, nothing in this definition shall be construed to include the offices of dentists currently licensed under Chapter 332, RSMo.

1. A facility operated primarily for the purpose of performing surgical procedures is one that provides surgical services to fifty-one percent (51%) or more of the patients treated or seen for any health condition, or one that derives fifty-one percent (51%) or more of its revenues from the provision of surgical services or related procedures.

2. The term ambulatory surgical center does not apply to any facility licensed as part of a hospital or any facility used as an office or clinic for the private practice of a physician, dentist or podiatrist.

3. A facility licensed as an ambulatory surgical center shall not use the term hospital in the name of the facility without approval of the Department of Health and Senior Services.

(C) Anesthesiologist. A physician licensed under Chapter 334, RSMo, who has successfully completed a postgraduate medical education program in anesthesiology approved by the Accreditation Council on Graduate Medical Education or the American Osteopathic Association.

(D) Anesthesiologist assistant. A person who meets each of the following conditions:

1. Has graduated from an anesthesiologist assistant program accredited by the American Medical Association's Committee on Allied Health Education and Accreditation or by its successor agency;

2. Has passed the certifying examination administered by the National Commission on Certification of Anesthesiologist Assistants;

3. Has active certification by the National Commission on Certification of Anesthesiologist Assistants;

4. Is currently licensed as an anesthesiologist assistant in the state of Missouri; and

5. Provides health care services delegated by a licensed anesthesiologist.

(E) Certified nurse anesthetist. A registered nurse licensed under Chapter 335, RSMo, who has been graduated from a school of nurse anesthesia accredited by the Council on Accreditation of Educational Programs of Nurse Anesthesia or its predecessor, and is certified or is eligible for certification as a nurse anesthetist by the Council on Certification of Nurse Anesthetists.

(F) Dentist means a person licensed to practice dentistry pursuant to Chapter 332, RSMo.

(G) Department means the Department of Health and Senior Services.

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

(I) Governmental unit means any city, county or other political subdivision of this state, or any department, division, board or other agency of any political subdivision of this state.

(J) Infection control officer. An individual who is a licensed physician, licensed registered nurse, has a bachelor's degree in laboratory science, or has similar qualifications and has additional training or educational preparation in infection control, infectious diseases, epidemiology and principles of quality improvement.

(K) Licensed practical nurse (LPN). A person who holds a valid license issued by the State Board of Nursing pursuant to Chapter 335, RSMo.

(L) Medical staff. A formal organization of physicians which may include dentists and podiatrists who are appointed by the governing body to attend patients within the ambulatory surgical center.

(M) Patient. A person admitted to the ambulatory surgical center by and upon the order of a physician, or dentist, or podiatrist in accordance with the orders of a physician.

(N) Person. Any individual, firm, partnership, corporation, company or association, or the legal successors of any of them.

(O) Physician means a person licensed to practice medicine pursuant to Chapter 334, RSMo and who has active or associate staff membership and privileges in a licensed hospital in the community.

(P) Physician with training or experience in the administration of anesthetics. A person licensed to practice medicine under Chapter 334, RSMo whose training and experience (credentials) have been evaluated by the medical staff and privileges granted to direct the anesthesia service or to administer anesthetics or both.

(Q) Podiatrist means a person licensed to practice podiatry pursuant to Chapter 330, RSMo.

(R) Qualified anesthesia personnel. An anesthesiologist who is a physician with training or experience in the administering of anesthetics, a certified registered nurse anesthetist or an anesthesiologist assistant.

(S) Registered nurse (RN). A person who holds a valid license issued by the State Board of Nursing pursuant to Chapter 335, RSMo.

(T) Root cause analysis. A process for identifying the basic or causal factor(s) that underlie variation in performance, including the occurrence or possible occurrence of a sentinel event.

(U) Sentinel event. An unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injury specifically includes loss of limb or function. The phrase "or the risk thereof" includes any process variation for which a reoccurrence would carry a significant chance of a serious adverse outcome.

(2) Procedure for Licensing.

(A) Application for a license to establish and operate an ambulatory surgical center shall be made in writing to the Department of Health on forms provided by it. Each application for a license, except applications from a governmental unit, shall be accompanied by an annual license fee of two hundred dollars ($200).

(B) In any facility, except hospitals where surgical procedures may be performed or licensed abortion facilities, a license to establish and operate an ambulatory surgical center shall be required in the absence of evidence demonstrating that the facility does not meet the definition established in subsection (1)(A) and paragraph (1)(A)1. of this rule. The evidence required shall include, but need not be limited to, statistical records of individuals treated, individuals receiving surgical procedures, and financial reports including


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revenue from surgical and related procedures and total revenues.

(C) The application shall be made by the person(s) or corporation operating the facility.

(D) A license shall not be issued or renewed by the Department of Health until a facility has been surveyed by a representative of the Bureau of Hospital Licensing and Certification and found to be in substantial compliance with the requirements of 19 CSR 30-30.020 and 19 CSR 30-30.030. Ambulatory surgical centers which also provide abortion services shall comply with the social service and counseling required by the Department of Health for the licensure of abortion facilities in 19 CSR 30-30.060(3)(H).

(E) The licensee shall notify the Department of Health in writing of any change of name of the administration.

(F) Separate licenses are required for facilities maintained on separate sites even though operated by the same owner.

(G) The license shall be conspicuously posted in a public area in the facility.

(H) If a facility ceases to provide patient care or to otherwise operate as an ambulatory surgical center within the definition in section 197.200.1, RSMo 1986 for a period in excess of fourteen (14) days without written approval of the Department of Health, the facility shall surrender its license to the Department of Health. The facility shall not operate again as an ambulatory surgical center until an application for an ambulatory surgical center license is submitted with assurance that the facility complies with the requirements of the rules of this chapter and a license is issued.

(I) An ambulatory surgical center which is licensed as part of a hospital does not require a separate license.

*AUTHORITY: section 197.225, RSMo 2000 and 197.154, RSMo Supp. 2006*. This rule was previously filed as 13 CSR 50-30.010. Original rule filed Dec. 2, 1975, effective Feb. 1, 1976. Amended: Filed Jan. 3, 1990, effective April 12, 1990. Amended: Filed Sept. 20, 2005, effective April 30, 2006. Amended: Filed Jan. 16, 2007, effective Aug. 30, 2007.*

**Original authority: 197.154, RSMo 2004 and 197.225, RSMo 1975, amended 1996.*

**19 CSR 30-30.020 Administration Standards for Ambulatory Surgical Centers**

*PURPOSE: The Division of Regulation and Licensure, Department of Health and Senior Services has the authority to establish standards for the operation of ambulatory surgical centers. This rule provides standards for the administration, medical staff, nursing staff and supporting services to ensure high quality services to users of ambulatory surgical centers.*

*PUBLISHER'S NOTE: The secretary of state has determined that the publication of the entire text of the material which is incorporated by reference as a portion of this rule would be unduly cumbersome or expensive. This material as incorporated by reference in this rule shall be maintained by the agency at its headquarters and shall be made available to the public for inspection and copying at no more than the actual cost of reproduction. This note applies only to the reference material. The entire text of the rule is printed here.*

(1) Organization, Administration, Medical Staff, Nursing Staff and Supporting Services.

(A) Governing Body.

1. The governing body is to establish and adopt bylaws by which it shall abide in conducting all business of the facility. Bylaws so adopted and changes are to be submitted to the Department of Health for its records.

2. Bylaws of the governing body shall provide for the selection and appointment of medical staff members based upon defined criteria and in accordance with an established procedure for processing and evaluating applications for membership. Applications for appointment and reappointment shall be in writing and shall signify agreement of the applicant to conform with bylaws of both the governing body and medical staff and to abide by defined professional ethical standards. Initial appointments to the medical staff shall not exceed twelve (12) months. Reappointments, which may be processed and approved at the discretion of the governing body on a monthly or other cyclical pattern, shall not exceed two (2) years.

3. The governing body shall select and employ an administrator who is a physician licensed in Missouri, a registered nurse (RN) licensed in Missouri or an individual who has at least one (1) year of administrative experience in health care; and shall notify the Department of Health of any change of administration within thirty (30) days after change has been made.

4. The governing body shall require in its bylaws that the ambulatory surgical center and medical staff abide by acceptable professional ethical standards.

5. Representatives of the Department of Health shall have access to inspect the ambulatory surgical center during normal working hours.

6. A written plan shall provide for the evacuation of patients, visitors and personnel in the event of fire or other disaster within the facility and for an alarm system to notify personnel. Personnel are to be acquainted with the evacuation plan to properly perform their duties in the event of a fire or disaster.

7. All fires occurring on the ambulatory surgical center premises shall be reported to the Department of Health within one (1) week giving the cause, location and extent of damage and personal injury, if any.

8. The administrator shall be responsible for the development and enforcement of written policies which prohibit smoking throughout the ambulatory surgical center except specific designated areas where smoking may be permitted. Each designated area shall have one hundred percent (100%) of the air supplied to the room exhausted.

9. Written smoking control policies shall be posted throughout the ambulatory surgical center.

10. Smoking shall be prohibited in any room or compartment where flammable liquids, combustible gases or oxygen are used or stored and in any other hazardous location. Those areas shall be posted with NO SMOKING signs.

11. The administrator shall assure that all patients admitted to the facility are under the care of a physician who is a member of the staff.

12. The administrator shall develop written procedures for receiving and investigating complaints regarding the facility, its physicians, dentists, podiatrists and employees practicing or working in the facility.

13. The administrator shall designate an individual duly qualified to act in his/her capacity during his/her absence.

14. The administrator shall assure the provision of adequate equipment in good repair within the facility to provide efficient services and protection to the patient and staff.

15. Personnel records shall be maintained on each employee and shall include job application, professional licensing information and health information.

16. If a patient is transferred to another health facility, essential medical information, including diagnosis, is to be transmitted with the patient to insure continuity of care.

(B) Medical Staff.

1. The medical staff of an ambulatory surgical center shall be an organized group which shall initiate and adopt, with approval of the governing body, bylaws, rules and policies governing their professional activities in the facility.


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2. Each member of the medical staff shall be a physician, dentist or podiatrist legally licensed to practice in Missouri.

3. Each member of the medical staff shall submit a written application for staff membership on an approved form to the governing body.

4. Surgical procedures shall be performed only by physicians, dentists or podiatrists who at the time are privileged to perform surgical procedures in at least one (1) licensed hospital in the community in which the ambulatory surgical center is located, thus providing assurance to the public that patients treated in the center shall receive continuity of care should the services of a hospital be required. As an alternative, the facility may submit a copy of a current working agreement with at least one (1) licensed hospital in the community in which the ambulatory surgical center is located, guaranteeing the transfer and admittance of patients for emergency treatment whenever necessary.

5. There shall be a chief of staff acceptable to the governing body and other officers and committees as is deemed necessary to meet the goals of the ambulatory surgical center.

6. The medical staff shall develop and utilize appropriate procedures for review and evaluation of surgical practices and techniques at least annually. In those instances when the medical staff membership numbers fewer than three (3), arrangements shall be made with the hospital medical staff where the physicians are privileged or with the medical staff of the hospital guaranteeing the transfer and admittance of patients for emergency treatment for an independent review and evaluation of surgical practices and techniques at least annually. Complete records shall be kept of these reviews and evaluations.

7. The medical staff shall assist in the maintenance of complete records on each patient.

8. The medical staff shall comply with professional ethical standards established, defined and approved by the medical staff.

9. The medical staff of each facility shall develop a policy stipulating which surgically removed tissues shall be sent to the pathologist for review. This policy shall be approved by the governing body.

10. The medical staff shall establish policies for the recommendation of discharge of a member by the governing body.

11. The medical staff bylaws shall require at least one (1) physician member of the medical staff to be on duty in the ambulatory surgical center at all times a patient is receiving or recovering from an anesthetic (local, general or intravenous sedation). Staffing shall be adequate to meet the needs of the patients.

12. The medical staff, as a body or through a committee, shall review and evaluate the quality and appropriateness of all aspects of medical care given at the facility.

13. The administrator shall bring to the attention of the chief of the professional staff any failure by members of that staff to conform with established policies of the facility regarding administrative matters, professional standards and the maintenance of adequate medical records.

(C) Nursing Services.

1. There shall be an organized nursing service under the direction of a professional RN with postgraduate education or experience in surgical nursing.

2. There shall be at least one (1) professional RN on duty in the ambulatory surgical center at all times a patient is in the facility.

3. Written policies and procedures consistent with generally accepted nursing practices are to be developed for the direction and guidance of nursing personnel.

4. All licensed practical nurses and other nursing personnel involved in patient care shall be under the direct supervision of a professional RN.

5. At least one (1) professional RN other than the individual administering anesthesia shall be available in each operating room during surgical procedures.

6. At least one (1) RN shall be in the recovery room during the patients' postanesthetic recovery period at a ratio of no more than four (4) patients to one (1) nurse.

7. Nursing personnel are to be familiar with the location, operation and use of electrocardiogram (EKG or ECG) equipment, pulse oximeter, blood pressure equipment and emergency and resuscitative equipment.

8. There shall be a mechanism for the review and evaluation on a regular basis of the quality and appropriateness of nursing services.

9. Policies shall be developed regarding the use of overtime. The policies shall be based on the following standards:

A. Overtime shall not be mandated for any licensed nursing personnel except when an unexpected nurse staffing shortage arises that involves a substantial risk to patient safety, in which case a reasonable effort must be applied to secure safe staffing before requiring the on-duty licensed nursing personnel to work overtime. Reasonable efforts undertaken shall be verified by the ambulatory surgical center. Reasonable efforts shall include pursuing all of the following:

(I) Reassigning on-duty staff;

(II) Seeking volunteers to work extra time from all available qualified nursing staff who are presently working;

(III) Contacting qualified off-duty employees who have made themselves available to work extra time, per diem staff, float pool and flex team nurses; and

(IV) Seeking personnel from a contracted temporary agency or agencies when such staffing is permitted by law or an applicable collective bargaining agreement and when the employer regularly uses the contracted temporary agency or agencies;

B. In the absence of nurse volunteers, float pool nurses, flex team nurses or contracted temporary agency staff secured by the reasonable efforts as described in (1)(C)9.A. and if qualified reassignments cannot be made, the ambulatory surgical center may require the nurse currently providing the patient care to fulfill his or her obligations based on the Missouri Nurse Practice Act by performing the patient care which is required;

C. The prohibition of mandatory overtime does not apply to overtime work that occurs because of an unforeseeable emergency or when an ambulatory surgical center and a subsection of nurses commit, in writing, to a set, predetermined staffing schedule or prescheduled on-call time. An unforeseeable emergency is defined as a period of unusual, unpredictable or unforeseeable circumstances such as, but not limited to, an act of terrorism, a disease outbreak, adverse weather conditions, or natural disasters which impact patient care and which prevent replacement staff from reporting for duty;

D. The facility is prohibited from requiring a nurse to work additional consecutive hours and from taking action against a nurse on the grounds that a nurse failed to work the additional hours or when a nurse declines to work additional consecutive hours beyond the nurse's predetermined schedule of hours because doing so may, in the nurse's judgement, jeopardize patient safety;

E. Subparagraph 19 CSR 30-30.020(1)(C)9.D. is not applicable if overtime is permitted under subparagraphs 19 CSR 30-30.020(1)(C)9.A., B., and C; and

F. Nurses required to work more than twelve (12) consecutive hours under subparagraphs 19 CSR 30-30.020(1)(C)9.A., B., or C. shall be provided the option to have at least ten (10) consecutive hours of uninterrupted off-duty time immediately following the worked time.

(D) Emergency Equipment.

1. Equipment shall be provided to handle emergencies resulting from the services


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rendered in the facility. The following shall be provided as a minimum: portable ECG oscilloscope, portable defibrillator, portable suction equipment, inhalation-resuscitation equipment, emergency tray and equipment for use in airway obstructions.

2. Procedures are to be developed to insure that emergency equipment is kept in good working order.

(E) Anesthesia Service.

1. The anesthesia service shall be under the direction of an anesthesiologist or a physician with training or experience in the administration of anesthetics. The clinical privileges of qualified anesthesia personnel shall be reviewed by the director of anesthesia service and the medical staff and approved by the governing body.

2. An anesthesiologist or physician with training or experience in the administration of anesthetics shall be on the premises and readily accessible during the administration of anesthetics—whether local, general or intravenous sedation—and the postanesthetic recovery period until all patients are alert or medically discharged. Qualified anesthesia personnel shall be present in the room throughout the conduct of all general anesthetics, regional anesthetics and monitored anesthesia care and shall continually evaluate the patient's oxygenation, ventilation, circulation and temperature. Oxygen analyzers, pulse oximeter and electrocardiography equipment shall be available.

3. Policies and procedures on the administration of anesthetics and drugs which produce conscious and deep sedation shall be developed by the medical staff in consultation with at least one (1) anesthesiologist and approved by the governing body.

4. Prior to undergoing general anesthesia, patients shall have a history and physical examination by a physician on the patient's record including the results of any necessary laboratory examinations. Each administration of a regional, general or intravenous sedation anesthetic shall be ordered by an anesthesiologist or a physician with training and experience in the administration of anesthetics. The patient records shall contain a preanesthetic evaluation and a postanesthetic note by qualified anesthesia personnel.

5. Periodic inspections shall be made of all areas where flammable anesthetics are administered or stored to insure safeguards are being observed by personnel and equipment meets safety standards. A written record of inspections shall be kept. If the administration of the facility provides written assurance to the Department of Health and Senior Services that no flammable anesthetics will be administered and the area is posted to that effect, safety inspections will not be required.

6. All anesthetics shall be administered by anesthesiologists, physicians with training or experience in the administration of anesthetics, certified registered nurse anesthetists or anesthesiologist assistants supervised by an anesthesiologist, except for local anesthetic agents which may be administered by the attending physician, dentist or podiatrist. Notwithstanding the provisions of sections 334.400 to 334.430, RSMo, or the rules of the Missouri State Board of Registration for the Healing Arts, the governing body of every ambulatory surgical center shall have full authority to limit the functions and activities that an anesthesiologist assistant performs in such ambulatory surgical center. Nothing in this paragraph shall be construed to require any ambulatory surgical center to hire an anesthesiologist who is not already employed as a physician prior to August 28, 2003.

7. Written procedures and criteria for discharge from the recovery service shall be approved by the medical staff.

8. There shall be a mechanism for the review and evaluation on a regular basis of the quality and scope of anesthesia services.

(F) Medical Records.

1. A medical record shall be maintained for every patient cared for in an ambulatory surgical center.

2. Medical records are to be filed for easy accessibility and available for inspection by duly authorized representatives of the Department of Health.

3. The medical record shall support the diagnosis or need for medical services and shall include the following: patient identification; chief complaint, pertinent history and preoperative physician's physical exam, including copies of any laboratory, X-ray, pathology, anesthesia record, preanesthesia and postanesthesia evaluation record and consultation reports; description of surgical procedures, treatments or observations on care provided, including complications, if any; signature or initials of physician on each clinical entry; signature or initials of nursing personnel on notes or observations; condition of patient on discharge; instructions given to patient on release from facility; copy of transfer form if patient is transferred to another health facility; and operative and anesthesia consent forms.

4. The facility shall establish and have approved by the facility governing body a medical record retention policy that meets its needs for clinical, educational, statistical or administrative purposes. All medical records shall be safeguarded against loss and unofficial use.

(G) Sterilizing and Supply.

1. Policies and procedures shall be established in writing for storage, maintenance and distribution of supplies and equipment.

2. Sterile supplies and equipment shall not be mixed with unsterile supplies and shall be stored in dustproof and moisture-free units. They shall be properly labeled.

3. Sterilizers and autoclaves shall be provided of appropriate type and necessary capacity to adequately sterilize instruments, utensils, dressings, water, operating room materials, as well as laboratory equipment and supplies. The sterilizers shall have approved control and safety features. The accuracy of instruments shall be checked periodically by an approved method. Adequate surveillance methods for checking sterilization procedures shall be employed. When contractual arrangements for sterile supplies, equipment and instruments have been approved by the Department of Health, on-premises sterilizing equipment is not required other than the required highspeed sterilizer.

4. The date of sterilization or date of expiration shall be marked on all sterile supplies and unused items shall be resterilized in accordance with written policies.

(H) Radiological and Pharmaceutical Services.

1. For radiology services performed in the center, the rules authorized by section 192.420, RSMo shall be met. Radiation protection shall be provided in accordance with 19 CSR 20-10.010—19 CSR 20-10.200 and the recommendations of the National Council on Radiation Protection and Measurements. There shall be written policies and procedures and records shall be kept of at least annual checks and calibrations of all X-ray and gamma beam therapy equipment. Only qualified personnel shall operate radiological equipment.

2. The use of drugs in the facility shall be under the direction of a designated individual in accordance with accepted standards of practice and applicable state and federal laws. There shall be procedures relating to procuring, storage, security, records, labeling, preparation, orders, administration, adverse reactions and disposal or other disposition of drugs. There shall be specific procedures for controlled drug security and recordkeeping.

3. All radiological services shall be under the direction of a qualified physician.

4. There shall be a mechanism for the review and evaluation on a regular basis of the quality and scope of radiological and pharmaceutical services.

(I) Laboratory Services.


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1. Laboratory procedures performed in an ambulatory surgical center shall be limited to routine tests (such as hemoglobin, hematocrit, leucocyte count, glucose, urinalysis and pregnancy tests). Laboratory services obtained under contract shall be from a laboratory located in a hospital licensed under section 197.010, RSMo 1986 or from a laboratory certified as an independent laboratory by the federal Health Care Financing Administration.

2. Procedures performed in the facility shall be appropriate for the services provided and shall be performed according to written or printed instructions. Instructions shall include calibration and control methods that assure the accuracy and precision of each patient test. Equipment shall be calibrated and maintained in conformance with manufacturers' instructions. All instructions shall be available in the facility.

3. The facility shall have access to a blood bank located in a hospital licensed under section 197.010, RSMo 1986 or to a regional blood center licensed by the federal Food and Drug Administration to provide blood for transfusion purposes. The blood bank or blood center shall have crossmatching capability and written procedures for investigating transfusion reactions.

4. Laboratory services shall be under the direction of a physician member of the medical staff.

(J) Supportive Services.

1. Provision shall be made in writing for the laundering and processing of institutional linen and washable goods. Services may be provided by an on-premises laundry operated by the facility or by an outside laundry through contractual agreement.

2. If food services are provided, services shall comply with 19 CSR 20-1.010.

(K) Infection Control.

1. There shall be an active multidisciplinary infection control committee responsible for implementing and monitoring the infection control program. The committee shall include, but not be limited to, the infection control officer, a member of the medical staff, registered professional nursing staff, quality improvement staff and administration. This program shall include measures for preventing, identifying, and investigating healthcare-associated infections (HAI) and shall establish procedures for: collecting data, conducting root cause analysis, reporting sentinel events and implementing corrective actions. These measures and procedures shall be applied throughout the ambulatory surgical center, including as part of the employee health program.

2. The ambulatory surgical center shall provide reports to the department as required by 19 CSR 10-33.050.

3. The infection control committee shall conduct an ongoing review and analysis of HAI data and risk factors. Priorities and goals related to preventing the acquisition and transmission of potentially infectious agents will be established based on risks identified.

4. Ambulatory surgical centers shall implement written policies and procedures outlining infection control measures for all patient care and support departments. These measures shall include, but are not limited to, an ambulatory surgical center-wide hand hygiene program that complies with the current Centers for Disease Control and Prevention (CDC) *Guideline for Hand Hygiene in Health-Care Settings*, which is incorporated by reference in this rule. A copy of the CDC *Guideline for Hand Hygiene in Health-Care Settings* may be obtained from the Superintendent of Documents, U.S. Government Printing Office (GPO), Washington, DC 20402-9371; telephone: (202) 512-1800. This rule does not incorporate any subsequent amendments or additions. At a minimum, the program shall require every health care worker to properly wash or sanitize his or her hands immediately before and immediately after each and every episode of patient care. Procedures shall include, at a minimum, requirements for the facility's infection control program to conduct surveillance of personnel in accordance with section 197.150, RSMo. Surveillance procedures also may include monitoring the employees' and medical staff's use of hand hygiene products. A mechanism approved by the ambulatory surgical center infection control committee for reporting and monitoring patient and employee infections shall be developed and implemented for all patient care and support departments in the ambulatory surgical center.

5. Orientation and ongoing education shall be provided to all personnel on the cause, effect, transmission and prevention of infections.

6. There shall be a mechanism for the review and evaluation on a regular basis of the quality and effectiveness of infection control throughout the facility.

(L) Any person having a complaint pertaining to the care rendered a patient in an ambulatory surgical center may direct the complaint in writing to the Missouri Department of Health, Bureau of Hospital Licensing and Certification, P.O. Box 570, Jefferson City, MO 65102. The person making the complaint shall be contacted by the Department of Health within five (5) working days of receipt of the complaint and the complaint shall be investigated by the Department of Health within twenty (20) working days of receipt of the complaint.

(M) Requests for deviations from the requirements of this rule shall be in writing to the Department of Health. Requests and approvals shall be made a part of the permanent Department of Health records for the facility. Licensed ambulatory surgical centers participating in innovative projects may be granted a waiver of exemption from certain requirements. Waivers may be granted by the chief of the Bureau of Hospital Licensing and Certification with the approval of the director of the Division of Health Resources.

*AUTHORITY: section 197.225, RSMo 2000 and 197.154, RSMo Supp. 2006.* This rule was previously filed as 13 CSR 50-30.020. Original rule filed Dec. 2, 1975, effective Feb. 1, 1976. Amended: Filed June 14, 1988, effective Oct. 13, 1988. Amended: Filed Jan. 3, 1990, effective April 12, 1990. Amended: Filed Sept. 20, 2005, effective April 30, 2006. Amended: Filed Jan. 16, 2007, effective Aug. 30, 2007.*

**Original authority: 197.154, RSMo 2004 and 197.225, RSMo 1975, amended 1996.*

**19 CSR 30-30.030 General Design and Construction Standards for Ambulatory Surgical Centers**

*PURPOSE: The Division of Health Resources, Department of Health has the authority to establish construction standards for ambulatory surgical centers. This rule provides standards for facilities to ensure sanitary and fire-safe facilities.*

*PUBLISHER'S NOTE: The publication of the full text of the material that the adopting agency has incorporated by reference in this rule would be unduly cumbersome or expensive. Therefore, the full text of that material will be made available to any interested person at both the Office of the Secretary of State and the office of the adopting agency, pursuant to section 536.031.4, RSMo. Such material will be provided at the cost established by state law.*

(1) All new ambulatory surgical centers and additions to and remodeling of existing licensed ambulatory surgical centers shall be designed to provide all of the facilities required by this rule and fire-safety standards, arranged to accommodate with maximum convenience all of the functions required by this rule and arranged to provide comfortable, attractive, sanitary, fire-safe,


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secure and durable facilities for the patients. This rule is applicable to ambulatory surgical centers which began operation or construction or renovation of a building to operate an ambulatory surgical center on any date after April 12, 1990. Existing ambulatory surgical centers licensed by the Department of Health prior to April 12, 1990 shall be maintained in compliance with the rules under which they were initially licensed and are not required to comply with the construction requirements for new ambulatory surgical centers until they are remodeled or expanded. The Department of Health, within its discretion and for good reason, may grant exceptions to this rule. These exceptions shall be in writing and shall be made a part of the Department of Health records for the facility.

(A) General Construction—Related Authorities.

1. Construction of all ambulatory surgical centers and additions to or remodeling of ambulatory surgical centers shall comply with all local and state regulations and codes.

(B) Planning and Construction Procedure.

1. Plans and specifications complying with 19 CSR 30-30.040 shall be prepared for the construction of all ambulatory surgical centers and any additions to and remodeling of ambulatory surgical centers. Plans for ambulatory surgical centers which in addition to other surgical procedures will offer abortion services shall incorporate facilities for patient counseling as required for licensed abortion facilities in 19 CSR 30-30.070(2)(Z). The plans and specifications shall be prepared by an architect or a professional engineer licensed to practice in Missouri. The plans and specifications shall have received written approval of the Department of Health prior to the submission of an application for licensure of the new facility. The license for a new ambulatory surgical center will not be issued prior to the facility being inspected and found in substantial compliance with this rule.

2. The Department of Health shall be notified within five (5) days after construction begins. If construction of the project is not started within one (1) year after the date of approval of the plans and specifications, the plans and specifications shall be amended if necessary to comply with the then current regulations before construction work commences (see 19 CSR 30-30.040 Preparation of Plans and Specifications for Ambulatory Surgical Centers).

(C) Site.

1. Adequate vehicular and pedestrian access shall be provided within the lot lines to the main entrance, ambulance entrance, community activities and services, including loading and unloading space for delivery trucks. Roads, walks, ramps and entrances shall be accessible to the physically handicapped. Details for accommodation of the handicapped shall be consistent with the guidelines contained in *A Guidebook to: The Minimum Federal Guidelines & Requirements for Accessible Design* published January 6, 1981, by the United States Architectural and Transportation Barriers Compliance Board.

2. Adequate off-street parking shall be provided. Space shall be provided at the ratio of two (2) spaces for each patient cart in the recovery room plus parking space to accommodate the maximum number of staff on duty at any one (1) time. A minimum of two (2) handicapped-accessible parking spaces shall be provided for use by the staff and patients.

3. Plans for proposed new ambulatory surgical centers and additions to ambulatory surgical centers should be reviewed by the local fire protection agency assigned to that area. Fire lanes shall be provided and kept clear to provide immediate access for fire-fighting equipment.

(D) General Design—Facilities.

1. The arrangement of the physical plant shall provide for separation of the administrative, business and public areas from patient service areas.

A. Administrative area—at a minimum shall consist of a business office with information center and telephone, administrator's office, medical records storage (may be in patient service area), sufficient to satisfy the requirements of 19 CSR 30-30.020(1)(F)4., lobby and waiting room, telephone available to public, handicapped-accessible public toilets for each sex, handicapped-accessible drinking fountain, and janitor's closet.

B. Patient service areas—at a minimum shall consist of two (2) or more patient change areas per sex with access to toilets; secure storage facilities for each patient's street clothing and belongings; staff lounge with storage for staff's clothing and personal effects, and handwashing facilities; examination room of at least one hundred (100) square feet with handwashing facilities; preoperative holding room sized for at least two (2) patients per operating room with each patient location being at least thirty-five (35) square feet; janitors' closet with sufficient space for equipment for maintaining the patient service area; laboratory, unless provisions have been made for off-premises laboratory services; postanesthesia recovery room with handwashing facilities, sized to accommodate at least two (2) patient stretchers per operating room with three feet (3') of clear space around the sides and foot of each stretcher; nurses' work station with medication storage and preparation facilities, storage space for emergency equipment; doctors' dressing room, toilet and handwashing facilities arranged to provide a one (1)-way traffic pattern so that personnel entering from outside surgery can change and move directly into the surgical suite corridor; nurses' dressing room, toilet and handwashing facilities; one (1) scrub-up facility for each operating room; materials processing facilities including a decontamination utility room with workcounter, sink, clinic sink with bedpan cleanser and space for holding soiled materials and trash, and a pass-thru window to an adjacent clean workroom with workcounter, sink, high speed sterilizer and space for storing sterilized and packaged clean supplies; and one (1) or more operating rooms.

(I) Operating rooms shall have a floor area of not less than two hundred twenty-five (225) square feet with a minimum dimension of not less than fifteen feet (15').

(II) The administration of general anesthetics in new ambulatory surgical centers is restricted to nonflammable agents. Any new ambulatory surgical center desiring to administer flammable anesthetics shall first receive the written permission of the Missouri Department of Health and will be required to include National Fire Protection Association (NFPA) safety design features for flammable anesthetizing locations into the building.

C. Support facilities—space for mechanical equipment, standby electric generator with automatic transfer switch, medical gas storage, housekeeping supply storage and a general storage room providing at least one hundred (100) square feet per operating room.

(E) General Design—Details.

1. A continuous system of unobstructed corridors and aisles shall extend through the enclosed portion of each story of the facility, connecting all rooms and spaces with each other and with all entrances, exitways and elevators except that mechanical equipment space need not be connected to the corridor system. Corridors providing access to operating rooms and postanesthesia recovery rooms shall be at least eight feet (8') wide, all other corridors shall be at least five feet (5') wide.

2. At least two (2) exits, remote from each other, shall be provided for each floor.

3. Exit doors and doors to operating rooms and recovery rooms shall be at least forty-four inches (44") wide. All other doors through which patients and personnel will pass shall be at least thirty-two inches (32") wide.

4. The width of stairways except stairways, to mechanical spaces, shall not be less than forty-four inches (44").

5. Exit discharge doors shall swing in the direction of exit traffic.

6. Ceilings in operating rooms shall not be less than nine feet (9'). Ceilings in all


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other rooms shall not be less than eight feet (8'), except that ceilings in corridors and storage rooms may be seven feet six inches (7' 6").

7. Ceilings in operating rooms shall have a smooth washable surface. All other ceilings may be of acoustical material.

8. The floor finish in operating rooms shall be seamless with an integral base covered with the floor and tightly sealed with the wall.

9. Walls shall be smooth and easily cleanable. Walls in operating rooms and recovery rooms shall have waterproof painted, glazed or similar washable surfaces.

10. Floors in the lobby, waiting room and offices shall be easily cleanable. Floors in operating rooms and recovery rooms shall be smooth, slip-resistant and washable.

11. Wall and ceiling surfaces of all required corridors and exitways shall be of a material treated so it does not have a flame-spread classification of more than twenty-five (25) according to the method for the *Fire Hazard Classification of Building Materials* of Underwriters' Laboratories, Inc. Rooms and small office spaces shall have wall and ceiling surfaces with a flame-spread rating of not more than seventy-five (75) when tested according to American Society of Testing and Materials (ASTM) Standard E-84. All floor covering shall have a minimum flame-spread rating of forty-five one hundredths (0.45) watts per square centimeter when tested according to NFPA 253-1978 (Flooring Radiant Panel Test).

12. Paper towel dispensers and soap dispensers shall be provided at all lavatories used for handwashing.

(F) Fire Safety Construction—Specifications and Details.

1. One (1)-story buildings shall be of not less than Type II (111) construction as described in the *Standard on Types Building Construction 1979* published by the NFPA. Fully sprinklered one (1)-story buildings may be of type II (000) construction.

2. Multistory buildings shall be of not less than Type II (222) construction. Fully sprinklered multistory buildings may be of not less than Type II (111) construction.

3. Walls enclosing stairways, elevator shafts, other vertical openings between floors and boiler rooms shall be of construction having a fire rating not less than that required for the structure.

4. The number of stories in any building housing an ambulatory surgical center shall be determine by counting the number of occupiable levels in the structure regardless of their location above or below grade.

5. Ambulatory surgical centers with a floor area of two thousand (2000) square feet or more shall be divided by one (1)-hour rated walls into at least two (2) smoke zones; each zone not exceeding one hundred fifty feet (150') in any dimension. Each smoke zone shall have at least one (1) means of egress which discharges directly to the outside.

6. In a building of multitenant occupancy, the ambulatory surgical center and the entirety of the surgical center's access to exit system shall be separated from other tenants by walls having a fire-resistance rating of at least one (1) hour.

7. Smoke detectors shall be installed in all habitable spaces in the ambulatory surgical center and in the access to exit corridor system at intervals not exceeding seventy-five feet (75') and no more than thirty feet (30') from the ends of corridors.

(G) Elevators.

1. If patient services are located on any floor other than the grade level, at least one (1) elevator is to be provided.

2. Inside dimensions of the elevator shall be at least five feet by seven feet (5'×7') clear inside to accommodate a wheeled stretcher and attendants. The elevator car door shall have a clear opening of not less than forty-four inches (44").

(H) Electrical Requirements.

1. Every room, including storage rooms, corridors and all other areas shall be sufficiently illuminated to facilitate efficient performance of all necessary work.

2. Operating and recovery rooms shall have general lighting in addition to special lighting units at the surgical tables and for each recovery unit.

3. All sources of light and power in the operating room shall comply with the *Standard for the use of Inhalation Anesthetics (Flammable and Nonflammable 1978)* published by the NFPA.

4. An approved automatically-operated, electrically-powered fire alarm system which will alert all areas of the facility when activated shall be installed including audible and visual alarm devices located throughout the ambulatory surgical center and its access-to-exit corridor system, manual pull stations near each exit door. The fire alarm system shall be interconnected with all required smoke detectors and extinguishment systems, if provided. The fire alarm system shall be connected directly to the fire department or a dispatch service.

5. An intercom, nurse call system or other means of communication connecting each operating room and the recovery room area to a constantly staffed location shall be installed to summon assistance during emergencies.

6. A generator with on-site fuel storage for at least four (4) hours of operation under load shall be provided as an emergency source of electricity and connected by an automatic transfer switch to certain circuits for lighting and power. The emergency electrical service shall be installed and arranged so that full voltage and frequency is available and supplying power to emergency loads within ten (10) seconds after normal power is interrupted. Emergency electric services shall be provided for the following:

A. Lighting—exitways, including exit signs; all operating room lights; all recovery room lights; minimal task lighting in all clinical areas; generator set location; and elevator if required; and

B. Power—all alarm systems; receptacles in operating and recovery rooms; the operating room communication system; the pump for central suction system, if provided; and elevator, if required.

(I) Heating, Ventilating and Air-Conditioning Equipment.

1. Air-conditioning, heating and ventilating equipment shall be provided, maintained and operated so as to provide an adequate degree of comfort to all occupants.

2. All air delivered to operating rooms shall be delivered at or near the ceiling of the room served and all air returned or exhausted shall be removed near the floor level. At least two (2) return or exhaust outlets shall be used in each operating room and located not closer than three inches (3") to the floor and not more than twelve inches (12") above the floor.

3. The ventilation systems shall be designed and balanced to provide the pressure relationship shown in Table I.

4. For the clinical areas, requirements for outdoor air changes may be deleted or reduced and total air changes per hour supplied may be reduced to twenty-five percent (25%) of the figures listed in Table I when the room is unoccupied and unused, provided that indicated pressure relationships are maintained. An interconnect with the general illumination light switch for each operating room shall be included to insure that the required ventilation rates including outdoor air are automatically resumed upon reoccupancy of the space. This does not apply to certain areas such as toilets and storage which would be considered as in use even though unoccupied.


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**TABLE I**
**Pressure Relationships and Ventilation of Certain Areas**

| Area Designation | Pressure Relationship to Adjacent Areas | Minimum Air Changes of Outdoor Air Per Hour | Minimum Total Air Changes Per Hour | All Air Exhausted Directly to Outdoors | Recirculated Within Room |
|---|---|---|---|---|---|
| Operating Room | P | 5 | 15 | Optional | No |
| Recovery | P | 2 | 26 | Optional | No |
| Patient Area Corridor | E | 2 | 24 | Optional | No |
| Treatment Room | E | 2 | 6 | Optional | No |
| Laboratory | N | 2 | 6 | Optional | No |
| Soiled Workroom | N | 2 | 4 | Yes | No |
| Clean Workroom | P | 2 | 4 | Optional | Optional |
| Toilet Room | N | | 10 | Yes | No |
| Janitor's Closet | N | | 10 | Yes | No |

P=Positive N=Negative E=Equal


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5. Ventilation systems for the surgical suite which includes the operating rooms, surgical corridor and support areas, and recovery rooms shall have two (2) filter beds. Filter bed no. 1 shall be located upstream of the air-conditioning equipment and have an efficiency rating of not less than twenty-five percent (25%). Filter bed no. 2 shall be located downstream of the air-conditioning equipment and have an efficiency rating of not less than ninety percent (90%). The ventilation systems serving all other areas shall have at least one (1) filter having an efficiency rating of not less than twenty-five percent (25%).

6. Space and access panels shall be provided for the easy maintenance and replacement of all filters installed in the ventilation equipment.

7. Ducts supplying air to the operating suite and recovery rooms shall be externally insulated downstream from the final filter.

8. Variable volume-ventilation systems may be used only in the administrative areas of ambulatory surgical centers.

(J) Plumbing.

1. The requirements of the current edition of the *National Plumbing Code* shall be complied with insofar as they may apply and to the extent they are not superseded by requirements specifically stated in these regulations.

A. Systems shall be designed to supply water to the fixtures and equipment on every floor at a minimum pressure of fifteen pounds per square inch (15 psi) during maximum demand periods.

B. Each water service main, branch main, riser and branch to a group of fixtures should be valved. Stop valves shall be provided at each fixture.

C. Hot, cold and chilled water piping and waste piping on which condensation may occur shall be insulated. Insulation of cold and chilled water lines shall include an exterior vapor barrier.

D. Backflow preventers (vacuum breakers) shall be installed on hose bibbs and on all fixtures to which hoses or tubing can be attached such as janitor's sinks and laboratory fixtures.

E. Hot water distribution systems with recirculating loops and pumps shall be arranged to provide hot water service at each fixture at all times.

F. The hot water-heating equipment shall have sufficient capacity to supply the water at temperatures between one hundred five degrees and one hundred fifteen degrees Fahrenheit (105°F–115°F) at a rate not less than five (5) gallons per hour per recovery stretcher.

G. Lavatories and sinks in patient service areas shall have the water supply spout mounted so that its discharge point is a minimum distance of five inches (5") above the rim of the fixture. All lavatories used by medical and nursing staff and food handlers except those in public toilets shall be trimmed with valves which can be operated without the use of hands.

H. Scrub sinks shall be equipped with faucets which can be operated without the use of hands.

*AUTHORITY: section 197.225, RSMo 1986. This rule was previously filed as 13 CSR 50-30.030. Original rule filed Dec. 2, 1975, effective Feb. 1, 1976. Amended: Filed Jan. 3, 1990, effective April 12, 1990.*

**19 CSR 30-30.040 Preparation of Plans and Specifications for Ambulatory Surgical Centers**

*PURPOSE: The Division of Health Resources, Department of Health has the authority to establish construction standards for ambulatory surgical centers. This rule provides procedures to follow in the submission of plans and specifications for new construction.*

(1) Preliminary Plans and Sketches.

(A) When construction is contemplated, either for new buildings additions to existing buildings or material alterations to existing buildings, the preliminary plans or sketches shall be submitted in duplicate to the Department of Health for review and approval before the preparation of working drawings is undertaken. The preliminary plans may be reviewed by the Department of Health in schematic form, but before they are declared acceptable for procedure with working drawings and specifications, they should also include the following information, stated briefly and not in detailed form required in working drawings and specifications:

1. Site plan showing scale, orientation, street names, topography, walks, drives, fire lanes, parking areas and utilities including fire hydrant location;

2. Plans and elevations of the buildings at a scale of not less than one-eighth inch to one foot no inches (1/8":1' 0");

3. Rooms and corridors, designated by name and number;

4. Windows. Note, wired glass where it is required;

5. Doors, including door swings. Identify fire doors by time rating and Underwriters' Laboratories label;

6. Plumbing fixtures. Show fixtures in proper shape and scale for positive recognition. Identify special types such as service sinks and clinic sinks;

7. Plans of rooms shall indicate principal items of furniture accurately scaled;

8. All other principal items of equipment such as boilers, chiller, cooling tower, electrical substations, tanks, air handlers, fan-coil units, kitchen equipment, laundry equipment, cabinets, counters and any other items which take up space and affect the final layout;

9. Fire and smoke-barrier partition designations;

10. Floor lines, top ceiling line and grade lines, designated and preferably dimensioned, and with basic elevations shown;

11. Ceiling heights of principal rooms and also of each room for which the rules establish a minimum ceiling height. Only one (1) typical room of a group need be so shown;

12. Area of each room for which the rules establish a minimum area. Only one (1) typical room of a group need be so noted; and

13. Brief noted descriptions of the general construction and finish; the structural system; the heating, ventilating and air-conditioning systems, including the fuel supply; the plumbing system including the water supply and sewage disposal; and the electrical system.

(B) In the case of a project which is an addition to an existing building, it will be necessary to give the Department of Health sufficient information about the existing building on which to base a determination of acceptability of the plans for the addition. This information shall cover all items required to be provided in an ambulatory surgical center by the rules of the Department of Health and shall be submitted in the form as required for the particular project by the Department of Health.

(2) Working Drawings and Specifications.

(A) Working drawings and specifications, complete in all respects, shall be submitted in duplicate, covering all phases of the construction project, including site preparation; paving; general construction; mechanical work, including plumbing, heating, ventilating and air conditioning; electrical work and all built-in equipment, including elevators, kitchen equipment, cabinet work, etc.

1. Each sheet of the plans and each set of the specifications shall identify the project by name and location and shall bear the names and addresses of the architect or professional engineer and the owner.


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2. Each sheet of the plans and each set of specifications shall bear the official seal and signature of the registered architect or registered professional engineer who prepared it.

3. Each set of the plans and each set of specifications shall bear the date of its completion or its latest revision.

4. The plans shall be on sheets of the same size, securely bound into complete sets, with the sheets in the proper order. The specifications shall be securely bound into complete sets.

(B) The working drawings and specifications shall include the following: the material set out in paragraphs (1)(A)1.–12. of this rule; courses and distances of property lines; dimensions and locations of any building, structures, easements, rights-of-way or encroachments on the site; details of party walls, and walls and foundation adjacent to lot line; detailed information by the city engineer or other official report as to established curbs, buildings lines, streets, alleys, sidewalks; all utilities including size, characteristics and location of these services, piping, mains, sewers, poles, wires, hydrants and manholes upon, over or under the site and location of high pressure gas lines within one thousand two hundred feet (1200') of the building; complete information as to the disposal of sanitary, storm water and subsoil drainage; official datum upon which elevations are based and benchmark established on or adjacent to the site; contours on elevations at two foot (2') intervals over site and elevations at the bottom of excavation; and thickness, consistency, character and estimated safe bearing value of various strata encountered.

*AUTHORITY: section 197.225, RSMo 1986. This rule was previously filed 13 CSR 50-30.040. Original rule filed Dec. 2, 1975, effective Feb. 1, 1976.*

**19 CSR 30-30.050 Definitions and Procedures for Licensing Abortion Facilities**

*PURPOSE: This rule defines terminology used in 19 CSR 30-30.060 and 19 CSR 30-30.070, and presents procedures to follow in making application for a license.*

(1) The following definitions shall be used in the interpretation and enforcement of 19 CSR 30-30.060 and 19 CSR 30-30.070:

(A) Abortion—The intentional destruction of an embryo or fetus in a woman's uterus or the intentional termination of a pregnancy of a woman with intent other than to increase the probability of a live birth or to remove a dead or dying embryo or fetus;

(B) Abortion facility—A facility in which the number of patients having abortions represents fifty-one percent (51%) or more of the patients treated or seen for any health condition or where fifty-one percent (51%) or more of the revenues of the facility are from abortions or procedures related to abortions;

(C) Administrator—A person who is designated to provide daily supervision over an abortion facility;

(D) Complication—Includes, but is not limited to, hemorrhage, infection, uterine perforation, cervical lacerations and retained products;

(E) Department—The Missouri Department of Health;

(F) Discharge summary—A statement completed by a physician or registered nurse on the condition of the patient at the time of discharge;

(G) First trimester—The first thirteen (13) weeks of gestation, based upon gestational age;

(H) Gestational age—The length of pregnancy measured from the onset of the last menstrual period;

(I) Health assessment—A determination of a patient's physical and mental status;

(J) Licensed practical nurse—A person licensed to practice practical nursing under the Nursing Practice Act, sections 335.011–335.096, RSMo 1986;

(K) Person—Any individual, firm, partnership, corporation or association;

(L) Physician—Any person licensed to practice medicine pursuant to Chapter 334, RSMo 1986;

(M) Registered nurse—An individual who is a graduate of an approved school of nursing and who is licensed to practice professional nursing under the Missouri Nursing Practice Act, sections 335.011–335.096, RSMo 1986; and

(N) Surgical technologist—An individual who is certified by the Association of Surgical Technologists, Inc.

(2) Procedures for Licensing Abortion Facilities.

(A) In any facility other than licensed ambulatory surgical facilities and hospitals where abortions may be performed, a license to establish and operate an abortion facility shall be required in the absence of evidence to support that the facility is not operating in accordance with the definition established in subsection (1)(B). The evidence required must include, but need not be limited to, statistical records of individuals treated and financial reports including revenue from abortions and procedures related to abortions and total revenues.

(B) Application for the licensing of an abortion facility shall be made in writing to the Department of Health on forms provided by the Department of Health. Each application for a license shall be accompanied by an annual license fee of two hundred dollars ($200).

(C) The application shall be made by the person(s) or corporation operating the facility.

(D) The licensee shall notify the Department of Health in writing of any change in the name of the facility or change in the name of the administrator.

(E) Separate licenses are required for facilities maintained on separate sites even though operated by the same owner.

(F) The license shall be conspicuously posted in a public area in the facility.

(G) A license shall not be issued by the Department of Health until a facility is in compliance with all requirements of 19 CSR 30-30.060 and 19 CSR 30-30.070.

*AUTHORITY: sections 197.200–197.240, RSMo 1986. Original rule filed July 15, 1987, effective Oct. 25, 1987.*

**19 CSR 30-30.060 Organization and Management for Abortion Facilities**

*PURPOSE: Section 197.205, RSMo 1986 authorizes the Department of Health to establish standards for the operation of abortion facilities in order to provide acceptable care in a safe environment. Abortion facilities are considered ambulatory surgical centers as defined by section 197.200(1), RSMo 1986 and are subject to licensure as required by section 197.205, RSMo 1986.*

(1) Governing Body, Administration and Medical Staff.

(A) The facility shall have a governing body which may be an individual owner(s), partnership, corporate body, association or public agency.

1. The governing body shall have full legal responsibility for determining, implementing and monitoring policies governing a facility's total operation and for ensuring that these policies are administered in a manner to provide acceptable care in a safe environment.

2. The governing body shall select and employ an administrator who is a physician licensed in Missouri, a registered nurse licensed in Missouri or an individual who has


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at least one (1) year of administrative experience in health care.

3. Bylaws of the governing body shall require that an individual who complies with paragraph (1)(A)2. of this rule shall be in charge in the absence of the administrator.

4. The department shall be notified in writing of any change in the designation of the administrator of the facility.

5. Governing body bylaws shall acknowledge that duly appointed ambulatory surgical center surveyors of the department shall be allowed to inspect the facility at any time the facility is in operation consistent with due regard for the medical condition and privacy of the on-site patients.

6. Bylaws of the governing body shall require that the medical staff, facility personnel and all auxiliary organizations shall be directly or indirectly responsible to the governing body through the administrator.

7. The governing body, through the administrator, shall establish criteria for the content of patients' records and shall provide for timely completion of those records and disciplinary action for noncompliance.

8. The governing body shall ensure that the abortion facility abides by all applicable state and federal laws.

(B) An administrator shall organize the administrative functions of the facility and establish a system of authorization, record procedures and internal controls.

1. The administrator shall be responsible for establishing effective security measures to protect patients, employees and visitors.

2. The reporting of suspected incidences of child abuse shall be made to the Division of Family Services as established under section 210.115.1, RSMo 1986.

3. The administrator shall be responsible for a written plan for evacuation of patients and personnel in the event of fire, explosion or other internal disaster. The plan shall be kept current and all personnel shall be knowledgeable of the plan.

4. All fires, explosions or other physical actions taken against the facility shall be reported to the department.

5. The administrator shall be responsible for the development and enforcement of written policies which prohibit smoking throughout the abortion facility except specific designated areas where smoking may be permitted. Each such designated area shall have one hundred percent (100%) of the air supplied to the room exhausted.

6. Written smoking control policies shall be posted throughout the abortion facility.

7. Smoking shall be prohibited in any room or compartment where flammable liquids, combustible gases or oxygen are used or stored and in any other hazardous location. These areas shall be posted with NO SMOKING signs.

8. The facility shall establish a program for identifying and preventing infections and for maintaining a safe environment. Infectious and pathological wastes shall be segregated from other wastes at the point of generation and shall be placed in distinctive, clearly marked, leak-proof containers or plastic bags appropriate for the characteristics of the infectious wastes. Containers for infectious waste shall be identified with the universal biological hazard symbol. All packaging shall maintain its integrity during storage and transport.

9. All reportable infectious or communicable diseases identified shall be reported to the Department of Health.

10. The facility shall have policies and procedures for the handling, processing, storing and transporting of clean and dirty laundry. The facility may provide laundry services at the facility or utilize contract services.

11. The administrator shall develop written personnel policies which contain at least the following:

A. Provisions for orientation of all personnel to the policies and objectives of the facility and participation by all personnel in appropriate employee training;

B. Provision for periodic evaluation of employees' performance;

C. Provisions for written job descriptions, including job qualifications; and

D. Provisions for licensed personnel to have current Cardiopulmonary (CPR) training so that at least one (1) licensed and trained personnel is on-site at all times patients are present during and following surgery.

12. The administrator shall be responsible for ensuring that the provisions of Chapter 188, Regulation of Abortions, RSMo 1986 are adhered to.

13. A personnel record shall be maintained on each employee and shall include documentation of each employee's orientation, health status, education and training, as well as verification of current licenses for physicians, registered nurses (RNs) and licensed practical nurses (LPNs).

(C) The medical staff shall develop and, with the approval of the governing body, shall adopt policies governing physician activities in the abortion facility.

1. Medical staff membership shall be limited to physicians.

2. Each physician requesting staff membership shall submit a written application to the administrator of the facility on a form approved by the governing body. Each application shall be accompanied by evidence of education, training, professional qualification, license and standards of performance.

3. The governing body, acting upon recommendations of the medical staff, shall approve or disapprove appointments. Written criteria shall be developed for privileges extended to each member of the staff. A formal mechanism shall be established for recommending to the governing body delineation of privileges, curtailment, suspension or revocation of privileges and appointments and reappointments to the medical staff.

4. Physicians performing abortions at the facility shall have staff privileges at a hospital within fifteen (15) minutes' travel time from the facility or the facility shall show proof there is a working arrangement between the facility and a hospital within fifteen (15) minutes' travel time from the facility granting the admittance of patients for emergency treatment whenever necessary.

5. Each facility shall arrange for at least one (1) physician who is board-certified or board-eligible by the American Board of Obstetrics and Gynecology or the American Osteopathic Board of Obstetrics and Gynecology to be available either as a staff member or as a consultant for the purpose of providing consultation as needed and to advise staff members with respect to maintenance of a satisfactory quality of treatment.

(2) Records.

(A) The facility shall maintain a daily patient roster of all patients receiving abortion services. This daily patient roster shall be retained for a period of two (2) years.

(B) The facility shall maintain a medical record according to professional standards for each patient. Information required for the individual abortion report required by section 188.052, RSMo 1986 shall be readily retrievable from the medical record.

(C) The medical record shall contain—a unique identifying record number, patient identifying information, name of physician, diagnosis, medical history and physical examination record, laboratory reports, tissue reports, anesthesia, allergies/drug reactions, physician's orders, clinical notes, counseling notes, patient consent form, medication administration records and discharge summary. All pharmaceutical agents administered shall be timed, dated and signed by the person making the entry.

(D) Medical records for adults shall be retained for seven (7) years from the time of discharge and medical records for minors shall be retained for seven (7) years from the


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time of discharge or two (2) years past the age the patient reaches majority, whichever is longer. All medical records shall be safeguarded against loss and unofficial use.

(E) Medical records are the property of the abortion facility and shall not be removed from the facility except by court order, subpoena, for the purposes of microfilming or for off-site storage approved by the governing body. Information provided with tissue sent to a laboratory, information provided for statistical purposes and information provided for any other purpose shall contain the unique identifying number, not the patient's name.

(3) Patient care services shall be under the direction of an RN. An RN shall be present in the clinical area whenever there is a patient in the procedure room or recovery room. An LPN or a surgical technician shall be present in the procedure room whenever there is a patient in the procedure room. The surgical technician shall be a certified surgical technologist or shall provide documentation of training in assisting abortion procedures.

(A) An RN or an LPN shall be present in the recovery room when a patient is in the recovery room.

(B) An abortion shall be performed only by a physician.

(C) A medical history shall be obtained and a health assessment including a pelvic examination shall be performed. There must be confirmation of pregnancy by clinical evidence and laboratory tests. The findings shall be used in determining the duration of gestation, identifying preexisting medical or other complications, and detecting any factors which could influence the choice of the procedure, anesthesia or preoperative and postoperative management. If the physician determines gestation is beyond the first trimester, an ultrasound examination shall be performed and results shall be recorded in the patient's chart.

(D) A physician shall be on the premises and immediately available for any assistance to a patient in the recovery room.

(E) A patient shall be fully reactive and her vital signs shall be stable before discharge from the facility.

(F) Written instructions shall be issued to all patients in accordance with the practice of the physician in charge of the abortion facility and shall include the following:

1. Symptoms of noticeable complications;

2. Activities to be avoided; and

3. Abortion facility emergency telephone numbers, available on a twenty-four (24)-hour basis, to be used by the patient should any complication occur or question arise.

(G) Professional and nonprofessional personnel providing patient care in the facility should be given the training and orientation period appropriate to the needs and level of preparation as required by the individual job description.

(H) A person who is trained to provide information on abortion procedures, alternatives, informed consent and family planning services shall be available to each patient to—

1. Assure written informed consent establishing that the patient understands the particular risk associated with the abortion technique to be used;

2. Prepare the patient for surgery in a manner that facilitates her safety and comfort; and

3. Assist the patient in reaching a decision about the method of birth control she will use, if any, after the procedure, respecting her choices.

(I) An emergency tray equipped to treat seizures, bleedings, anaphylactic shock, respiratory arrest and cardiac arrest shall be immediately available to the procedure room and recovery room.

(J) Each abortion facility shall develop a quality assurance program that includes all health and safety aspects of patient care and shall include a review of appropriateness of care. Results of the quality assurance program shall be reviewed at least quarterly by the administrator, director of patient care, a representative of the medical staff and the governing body. The quality assurance program shall include a review of at least the following:

1. Completeness of clinical records;

2. Incidence of morbidity and mortality;

3. Intraoperative and postoperative complications;

4. All cases transferred to a hospital;

5. All cases that resulted in a length of stay of more than twelve (12) hours;

6. Errors in diagnosis;

7. Problems in compliance with state and local laws and regulations; and

8. All cases in which the gestational age was determined to be beyond eighteen (18) weeks.

(K) The quality assurance program must show evidence of action taken as a result of the identification of the problems.

(L) Emergency drugs, oxygen and intravenous fluids shall be available in the procedure room to stabilize the patient's condition when necessary. A manual breathing bag, suction machine and endotracheal equipment shall be located in the clinical area for immediate access.

(4) Laboratory Services.

(A) All fetal tissue shall be grossly examined at the time of the procedure by the attending physician. The results of the tissue examination shall be recorded in the patient's chart.

(B) In the absence of visible fetal parts or placenta, the tissue may be examined under a low-power microscope for the detection of villi. If this examination is inconclusive, the tissue shall be sent to a pathology laboratory for microscopic evaluation.

(C) All tissue obtained from abortions, except tissue submitted to a pathologist for analysis, shall be submerged in a preservative solution and shall be transported in a leakproof container to a facility with a waste sterilizer or an incinerator approved by the Department of Natural Resources. If kept for more than twelve (12) hours, all tissue shall be refrigerated.

(D) The following laboratory procedures shall be performed on every abortion patient: hematocrit; urinalysis, including pregnancy test; and Rh typing.

(E) Anti-Rh immune globulin therapy shall be given to all Rh negative patients upon completion of the abortion procedure. If for any reason a patient refuses this therapy, this refusal shall be noted by the physician in the clinical record, and, if possible, documented by the patient's signature on appropriate release forms in order to protect the physician and the facility.

(5) Complaints. Any persons having a complaint pertaining to the care of a patient rendered by an abortion facility shall direct the complaint in writing to the Missouri Department of Health, Bureau of Hospital Licensing and Certification, P.O. Box 570, Jefferson City, MO 65102. The person making the complaint shall be contacted by the Department of Health within five (5) working days of receipt of the complaint and the complaint shall be investigated by the Department of Health within twenty (20) working days of receipt of the complaint.

*AUTHORITY: sections 197.200—197.240, RSMo 1986. Original rule filed July 15, 1987, effective Oct. 25, 1987. Amended: Filed June 14, 1988, effective Oct. 13, 1988.*

**19 CSR 30-30.070 Physical Standards for Abortion Facilities**

*PURPOSE: Section 197.200, RSMo 1986 authorizes the Department of Health to establish physical standards for abortion facilities in order to provide acceptable care in a safe*


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*environment. Abortion facilities are considered ambulatory surgical centers as defined by section 197.200(1), RSMo and are subject to licensure as required by section 197.205, RSMo 1986.*

*PUBLISHER'S NOTE: The publication of the full text of the material that the adopting agency has incorporated by reference in this rule would be unduly cumbersome or expensive. Therefore, the full text of that material will be made available to any interested person at both the Office of the Secretary of State and the office of the adopting agency, pursuant to section 536.031.4, RSMo. Such material will be provided at the cost established by state law.*

(1) Requests for deviations from requirements on physical facilities shall be in writing to the Department of Health. Approvals for deviations shall be in writing and both requests and approvals shall be made a part of the permanent Department of Health records for the abortion facility.

(2) Any abortion facility constructed or renovated after October 25, 1987 shall have plans prepared by an architect or engineer registered in Missouri. These plans shall be submitted to the department for review and approval prior to construction. New abortion facilities shall have the following:

(A) At least two (2) remote exits shall be provided for each floor directly to the outside or through an enclosed stairway or passageway to the outside;

(B) Corridors serving patients shall be at least six feet (6') wide;

(C) All doors through which patients pass shall be at least forty-four inches (44") wide and of solid-core construction;

(D) One (1)-story buildings shall be at least of Type II (111) protected noncombustible construction as described in *Standard on Types of Building Construction 1979* published by the National Fire Protection Association;

(E) Multistory buildings shall be constructed of at least Type II (222) fire-resistive construction as described in *Standard on Types of Building Construction* published by the NFPA, or shall be protected throughout by an approved automatic sprinkler system;

(F) Multistory buildings shall have at least one (1) elevator. The elevator cab shall be at least five feet by seven feet (5' × 7') clear inside. The car door shall have a clear opening of not less than forty-four inches (44");

(G) Trickle-charge battery pack units shall be located to provide emergency lighting in the procedure room, recovery room, exit corridors and exit stairs to grade;

(H) A manual fire alarm break station shall be located near each exit and connected to a local audible alarm which can be heard throughout the facility;

(I) At least two (2) ABC-type fire extinguishers are to be located in the facility, one (1) in the clinical area;

(J) Illuminated exit signs shall be located above each exit and illuminated directional exit signs shall be located where needed to direct patients and personnel to exits in event of an emergency;

(K) Ceiling, wall and floor finishes in the clinical area including the procedure rooms, recovery room, personnel change rooms, central sterile and supply, janitor's closet and laboratory shall be smooth and easily cleanable;

(L) Scrub-up facilities shall be knee- or foot-operated and provided at the rate of one (1) per procedure room. Scrub-up facilities shall be located outside but immediately available to the procedure room;

(M) Procedure rooms shall have the following:

1. A minimum length and width of twelve feet (12');

2. A minimum ceiling height of nine feet (9');

3. A door with a minimum width of forty-four inches (44"); and

4. There shall be no windows in the room except there may be a fixed-view window in the wall between the procedure room and the adjacent corridor;

(N) The recovery room shall be separated from the procedure room and be of sufficient size to accommodate at least four (4) recovery beds or recliners for each procedure room. There shall be three feet (3') of clear space on both sides and at the foot of each recovery bed or recliner;

(O) The procedure room and recovery room shall be provided with a minimum of six (6) air changes per hour. Air supplied to all areas shall be filtered through a filter with at least a twenty-five percent (25%) efficiency rating;

(P) Personnel change rooms shall be provided for each sex and located convenient to the procedure room. Each change room shall be equipped with a toilet and lavatory;

(Q) The laboratory shall be equipped with a counter, sink and refrigerator;

(R) The procedure room shall be equipped with a ceiling-mounted surgical light, operating table or a conventional gynecological examining table with accessories, closed cabinets for equipment and sufficient tables to hold an emergency tray and other necessary equipment;

(S) There shall be one (1) electrical outlet in the procedure room for the emergency light and at least one (1) duplex outlet on each wall;

(T) There shall be one (1) electrical outlet in the recovery room for the emergency light and at least one (1) duplex outlet for each two (2) recovery beds or recliners;

(U) Piped-in or portable oxygen and suction equipment shall be located in the recovery room;

(V) The sterilizing room shall be equipped with a steam sterilizer, counter and sink, and storage space for clean supplies. Air pressure in this room shall be positive in relation to adjacent areas;

(W) The soiled/decontamination room shall be equipped with a counter and sink. This room shall be equipped with a constant running exhaust;

(X) A patient toilet with lavatory shall be located convenient to the recovery room. This room shall be equipped with a constant running exhaust;

(Y) At least two (2) patient change rooms with secure storage for personal effects shall be provided; and

(Z) Office space, waiting room, record storage space and counseling rooms shall be provided. Counseling rooms shall be separate and not smaller than ten feet by ten feet (10' ×10').

(3) Any abortion facility in operation at the time these rules are adopted shall comply with the following:

(A) Smoke detectors shall be located in all rooms and in corridors at thirty-feet (30') intervals unless the building is rated Type II (222) fire-resistive or if it is a one (1)-story building rated Type II (111) protected-noncombustible as described in *Standard on Types of Building Construction 1979* published by the NFPA. If the building is multistoried and rated combustible, it shall be protected throughout by an approved automatic sprinkler system;

(B) There shall be a system of corridors, passageways and elevators adequate in size and arrangement to allow a patient on a stretcher to be moved from any point in the abortion facility to a street-level exit;

(C) Space shall be provided for waiting, registration, counseling, medical evaluation, examination and referral. This space shall be equipped with suitable furnishings and accommodations;

(D) Dressing rooms shall be provided for the privacy, physical comfort and convenience of patients and personnel;


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(E) At least one (1) procedure room shall be adequately equipped, supplied and staffed to safely perform abortions. The procedure room shall be equipped with an operating table or a conventional gynecologic examining table with accessories, a closed cabinet for equipment and tables to hold an emergency tray and other necessary equipment. The procedure room shall be well lighted and maintained at a comfortable temperature;

(F) Personnel change rooms and scrub-up facilities shall be located convenient to the procedure room;

(G) A utility room with facilities for steam sterilization and space for storage of clean and sterilized supplies shall be provided. There shall be sufficient surgical instruments sterilized and available for each patient who presents herself for an abortion. The room shall be arranged to prevent cross traffic of clean and dirty material;

(H) The recovery room shall be separate from the procedure room and be of sufficient size to accommodate at least four (4) recovery beds or recliners for each procedure room. The recovery room shall be well-lighted and maintained at a comfortable temperature. Recovery beds or recliners shall be spaced to permit easy staff access to each patient;

(I) Piped-in or portable oxygen and suction equipment shall be located in the recovery room;

(J) Trickle charge battery pack units shall be located to provide emergency lighting in the procedure room, recovery room, exit corridors and exit stairs to grade;

(K) A manual fire alarm break station shall be located near each exit and connected to a local audible alarm which can be heard throughout the facility;

(L) At least two (2) ABC-type fire extinguishers shall be located in the facility, one (1) in the clinical area;

(M) Illuminated exit signs shall be located above each exit door and illuminated directional exit signs shall be located where needed to direct patients and personnel to exits in event of an emergency;

(N) Wall and floor finishes in the procedure room, recovery room and the sterilization area shall be smooth and easily cleanable;

(O) The laboratory shall be equipped with a counter, sink and refrigerator; and

(P) At least two (2) remote exits shall be provided for each floor. Each exit shall discharge directly to the outside or through an enclosed stairway or passageway to the outside.

*AUTHORITY: sections 197.200–197.240, RSMo 1986. Original rule filed July 15, 1987, effective Oct. 25, 1987.*

**19 CSR 30-30.080 Definitions Relating to Birthing Centers and Procedures for Licensing Birthing Centers**

*PURPOSE: This rule defines terminology used in this chapter and establishes procedures for licensing birthing centers.*

(1) The following definitions shall be used in the interpretation and enforcement of 19 CSR 30-30.090 through 19 CSR 30-30.110:

(A) Administrator—A person who is designated to provide daily supervision and the administration of the birthing center;

(B) Birthing center—A facility, not licensed as part of a hospital, which provides maternity care away from the mother's usual residence and where low risk births are planned to occur following a normal uncomplicated pregnancy;

(C) Certified nurse-midwife (CNM)—A person licensed to practice professional nursing under section 335.046, RSMo and currently certified by examination by the American College of Nurse-Midwives;

(D) Complication—A condition according to written risk criteria of the birthing center that contraindicates continued care in the birthing center;

(E) Department—The Missouri Department of Health;

(F) Discharge plan—A plan for continuing maternal and infant health care following birth;

(G) Health assessment—A determination of a patient's physical and mental status;

(H) Low risk—Normal, uncomplicated prenatal course as determined by adequate prenatal care and prospects for a normal, uncomplicated birth as defined by reasonable and currently accepted criteria of maternal and fetal health;

(I) Person—Any individual, firm, partnership, corporation or association;

(J) Physician—A person licensed to practice medicine under Chapter 334, RSMo who has admitting privileges at a hospital;

(K) Primary care giver—A physician or a certified nurse-midwife who has attended the mother during the prenatal period, will be present at delivery and will be responsible for care during the puerperium period; and

(L) Qualified personnel—A person trained and competent in the services which s/he provides and is licensed or certified as required by statute or professional standard.

(2) The following procedures are required for licensing a birthing center:

(A) A license to establish and operate a birthing center shall be required of any facility other than a hospital or the mother's residence where births are planned to occur and where childbirth deliveries may be performed;

(B) Application for licensure of a birthing center shall be made in writing to the department on forms provided by the department. Each application for a license shall be accompanied by an annual license fee of two hundred dollars ($200);

(C) The application shall be made by the person(s) or corporation operating the facility;

(D) The licensee shall notify the department in writing of any change in the name of the facility or change in the ownership;

(E) Separate licenses are required for facilities maintained on separate sites even though operated by the same owner;

(F) The license shall be conspicuously posted in a public area in the facility; and

(G) A license shall not be issued by the department until a facility is in compliance with all requirements of 19 CSR 30-30.090. In addition, a facility shall be in compliance with 19 CSR 30-30.100 or 19 CSR 30-30.110, depending on the number of birthing rooms in the facility.

*AUTHORITY: section 197.225, RSMo 1994.* Emergency rule filed May 1, 1995, effective May 10, 1995, expired Sept. 7, 1995.* Original rule filed May 1, 1995, effective Nov. 30, 1995. Emergency amendment filed June 19, 1998, effective July 1, 1998, expired Feb. 25, 1999. Amended: Filed June 19, 1998, effective Jan. 30, 1999.*

**Original authority 1975, amended 1986.*


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MISSOURI DEPARTMENT OF HEALTH
HOSPITAL LICENSING AND CERTIFICATION
**APPLICATION FOR BIRTHING CENTER LICENSE**

P.O. BOX 570
JEFFERSON CITY, MISSOURI 65102-0570

☐ INITIAL APPLICATION ☐ RENEWAL APPLICATION

In accordance with the requirements of the Missouri Ambulatory Surgical Center Licensing Law (Sections 197.200 through 197.240, RSMo), application is hereby made for a license to conduct and maintain a Birthing Center (see Missouri Ambulatory Surgical Center Licensing Law "Definitions" Section 197.200, subsection (1), RSMo).

DO NOT WRITE IN THIS SPACE
LICENSE NO.
DATE
CERTIFICATE NO.
DATE MAILED

NAME OF FACILITY (NAME TO APPEAR ON LICENSE) TELEPHONE NO.

ADDRESS (STREET AND NUMBER) (CITY) (ZIP CODE)

COUNTY ADMINISTRATOR

**MANAGEMENT**

NON PROFIT
☐ CORPORATION
☐ OTHER (SPECIFY)

PROPRIETARY
☐ INDIVIDUAL ☐ CORPORATION
☐ PARTNERSHIP ☐ OTHER (EXPLAIN)

CHIEF OFFICER OF GOVERNING BODY LEGAL NAME OF OPERATING CORPORATION

IF OPERATED BY MANAGEMENT CONSULTANT, NAME OF FIRM

STAFFING (numbers):
PERSONNEL PHYSICIANS

OB/GYN CONSULTANT
NAME:
QUALIFICATIONS:

NO. OF ABORTIONS PER YEAR CERTIFIED NURSE MIDWIFE

STATE OF MISSOURI

City of _____

County of _____

_____ (PRESIDENT OF BOARD OF TRUSTEES, OWNER, OR ONE PARTNER OF PARTNERSHIP) and _____ (ADMINISTRATOR) being duly sworn by me on their oath, deposes and says that they have read the foregoing application and that the statements contained therein are correct and true and of their knowledge; and further gives assurance of the ability and intention of the _____ (EXACT LEGAL NAME) Ambulatory Surgical Center to comply with the regulations and codes promulgated under the Missouri Ambulatory Surgical Center Licensing Law (sections 197.200 through 197.240, RSMo), Regulations and Codes.

It is further certified that the _____ (NAME OF FACILITY) will comply with all recommendations for correction and/or improvements as contained in the most recent Licensing Survey Report prepared by the Department of Health and submitted to said Ambulatory Surgical Center.

Signed _____ (PRESIDENT OF BOARD OF TRUSTEES, OWNER OR ONE PARTNER OF PARTNERSHIP)

Signed _____ (ADMINISTRATOR)

Signed and sworn to before me this _____ day of _____, 19____

_____ (NOTARY PUBLIC)

My commission expires _____, 19____

MO 580-0013 (11-86) HL 16 (R1/87)


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**19 CSR 30-30.090 Organization and Management Standards for Birthing Centers**

*PURPOSE: This rule establishes standards for the operation of birthing centers in order to provide care in a safe environment.*

(1) The center shall have a governing body which may be individual owner(s), partnership, corporate body, association or public agency.

(A) The governing body shall have full legal responsibility for determining, implementing and monitoring policies governing the center's total operation and for ensuring that the policies are administered in a manner to provide acceptable care in a safe environment.

(B) The governing body shall select and employ one (1) of the following as an administrator: a physician licensed in Missouri, a certified nurse-midwife (CNM), a registered nurse licensed in Missouri or an individual with a bachelor's degree in a related field and at least one (1) year of administrative experience in health care.

(C) The governing body shall require that an individual who complies with subsection (1)(B) of this rule shall be in charge when the administrator is unavailable in person or by telecommunications.

(D) Governing body bylaws shall acknowledge that duly appointed representatives of the department shall be allowed to inspect the center operation at any time, with consideration for client privacy and confidentiality.

(E) Bylaws of the governing body shall require that the clinical staff, center personnel and all auxiliary organizations directly or indirectly be responsible to the governing body through the administrator.

(F) The governing body, through the administrator, shall establish criteria for the content of patients' records, provision for their timely completion and disciplinary action on occasion of noncompliance.

(G) The governing body shall ensure that the birthing center abides by all applicable state and local laws.

(2) The administrator shall organize the administrative functions of the center and establish a system of authorization, record procedures and internal controls.

(A) The administrator shall be responsible for establishing effective security measures to protect patients, employees and visitors.

(B) The administrator is responsible for assuring that all patients admitted to the center are under the care of a physician or CNM practicing pursuant to a collaborate agreement with a physician who is a member of the clinical staff.

(C) A certificate of live birth shall be filed in accordance with section 193.085, RSMo.

(D) The administrator shall develop procedures and have a written agreement with a licensed ambulance service for emergency transportation. If a written agreement with the ambulance service cannot be achieved due to reasons that are neither regulatory or statutory, the administrator can request a waiver or mediation from the department.

(E) The administrator shall have procedures and a written transfer agreement with a hospital providing emergency, obstetrical and newborn services. If a written agreement with a licensed hospital cannot be achieved due to reasons that are neither regulatory or statutory, the administrator can request a waiver or mediation from the department. Peer review report may be submitted as evidence for mediation.

(F) The administrator shall be responsible for a written plan for evacuation of patients and personnel in the event of fire, explosion or natural disaster. The plan shall be kept current and all personnel shall be knowledgeable of the plan.

(G) The administrator shall be responsible for developing, enforcing and posting written policies which prohibit smoking throughout the birthing center.

(H) Smoking or open flames shall be prohibited in any room or compartment where flammable liquids, combustible gases or oxygen are used or stored and in any other hazardous location. These areas shall be posted with NO SMOKING OR OPEN FLAME signs.

(I) The administrator shall establish a program for identifying and preventing infections and for maintaining a safe environment. The center shall be responsible for identifying infections up to thirty (30) days postpartum in the mother and the infant unless and until they are transferred to another healthcare provider prior to thirty (30) days. Infectious and pathological wastes shall be segregated from other wastes at the point of generation and shall be placed in distinctive, clearly marked, leak-proof containers or plastic bags appropriate for the characteristics of the infectious wastes. Containers for infectious waste shall be identified with the universal biological hazard symbol. All packaging shall maintain its integrity during storage and transport. Infectious waste shall be disposed of in accordance with provisions of 10 CSR 80-7.010.

(J) The administrator shall establish policies and procedures for the handling, processing, storing and transporting of clean and dirty laundry. The facility may provide laundry services on-site or utilize contract services.

(K) The administrator shall develop written personnel policies which contain at least the following:

1. Provision for orientation of all personnel to the policies and objectives of the center and participation by all personnel in appropriate employee training;

2. Provision for periodic evaluation of employees' performance including clinical skills, resuscitation and use of equipment; and

3. Provision for written job descriptions, including job qualifications system for the completion and storage of medical records.

(L) A personnel record shall be maintained on each employee and shall include documentation of each employee's orientation, education, training and health information, as well as verification of current licenses for physicians, registered nurses and licensed practical nurses and documentation of certification for nurse-midwives.

(3) Clinical practice guidelines for the management of routine and emergency care of the mother and her fetus/newborn in pregnancy, birth and postpartum until discharge from care by the center, whether through completion of the program or referral or transfer to other levels of care, shall be drafted by a physician or certified nurse midwife who has clinical staff membership at the birthing center. The guidelines shall be available on-site at all times. Documentation of periodic review and revision are required.

(A) Clinical staff membership shall include physicians or CNMs, or both, but, as defined by the birth center bylaws, may also include other health professionals to provide service at the birth center. A physician or CNM practicing pursuant to a collaborative practice agreement with a physician shall be in attendance and responsible for intrapartum management.

(B) On a form approved by the governing body, each health professional requesting clinical staff membership shall submit a written application to the administrator of the center. Each application shall be accompanied by evidence of education, training, professional qualification, health status certification and licensure.

(C) A written procedure shall be established for recommending to the governing body delineation of privileges; curtailment, suspension or revocation of privileges; and appointments and reappointments to the clinical staff. The governing body, acting upon recommendations of the clinical staff, shall


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approve or disapprove appointments. Written criteria shall be developed for privileges extended to each member of the clinical staff.

(D) Each birth center shall have at least one (1) physician who is responsible for the following:

1. Sign collaborative practice agreement and meet any other requirements of Missouri law for collaborative practice;

2. Review and sign clinical practice guidelines and risk assessment criteria at least annually; and

3. Be available in person or by telecommunication for consultation.

(4) The center shall maintain a system for the completion and storage of medical records.

(A) The daily patient roster shall be retained for two (2) years.

(B) The medical record shall contain

1. A unique identifying medical record number;

2. Client identifying information;

3. Allergies;

4. Consent;

5. Maternal history;

6. Maternal and newborn physical examinations;

7. Laboratory test results;

8. Initial risk assessment and periodic updates;

9. Interval prenatal evaluations;

10. Problem identification, plan, and follow-up;

11. Labor and birth records, including apgars;

12. Newborn and postpartum recovery records;

13. Medication record, including any drug, and the dose, time, date and person administering;

14. Discharge plan; and

15. Postpartum and infant follow-up visits up to thirty (30) days after the birth or documentation of transfer to another health care provider.

(C) All medical records shall be safeguarded against loss and unofficial use. Medical records for adults and newborns shall be retained as required by the statute of limitations under section 516.105, RSMo.

(D) Medical records are the property of the birthing center and shall not be removed from the center except by court order, subpoena, for microfilming or for off-site storage approved by the governing body. Information provided for statistical purposes shall contain the unique identifying number, not the patient's name.

(5) Patient care services shall be under the direction of a physician or a CNM practicing pursuant to a collaborative practice arrangement with a physician.

(A) Women registering for care at the birthing center and their families shall be informed and shall provide written acknowledgment that they have been informed of the benefits and risks of the services available at the center. They shall be made aware of the risk criteria used for admission and referral.

(B) Birth center clients are limited to those women who are initially determined to be at low maternity risk and who are evaluated regularly throughout pregnancy to assure that they remain at low risk for a pregnancy outcome.

1. Each birth center shall establish a written risk assessment system which shall be a part of the clinical practice guidelines. The individual risk assessment shall be included in the client's medical record.

2. The general health status and risk assessment shall be determined by a physician, CNM or other advanced practice nurse after obtaining a detailed medical history, performing a physical examination and taking into account family circumstances and other social and psychological factors. The client shall be transferred to a hospital if complications occur requiring medical or surgical intervention under the center's written risk criteria.

(C) The center shall provide at least one (1) CNM or physician for each three (3) women in active labor. In addition a qualified staff member shall be available for each client during the entire time the client is in the birth center. All clinical staff shall provide services during labor and delivery in accordance with the policies developed by clinical staff and approved by the governing body.

(D) Qualified personnel and clinical staff of the birth center shall be trained in infant and adult resuscitation and recertified according to standards set by the American Heart Association and the American Pediatric Association.

(E) A primary care giver shall remain on the premises and be immediately available for assistance to the patient during labor, delivery and immediate postpartum stages.

(F) A primary care giver shall be responsible for ensuring and documenting prenatal care, health history, physical examination, and appropriate laboratory studies which shall be placed in the medical record at time of admission in preparation for delivery.

(G) A patient shall meet discharge criteria as defined in the clinical practice guidelines prior to discharge from the facility.

(H) Labor shall not be inhibited, stimulated or augmented with chemical agents during the first or second stage of labor.

(I) General and induction anesthesia shall not be administered. Local and pudendal anesthesia may be administered by a physician or CNM practicing pursuant to a collaborative practice arrangement with a physician if use of the drugs conforms with Missouri law and written clinical practice guidelines of the birth center.

(J) A program for prompt follow-up care and postpartum evaluation after discharge shall be developed and implemented. The follow-up shall include assessment of infant health including physical examination, laboratory screening tests at appropriate times, maternal postpartum status, instruction in child care including immunizations, referral to sources of pediatric care, provision of family planning services, and assessment of mother-child relationship including breast feeding.

(K) The center shall be responsible for detection of Rh incompatibility and administration of RhoGAM as appropriate.

(L) At a minimum, there shall be provision for nutritious liquids and snacks in accordance with 19 CSR 20-1.010.

(M) Prophylactic eye treatment as required in section 210.070, RSMo shall be provided.

(N) Drugs shall be stored and handled under proper security and environmental conditions and shall be accessible only to authorized persons. Drugs shall be administered and disposed only by licensed practitioners in accordance with applicable state laws and rules. The use of IV's shall be restricted to hydration only or to the establishment of a central line prior to transport to emergency facilities. No IV drugs such as pitocin shall be used for inducement or augmentation of labor.

(O) An emergency drug kit shall be available which includes oxygen, a Deelee suctioning trap or other appropriate equipment for emergency suctioning.

(P) An adequate supply of sterile items shall be available.

(6) The birthing center shall provide a quality assurance program that includes all health and safety aspects of patient care for both mother and newborn and shall include a review of appropriateness of care. Results of the quality assurance program shall be reviewed at least quarterly by the governing body.

(A) The quality assurance program shall include, but not be limited to, the following:

1. A review of the medical record;

2. A determination that every mother-infant pair have an identified source of primary care and have available methods by


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which to contact that individual after discharge;

3. Incidences of morbidity and mortality of mother and infant;

4. Postpartum infections;

5. A review of all cases transferred to a hospital for delivery, care of the infant or postpartum care of the mother;

6. A review of all cases that resulted in a length of stay of more than twelve (12) hours beyond the birth of the baby;

7. Incidents, problems, and potential problems identified by the staff of the birthing center; and

8. Problems with compliance with state laws and rules.

(B) The quality assurance program shall show evidence of action taken as a result of the identification of a problem, including documented outcome and evaluation.

(7) A birthing center shall provide for essential laboratory services, including, but not limited to, hemoglobin or hematocrit, urinalysis, microscopic analysis and culture, blood type and Rh, syphilis, hepatitis B, rubella, pap smears and pregnancy tests.

(A) Laboratory services may be provided on-site or through a certified laboratory in accordance with federal regulations.

(B) When services are provided by arrangement with an outside provider, the original copy of the signed and dated report shall become part of the mother's permanent record at the birthing center.

(C) Results of tests completed at the birthing center shall be entered, dated and signed in the mother's or child's record by the individual who performed the test. Abnormal test results shall be followed up by the primary provider in accordance with birth center risk criteria and clinical practice guidelines.

*AUTHORITY: section 197.225, RSMo 1994.* Emergency rule filed May 1, 1995, effective May 10, 1995, expired Sept. 7, 1995. Original rule filed May 1, 1995, effective Nov. 30, 1995. Emergency amendment filed June 19, 1998, effective July 1, 1998, expired Feb. 25, 1999. Amended: Filed June 19, 1998, effective Jan. 30, 1999.*

**Original authority 1975, amended 1986.*

**19 CSR 30-30.100 General Design and New Construction Standards for Birthing Centers**

*PURPOSE: Section 197.225, RSMo authorizes the Department of Health to establish physical standards for birthing centers in order to provide care in a safe environment. Birthing centers are considered ambulatory surgical centers as defined by section 197.200(1), RSMo and are subject to licensure as required by section 197.205, RSMo. This rule establishes up-to-date construction requirements for new birthing center construction to help ensure accessible, functional, fire-safe and sanitary facilities. A new birthing center is one for which plans are submitted to the Department of Health after the adoption of this rule for the construction of a new facility, expansion or renovation of an existing birthing center or the conversion of an existing facility not previously and continuously licensed as a birthing center under Chapter 197, RSMo.*

*PUBLISHER'S NOTE: The publication of the full text of the material that the adopting agency has incorporated by reference in this rule would be unduly cumbersome or expensive. Therefore, the full text of that material will be made available to any interested person at both the Office of the Secretary of State and the office of the adopting agency, pursuant to section 536.031.4, RSMo. Such material will be provided at the cost established by state law.*

(1) Planning and Construction Procedures.

(A) Any birthing center constructed or renovated after the date of the adoption of this rule shall have plans and specifications prepared by an architect registered in Missouri. These plans and specifications shall be submitted to the department for review and approval prior to beginning of construction. The design and construction of birthing centers shall conform to the most stringent requirements of this rule and the local governing building code.

(B) The Department of Health shall be notified in writing within five (5) days after construction begins. If construction of the project is not started within one (1) year after the date of the approval of the plans and specifications, the plans and specifications shall be resubmitted to the Department of Health for its approval and shall be amended, if necessary, to comply with the then current rules before construction work begins.

(C) Requests for variations from requirements on physical facilities shall be requested in writing to the Department of Health and must contain information which demonstrates the providers ability to meet the intent or objectives of the rule through alternative methods. Approvals for deviations shall be requested in writing and both requests and approvals shall be made a part of the permanent Department of Health records for the birthing center.

(D) Where renovation or replacement work is done within an existing facility, all new work or additions, or both, shall comply with the applicable sections of this rule.

(E) Birthing centers which expand their capacity to four (4) or more birthing rooms must comply throughout the facility with the applicable requirements for birthing centers of this size or larger.

(F) References in this rule to, National Fire Protection Association (NFPA), publications are those contained in the twelve (12)-volume 1994 Compilation of NFPA Codes, Standards, Recommended Practices and Guides. Where there are discrepancies between referenced NFPA publication requirements and this rule, the requirements of this rule shall apply.

(2) Design Considerations for the Physically Handicapped. Roads, parking facilities, walks, ramps and entrances shall be accessible and usable by persons who are physically disabled. At least one (1) toilet, telephone and drinking fountain which are accessible for use by handicapped public and clinic patients shall be provided on each floor of a birthing center. Elevator controls and alarms shall be accessible to wheelchair occupants and shall be provided with tactile signage for the visually impaired. Design details for handicapped accessible facilities shall be consistent with the *Guidebook to: The Minimum Federal Guidelines of Requirements for Accessible Design* published January 6, 1981 by the United States Architectural and Transportation Barriers Compliance Board.

(3) Site.

(A) Adequate vehicle and pedestrian access, including loading and unloading space for delivery vehicles, shall be provided within the lot lines to the main entrance, emergency vehicular entrance, community activities and services.

(B) Adequate off-street parking shall be provided. Space shall be provided at the ratio of one (1) space for each of the maximum number of staff persons on duty at any given time plus one (1) parking space for the patient capacity of the birthing and examination rooms in the licensed facility.

(C) Fire lanes shall be provided and kept clear to provide immediate access for fire fighting equipment.

(4) General Birthing Center Design Considerations. The arrangement of the physical plant for a birthing center shall provide for separation of administrative/public, prenatal


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clinic and birthing suite areas. The birthing suite shall be in a location in the facility that precludes unnecessary traffic through the suite.

(5) Administrative/Public Areas. These areas shall include a business office with a public information center and staff telephone, administrator's enclosed office, medical records storage for at least two (2) years of patient records, public lobby and waiting room, public telephone, public toilet and a drinking fountain.

(6) Staff Areas. An area shall be provided to include secure storage for personal effects, handicapped accessible toilet, shower, change and lounge area sufficient to accommodate staff needs as defined by the program.

(7) Prenatal Clinic and Preadmission Screening Area. This area shall include:

(A) At least one (1) room with a minimum size of two hundred fifty (250) square feet for group education. In birthing centers with fewer than four (4) birthing rooms in response to the program of the facility but in no case shall it be smaller than one hundred twenty (120) square feet;

(B) At least one (1) examination room of not less than ninety (90) square feet and a minimum dimension of nine feet (9'). Each examination room shall be equipped with hand washing facilities. In birthing facilities with only one (1) birthing room, the required examination room shall be equipped to serve as a stand-by birthing room. Examination facilities shall be separate from, but adjacent to, the waiting room and birthing suite; and

(C) A laboratory equipped with a counter, sink and refrigerator which is required if the laboratory performs on-site laboratory work. This requirement may be met by a contractual provision for off-premises laboratory services.

(8) Birthing Suite. The birthing suite shall include at least one (1) birthing room with the following minimum dimensions: length and width of twelve feet (12'), ceiling height of eight feet (8'), and a door three feet (3') in width.

(A) Hand washing facilities shall be located in each birthing room. Lavatories shall be sized for scrubbing and equipped with faucets which are knee, foot or otherwise designed to operate without the use of hands.

(B) Each birthing room shall be equipped with a labor/delivery bed large enough for mother and baby, examination light, capacity to keep the infant warm, storage facilities for supplies and sufficient tables to hold an emergency tray and other necessary equipment.

(C) A toilet with lavatory shall be directly accessible to the birthing room so patients will not be required to enter the corridor. One (1) toilet may serve up to two (2) birthing rooms. No fewer than ten percent (10%) of the birthing rooms shall be served by handicapped accessible toilets. In birthing centers with fewer than four (4) birthing rooms, one (1) handicapped-accessible patient toilet may be provided which is conveniently located to and easily accessible from the birthing rooms without having patients traverse public areas.

(D) A shower shall be conveniently located to and easily accessible from the birthing rooms without requiring patients to traverse public areas. One (1) shower may serve not more than twelve (12) birthing rooms. At least one (1) patient shower shall be handicapped-accessible.

(E) Piped-in oxygen and clinical vacuum shall be provided in each birthing room. Birthing centers with fewer than four (4) birthing rooms may use portable medical gas and vacuum services.

(F) Emergency equipment including intravenous fluids and resuscitation equipment shall be located in near the birthing rooms.

(9) Service and Staff Support Facilities. The birthing suite shall include:

(A) A clean work and sterile storage room equipped with a sterilizer, counter and sink, and storage space for clean supplies;

(B) A separate soiled/decontamination utility room equipped with a clinic sink, counter and sink;

(C) A separate staff-only toilet with a constant running exhaust and a lavatory conveniently located to the birthing suite;

(D) A staff station providing visual supervision of the birthing rooms and support facilities;

(E) A medication storage and preparation station equipped with a sink and refrigerator;

(F) Storage space for emergency equipment; and

(G) Janitor's closet equipped with a mop sink and having sufficient space for the cleaning equipment used to maintain the birthing procedure area. Birthing centers with fewer than four (4) birthing rooms are required to have only one (1) janitor's closet to serve the entire facility. In multi-storied birthing centers at least one (1) janitor's closet shall be provided on each floor.

(10) General Support Facilities. Each birthing center shall include:

(A) Adequate space for the housing and maintenance of mechanical, plumbing and electrical equipment;

(B) Oxygen storage facilities which, if located inside the birthing center, shall be exhausted to prevent the accumulation of quantities of spilled gases. Medical gas storage and distribution systems shall comply with "NFPA 99, Standard for Health Care Facilities, 1993 Edition" in *1994 National Fire Codes*, Volume 5;

(C) Housekeeping supply and general storage rooms;

(D) A janitor's closet, including a mop sink, to serve the public, business and preadmission clinic areas;

(E) In birthing centers proposing to process laundry on-site, laundry facility design and laundry equipment of a quality to be capable of producing sanitized linen; and

(F) At a minimum, provisions for shelf storage and refrigerated storage of prepackaged nourishments. Provisions shall be made for serving prepackaged nourishments to birthing patients. In birthing centers proposing to prepare food on-site, the design of the dietary facilities must be acceptable to the department and comply with 19 CSR 20-1.010.

(11) Details and Finishes.

(A) A continuous system of unobstructed corridors and aisles shall be provided which connects all rooms and space with each other and all entrances, exits and elevators. Corridors shall be separated from other areas by walls which resist the passage of smoke.

(B) Each exit shall discharge to the outside or through an enclosed stairway or passageway to the outside.

(C) Required exit stairs shall discharge directly to the outside or into a rated fire corridor which extends from the stair discharge to the outside. The fire-resistance rating of fire corridor walls shall be not less than the rating of the stair enclosure requirement located in section (12) of this rule.

(D) Corridors shall be at least six feet (6') wide. All other corridors and aisles shall be at least four feet (4') wide.

(E) Exit doors shall swing in the direction of exit travel.

(F) All doors, procedure rooms and exits shall be at least three feet (3') wide.

(G) All corridor doors shall be of solid wood construction or its equivalent.

(H) Each birthing room shall have an operable window in the outside wall. The window sill shall be not more than three feet (3') above the floor. Easily washable window treatments, such as vertical hanging vinyl blinds, shall be installed to control light and


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glare. All window treatments shall be inherently flame retardant.

(I) At least one (1) ABC-type fire extinguisher, compliant with "NFPA 10, Standard for Portable Fire Extinguisher," 1990 Edition, 1994 *National Fire Code*, Volume 1, shall be located near each exit on each floor of the birthing center and at the birthing suite's staff station.

(J) A paper towel dispenser and soap dispenser shall be provided at all lavatories used for hand washing.

(K) Finish materials installed on the walls, floors and ceilings in the birthing rooms shall be smooth and washable.

(L) Ceiling, wall and floor finishes shall be smooth and easily cleanable in toilets and bath facilities. Utility and storage rooms used for washing, sterilization and supplies shall have smooth and easily cleanable ceiling, wall and floor finishes.

(M) Floor and wall penetrations by pipes, ducts, and conduits shall be tightly sealed to minimize entry of rodents and insects. Joints of structural elements shall be similarly sealed.

(12) Construction, Including Fire-Resistive Requirements.

(A) Construction of freestanding birthing centers shall comply with "NFPA 101 Section 12-6, New/Ambulatory Health Care Centers, 1994 Edition", 1994 *National Fire Codes*, Volume 5 and this rule.

(B) Multistoried buildings rated combustible Type V shall be protected throughout by an approved automatic sprinkler system. The number of stories in a building housing a birthing center shall be determined by counting all occupiable levels in the building.

(C) Birthing centers shall be separated from other tenants and occupancies by walls having at least a one (1)-hour fire-resistance rating. These walls shall extend from the floor slab below to the floor or roof slab above.

(D) Every stairway, elevator shaft, light and ventilation shaft, chute and other openings between stories shall be enclosed or protected to prevent the spread of fire or smoke from one (1) floor to another. The fire-resistance rating of the enclosure or protection shall be not less than the structural floor separation requirements of "NFPA 220, Standard on Types of Building Construction, 1992 Edition," 1994 *National Fire Code*, Volume 5 for the fire-resistive building type classification required by subsection (12)(A).

(13) Elevators.

(A) Multistoried buildings shall have at least one (1) elevator if birthing room services are located on any floor other than the grade level (main entrance) floor.

(B) The elevator cab shall be at least five feet by seven feet (5' x 7') clear inside. The car door shall have a clear opening of not less than three feet (3').

(C) Elevators shall be equipped with a two (2)-way special service switch to permit cars to bypass all landing button calls and be dispatched directly to any floor.

(D) Elevators shall be equipped with an automatic leveling device of the two (2)-way automatic maintaining type with an accuracy of plus or minus one-half inch (±1/2").

(E) Elevator call buttons, controls and door safety stops shall be of a type that will not be activated by heat or smoke.

(14) Mechanical Requirements.

(A) Heating, ventilating and air conditioning (HVAC) equipment shall be mandated to operate at an ambient temperature of sixty-eight to eighty-five degrees Fahrenheit (68–85°F).

(B) Air supplied to all areas shall be filtered through a filter with at least a twenty-five percent (25%) efficiency rate. Filter efficiencies shall be average atmospheric dust spot efficiencies.

(C) Required exhaust fans shall be non-switched and constant running. All exhaust fans shall be installed at the discharge end of the duct.

(D) The HVAC systems shall be designed and balanced to provide pressure relationships and air change rates shown in the following table:


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**Pressure Relationships and Ventilation of Areas in Birthing Centers**

| Area Designation | Pressure Relationship to Adjacent Areas | Minimum Air Changes of Outside Air Per Hour Supplied to Room | Minimum Total Air Changes Per Hour Supplied to Room | All Air Exhausted Directly to Outdoors | Recirculated Within Room |
|---|---|---|---|---|---|
| Birthing Room | P | 2 | 10 | Optional | No |
| Birthing Suite Corridor | E | 2 | 4 | Optional | No |
| Examination Rooms | E | 2 | 6 | Optional | No |
| Soiled/Decontamination Workroom | N | 2 | 10 | Yes | No |
| Clean/Sterile Workroom | P | 2 | 4 | Optional | Optional |
| Laboratory | N | 2 | 6 | Optional | No |
| Toilet Room | N | — | 10 | Yes | No |
| Janitor's Closet | N | — | 10 | Yes | No |
| Other Area | E | 2 | 4 | Optional | No |

P=Positive N=Negative E=Equal


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(15) Plumbing and Other Piping Systems.

(A) Systems shall be designed to supply water to the fixtures and equipment on every floor at a minimum pressure of fifteen pounds per square inch (15 psi) during maximum demand periods.

(B) Each water service main, branch main, riser and branch to a group of fixtures shall be valved. Stop valves shall be provided at each fixture.

(C) Cold and chilled water piping and waste piping shall be insulated. Insulation of cold and chilled water lines shall include an exterior vapor barrier.

(D) Reduced pressure backflow preventers shall be installed where the water service enters the building and on hose bibbs and on all fixtures to which hoses or tubing can be attached such as janitors' sinks and laboratory fixtures.

(E) Hot water distribution systems shall provide one hundred ten degree Fahrenheit (110°F) water at each fixture at all times.

(F) Sinks in patient service areas shall have the water supply spout mounted so that its discharge point is a minimum distance of five inches (5") above the rim of the fixture. All lavatories used by medical and nursing staff shall have valves which can be operated without the use of hands.

(16) Electrical Requirements.

(A) Every room, including storage rooms, corridor and all other areas shall be sufficiently illuminated.

(B) Trickle charge battery pack units, complying with the standards of "Article 700, Emergency Systems, NFPA 70, *National Electrical Code*, 1994 Edition," in *National Fire Code*, Volume 3, shall be located to provide emergency lighting in the birthing rooms, exit corridors, exit signs, electrical branch panel rooms and exit stairs to point of discharge at grade. These fixtures shall be tested at least quarterly with the tests documented in writing. An emergency stand-by power system is not required in birthing centers.

(C) There shall be one (1) electrical outlet in each birthing room for the trickle charge emergency light and at least one (1) duplex outlet on each wall.

(D) Electrical outlets installed in wet locations, such as the patient toilet areas, shall be ground fault interrupter types.

(E) In birthing center of four (4) or more birthing rooms, an electrically powered fire alarm system shall be installed which will alert all areas of the facility when activated. A fire alarm manual pull station shall be located near each exit and at the staff station. The initiation of this fire alarm system shall be by manual means and by automatic means of any required detection devices.

(F) Birthing centers shall have smoke detectors interconnected with the fire alarm system in all rooms and at thirty-foot (30') intervals in corridors. Birthing centers located in completely sprinklered buildings require only the corridor detectors. In birthing centers of fewer than four (4) birthing rooms, the fire alarm system may consist of the individual required smoke detectors, provided the local alarm may be heard throughout the occupied areas of the birthing center.

*AUTHORITY: section 197.225, RSMo 1994.* Emergency rule filed May 1, 1995, effective May 10, 1995, expired Sept. 7, 1995. Original rule filed May 1, 1995, effective Nov. 30, 1995. Emergency amendment filed June 19, 1998, effective July 1, 1998, expired Feb. 25, 1999. Amended: Filed June 19, 1998, effective Jan. 30, 1999.*

**Original authority 1975, amended 1986.*

**19 CSR 30-30.110 General Design and Construction Standards for Existing Birthing Centers**

*PURPOSE: Section 197.225, RSMo authorizes the Department of Health to establish physical standards for birthing centers in order to provide care in a safe environment. Birthing centers are considered ambulatory surgical centers as defined by section 197.200(1), RSMo and are subject to licensure as required by 197.205, RSMo. This rule establishes physical plant requirements for licensing existing birthing centers. Existing birthing centers are those birthing facilities already in operation at the time these rules are adopted.*

*PUBLISHER'S NOTE: The publication of the full text of the material that the adopting agency has incorporated by reference in this rule would be unduly cumbersome or expensive. Therefore, the full text of that material will be made available to any interested person at both the Office of the Secretary of State and the office of the adopting agency, pursuant to section 536.031.4, RSMo. Such material will be provided at the cost established by state law.*

(1) General Standards.

(A) Any birthing center existing and in continuous operation prior to the date of the adoption of this rule will be inspected by the Department of Health to determine compliance with this rule. Existing birthing centers shall comply with all applicable local regulations and codes and shall hold a certificate of occupancy from the local building authority.

(B) Requests for deviations from requirements on physical facilities shall be requested in writing to the Department of Health and must contain information which determines that the respective intent or objectives of this rule have been met. Approvals for deviations shall be requested in writing and both requests and approvals shall be made a part of the permanent Department of Health records for the birthing center.

(C) References in this rule to, National Fire Protection Association (NFPA), publications are those contained in the twelve (12)-volume 1994 compilation of *National Fire Codes*. Where there are discrepancies between referenced NFPA publication requirements and this rule, the requirements of this rule shall apply.

(2) Access for the Physically Handicapped. Existing birthing centers are required by the United States Department of Justice to currently comply with the federal requirements for accessible design established under the Americans With Disabilities Act. Evidence of compliance as determined by a local authority or other independent third party shall be provided to the department by the owner of the facility.

(3) Site.

(A) Adequate vehicular and pedestrian access shall be provided to the main entrance, emergency vehicular entrance and service entrance.

(B) Adequate parking shall be available in proportion to the number of patients and staff normally occupying the facility.

(C) Means of immediate access to the building for fire fighting and ambulance service personnel and equipment shall be provided.

(4) Administrative/public areas shall include business office with staff telephone and administrator's office, medical records storage for at least two (2) years of active patient records, public lobby and waiting room, telephone, toilet, at least one (1) room for education and training and at least one (1) examination room. In existing birthing centers having only one (1) regular birthing room, one (1) examination room shall be sized and equipped to serve as a stand-by birthing room.

(5) Birthing rooms shall include at least one (1) birthing room sized to accommodate the equipment, personnel and circulation area


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necessary to accomplish infant delivery; each birthing room door shall be ample in width and conformation to accommodate ambulance stretchers or infant transport warmer.

(A) Hand washing facilities operable without the use of hands shall be accessible within each birthing room and each examination room.

(B) Each birthing room shall be equipped with a bed or delivery chair, storage facilities for supplies, and sufficient tables to hold emergency and other necessary equipment.

(C) A toilet with lavatory and shower shall be easily accessible from the birthing rooms without traversing public areas.

(D) Piped-in or portable oxygen and vacuum service shall be available to each birthing room.

(6) Service and Staff Support Facilities for the Birthing Suite. These facilities shall include:

(A) A clean work and sterile storage area, and storage space for clean supplies;

(B) A separate soiled/decontamination utility area equipped with a counter and sink;

(C) A separate toilet with lavatory for staff;

(D) An area shall be provided for the preparation and storage of medication; and

(E) A staff work area for charting located to permit visual supervision of the birthing suite.

(7) General Support Facilities. These facilities shall include:

(A) Adequate space for the housing and maintenance of mechanical, plumbing and electrical equipment;

(B) Medical gas shall be stored and distributed in accordance with "NFPA 99, Standard for Health Care Facilities, 1993 Edition," in *1994 National Fire Code,* Volume 5; and

(C) Housekeeping supply and general storage areas appropriate to fulfill the needs of the facility.

(8) Details and Finishes.

(A) A continuous system of unobstructed corridors and aisles shall extend through the enclosed portion of each story of the birthing facility, connecting all rooms and spaces with each other and with all entrances, exitways and elevators. Mechanical equipment space need not be connected to the corridor system. Corridors shall be separated from all other areas by partitions constructed to resist the passage of smoke.

(B) At least two (2) remote exits shall be provided for each patient floor. Each exit shall discharge to the outside or through an enclosed stairway or passageway to the outside.

(C) Required exit stairs shall discharge directly to the outside or into an enclosed corridor which extends from the stair discharge to the outside. The fire-resistance rating of the enclosure of a corridor extension of a stair shall be not less than the rating required for the stair enclosure as stated in subsection (9)(D) of this rule.

(D) Corridors serving as a means of access to exit for patients in the birthing suite shall be arranged and of sufficient width to facilitate the movement of patients on stretchers.

(E) Exit doors shall swing in the direction of exit travel.

(F) All doors through which birthing patients pass to access birthing rooms and exits shall be of ample width to accommodate ambulance stretchers and warmers.

(G) Where outside windows exist in the birthing room, washable window treatments shall be installed to control light and glare.

(H) Where outside windows are provided in other areas of the facility, window treatments shall be installed to control light and glare.

(I) At least one (1) ABC-type fire, extinguisher, compliant with "NFPA 10, Standard for Portable Fire Extinguishers, 1990 Edition" *1994 National Fire Code*, Volume 1, shall be located on each floor occupied by the birthing center, including the basement.

(J) A paper towel dispenser and soap dispenser shall be provided at all lavatories used for hand washing.

(K) Ceiling, wall and floor finishes in toilets, bath facilities and utility and storage rooms designed for washing, sterilizing and storage shall be easily cleanable.

(L) Finish materials installed on the walls, floors, and ceilings in the birthing rooms shall be washable. The floors shall not be physically affected by frequent wet cleaning with cleaning and germicidal cleaning agents.

(M) Floor and wall penetrations by pipes, ducts and conduits shall be tightly sealed to minimize entry of rodents and insects. Joints of structural elements shall be similarly sealed.

(9) Construction, Including Fire-Resistive Requirements.

(A) Construction of freestanding birthing centers shall comply with "NFPA 101, Section 13-6, Existing Ambulatory Health Care Centers, 1994 Edition," in *1994 National Fire Codes*, Volume 5 and to the minimum requirements of this rule.

(B) Multistoried buildings rated combustible Type V shall be protected throughout by an approved automatic sprinkler system.

(C) Birthing centers shall be separated from other tenants and occupancies by walls having at least a one (1)-hour fire-resistance rating. These walls shall extend from the floor slab below to the floor or roof slab above.

(D) The number of stories in a building housing a birthing center shall be determined by counting all patient care areas in the building.

(E) Every stairway, elevator shaft, light and ventilation shaft, chute and other openings between stories shall be enclosed or protected to prevent the spread of fire or smoke from one (1) floor to another. The fire-resistance rating of the enclosure or protection shall be not less than the structural floor separation requirements of "NFPA 220, Standard on Types of Building Construction, 1992 Edition," in *1994 National Fire Codes*, Volume 5 for the fire-resistive building type classification required by subsection (9)(A) of this section.

(10) Elevators.

(A) Multistory buildings shall have at least one (1) elevator if patient services are located on any floor other than the grade level (birthing center's main entrance) floor.

(B) The elevator cab and door opening shall be of sufficient size to facilitate the movement of a patient on an ambulance stretcher.

(11) Mechanical Requirements.

(A) Heating, ventilating and cooling equipment shall be provided, maintained and operated to provide ambient temperatures of sixty-eight to eighty-five degrees Fahrenheit (68–85°F).

(B) All toilets and soiled materials holding/workrooms shall be exhausted to the outside by exhaust fans.

(12) Plumbing and Other Piping Systems.

(A) Systems shall be designed to supply water to the fixtures and equipment on every floor at an adequate pressure for their practical use.

(B) Reduced pressure backflow preventers shall be installed where the water service enters the building and on hose bibbs and on all fixtures, such as janitors' sinks and laboratory fixtures, to which hoses or tubing can be attached.

(C) Hot water distribution systems shall be delivered to each fixture at a temperature which precludes the hazard of scalding.


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(13) Electrical Requirements.

(A) Every room, including storage rooms, corridor and all other areas shall be sufficiently illuminated to facilitate efficient performance of all necessary tasks.

(B) Trickle charge battery pack units, complying with the standards of "Article 700, NFPA 70, *National Electrical Code*, 1994 Edition," in *National Fire Codes*, Volume 3 shall be located to provide emergency lighting in the birthing rooms, exit corridors, exit signs, electrical branch panel rooms and exit stairs to point of discharge at grade. These fixtures shall be tested at least quarterly with the tests documented in writing. An emergency stand-by power system is not required in birthing centers.

(C) There shall be one (1) electrical outlet for the emergency light and at least two (2) additional duplex outlets in each birthing room.

(D) The fire alarm system in existing birthing rooms may consist of the local alarms from the required smoke detectors provided the alarm from any one (1) of the detectors may be heard throughout the occupied areas of the birthing center. Existing birthing centers with building configurations which preclude a local alarm from alerting all birthing center occupants must have an electrically powered fire alarm system which will alert all areas of the facility when activated.

(E) Existing birthing centers shall have smoke detectors installed at thirty-foot (30') intervals in all rooms and in corridors. All required smoke detectors in existing birthing centers may be battery powered. Battery-powered smoke detectors shall be tested at least quarterly with the tests documented in writing.

*AUTHORITY: section 197.225, RSMo 1994.* Emergency rule filed May 1, 1995, effective May 10, 1995, expired Sept. 7, 1995. Original rule filed May 1, 1995, effective Nov. 30, 1995. Emergency amendment filed June 19, 1998, effective July 1, 1998, expired Feb. 25, 1999. Amended: Filed June 19, 1998, effective Jan. 30, 1999.*

**Original authority 1975, amended 1986.*


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**IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF MISSOURI CENTRAL DIVISION**

| | | |
|---|---|---|
| COMPREHENSIVE HEALTH OF PLANNED PARENTHOOD GREAT PLAINS, et al., | ) | |
| Plaintiffs, | ) | |
| v. | ) | Case No. 16-4313-CV-C-HFS |
| RANDALL WILLIAMS et al., | ) | |
| Defendants. | ) | |

**DECLARATION OF HAROLD C. KIRBEY**

I, Harold C. Kirbey, declare as follows:

1. I am of sound mind, above the age of eighteen years, capable of making this affidavit, and personally acquainted with the facts herein stated.

2. I am the Division Director for the Division of Community and Public Health for the Missouri Department of Health and Senior Services ("DHSS"). I am a custodian of the records for that Division. The Division maintains DHSS records in the ordinary course of business.

3. I am aware that a Missouri statute requires the attending physician to complete and file an individual abortion report for each abortion that is performed or induced. Mo. Rev. Stat. § 188.052.1. The same Missouri statute requires any physician who provides post-abortion care to a woman for a complication to complete and file an individual complication report. Mo. Rev. Stat. § 188.052.2. Both the abortion reports and the complication reports are required to be filed within 45 days of the abortion, or the post-abortion care. Mo. Rev. Stat. § 182.052.3. The content of these





EXHIBIT 4

reports is kept confidential, to be used by DHSS for collating and evaluating data and providing statistical reports based on such data. Mo. Rev. Stat. § 182.052.5.

4. In the ordinary course of business, these abortion reports and complication reports are collected and retained by the Division of Community and Public Health, at or near the time that such reports are submitted. It is part of the regular course of business for DHSS to accept and retain submitted abortion reports and complication reports.

5. DHSS regulations define the word "complication," stating that this term "includes, but is not limited to, hemorrhage, infection, uterine perforation, cervical lacerations and retained products." 19 CSR § 30-30.050(1)(D).

6. A diligent search of DHSS records has failed to locate any individual complication reports filed by Reproductive Health Services of Planned Parenthood of the St. Louis Region ("RHS"), or any individual complications reports regarding post-abortion care provided at RHS's facility in St. Louis, from January 1, 2002 to the present.

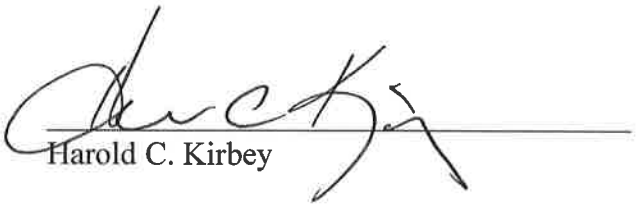
7. A diligent search of DHSS records has identified numerous abortion reports filed by RHS, pursuant to Mo. Rev. Stat. § 188.052, during the same time period. These abortion reports do not include any information about post-abortion care for complications.

8. A diligent search of DHSS records has failed to locate any individual complication reports filed by Comprehensive Health of Planned Parenthood Great Plains or any of its predecessor entities (collectively, "Comprehensive Health"), or any individual complication reports regarding post-abortion care provided at Comprehensive Health's Columbia and Kansas City facilities, from January 1, 2002 to the present.

9. A diligent search of DHSS records has identified numerous abortion reports filed by Comprehensive Health, pursuant to Mo. Rev. Stat. § 188.052.1, during the same time period. These abortion reports do not include any information about post-abortion care for complications.

I declare, under penalty of perjury, that the foregoing is true and correct.

Dated: March 30, 2017



Harold C. Kirbey

**IN THE UNITED STATES DISTRICT COURT**
**WESTERN DISTRICT OF MISSOURI**
**CENTRAL DIVISION**

| | | |
|---|---|---|
| COMPREHENSIVE HEALTH OF PLANNED PARENTHOOD GREAT PLAINS, et al. | ) | |
| Plaintiffs, | ) | Case No. 2:16-cv-04313-HFS |
| v. | ) | |
| DR. RANDALL WILLIAMS, et al., | ) | |
| Defendants. | ) | |

# PLACEHOLDER FOR EXHIBIT 5

# ABBOTT AMBULANCE, INC RECORDS

# (FILED UNDER SEAL)

**IN THE UNITED STATES DISTRICT COURT**
**WESTERN DISTRICT OF MISSOURI**
**CENTRAL DIVISION**

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|---|---|---|
| COMPREHENSIVE HEALTH OF PLANNED PARENTHOOD GREAT PLAINS, et al. | ) | |
| Plaintiffs, | ) | Case No. 2:16-cv-04313-HFS |
| v. | ) | |
| DR. RANDALL WILLIAMS, et al., | ) | |
| Defendants. | ) | |

# PLACEHOLDER FOR EXHIBIT 6

# ST. LOUIS CITY FIRE DEPARTMENT

# RECORDS

# (FILED UNDER SEAL)

**IN THE UNITED STATES DISTRICT COURT**
**WESTERN DISTRICT OF MISSOURI**
**CENTRAL DIVISION**

| | | |
|---|---|---|
| COMPREHENSIVE HEALTH OF PLANNED PARENTHOOD GREAT PLAINS, et al. | ) | |
| Plaintiffs, | ) | Case No. 2:16-cv-04313-HFS |
| v. | ) | |
| DR. RANDALL WILLIAMS, et al., | ) | |
| Defendants. | ) | |

# PLACEHOLDER FOR EXHIBIT 7

# RHS DISCOVERY DOCUMENTS

# (FILED UNDER SEAL)

**IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF MISSOURI CENTRAL DIVISION**

| | | |
|---|---|---|
| COMPREHENSIVE HEALTH OF PLANNED PARENTHOOD GREAT PLAINS, et al., | ) | |
| Plaintiffs, | ) | |
| v. | ) | Case No. 16-4313-CV-C-HFS |
| RANDALL WILLIAMS et al., | ) | |
| Defendants. | ) | |

**SUPPLEMENTAL DECLARATION OF ANDREW STEELE, M.D.**

I, Andrew Steele, declare as follows:

1. I submit my declaration in my personal capacity alone, and do not speak for or act as an authorized representative of Saint Louis University, SSM Health, or any other entity of whom I am a member. I hold these statements to be true and accurate to a reasonable degree of medical certainty, based on: my education, training, review of published documents; and based on my extensive surgical experience including caring for post-abortal complications.

2. I disagree with Dr. Eisenberg's implication that the normal standard practice is to perform surgeries such as D&C and hysteroscopy in an office setting, stating that these were done "frequently" and "routinely" in physician's offices (Eisenberg Declaration, ¶¶ 21 and 22). Dr. Eisenberg also states that surgeries done in the office are "very common" but provides no proof to support the assertion except the general rate of miscarriage in the population. While surgeries such as dilation and curettage (D&C) and hysteroscopy *can* be performed in an office setting in selected cases, my experience as a gynecologic surgeon is that they are most commonly performed in a hospital-based operating suite or ambulatory surgical center. In fact,


EXHIBIT 8

according to research published by the RAND Corporation, non-elective D&C for evacuation of a first trimester missed abortion (miscarriage), hysteroscopy, and non-obstetric D&C were all in the top 100 procedures done in California ASC's and hospitals.[i] It is the common and routine practice to perform D&C's for miscarriage and gynecologic indications, as well as hysteroscopy, in hospitals or ASC's.

3. I further disagree with Dr. Eisenberg's assertion that procedures such as D&C, hysteroscopy and LEEP -- which *can* be done in select and properly equipped offices -- are equivalent in risk to D&C or D&E for pregnancy termination. In fact, office hysteroscopy and LEEP are safer and so cannot serve as appropriate comparisons. In reviewing published literature on office hysteroscopy, the published scientific studies demonstrate complication rates for office hysteroscopy that are consistently lower than the surgical abortion complication rates of 0.3% to 0.89% quoted by Dr. Eisenberg himself (Exhibit 3 point 6).[ii,iii,iv] Scientific studies concerning LEEP procedures for the evaluation of abnormal PAP smears also report lower rates of complications.[v] In regards to office D&C unrelated to pregnancy or miscarriage, that practice is not currently held to be a standard primary step in the evaluation of abnormal gynecologic bleeding and so I was not able to find comparison studies to either refute or confirm Dr. Eisenberg's assertions. [vi] I have already provided peer-reviewed, published data on pregnancy terminations from over 40,000 abortions done in Europe. In that study, the reported rates of abortion-related hemorrhage (5.6%) and significant injury (1.8%)[vii] from surgical abortion were even higher than Dr. Eisenberg's figures, and much higher than reported complication rates for LEEP and office hysteroscopy. Thus, scientific findings suggest that surgical abortion is not analogous to office hysteroscopy and LEEP, with the latter procedures being much safer than

surgical terminations of pregnancy such as D&C and D&E; they should not be used as comparisons.

I declare, under penalty of perjury, that the foregoing is true and correct.

Dated: March 31, 2017

*/s/ Andrew Steele*
Andrew Steele, M.D.

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[i] Vogt WB and Romley JA. "California Ambulatory Surgery Centers: Technical Report". RAND Health. RAND Corporation and the California HealthCare Foundation. Santa Monica CA. 2009. PG 62. Appendix A: Top 100 Procedures for ASC's or Hospitals. CPT Codes 59820, 58558, 58120.

[ii] Hinkley M, Amin A. "1000 Office based hysteroscopies prior to In Vitro Fertilization". *JSLS*. Apr-June 2004; 8(2)103-107.

[iii] Change CC. "Efficacy of office diagnostic hysterofibroscopy". *J Minim Invasive Gynecol*. Mar 2007. 14(2): 172-5.

[iv] Mairos J, Di Martino P. "Office hysteroscopy. An operative gold standard technique and an important contribution to patient safety." Gynecol Surg. Mar 2016. 12:111-114.

[v] Santesso et al. "Systemic reviews and meta-analysis of benefits and harms of cryotherapy, LEEP, and cold knife conization to treat cervical intraepithelial neoplasia". Int J Gynaecol and Obstet. Mar 2016. 132(3):266-71.

[vi] Munro M. "Investigation of women with postmenopausal uterine bleeding: Clinical Practice Recommendations". *Perm J*. Winter 2014. 18(1): 55-70.

[vii] Niinimaki M et al., "Immediate complications after medical compared with surgical termination of pregnancy." *Obstet Gynecol*. Oct 2009. 114(4): 795-804.

# *Currently 120 Ambul. Surgery Centers in Missouri*

| FID | Fac Type | Facility Name | City | County | CMS Provider# | Region | Accred? |
|---|---|---|---|---|---|---|---|
| S159 | | Surgery Center at the Forum | Columbia | BOONE | Pending | Central | ☑ |
| S079 | | Columbia Endoscopy Center | Columbia | BOONE | 26C0001085 | Central | ☐ |
| S129 | | Surgical Center at Columbia Orthopaedic Grou | Columbia | BOONE | 26C0001131 | Central | ☑ |
| S085 | | Surgery Center of Columbia | Columbia | BOONE | 26C0001088 | Central | ☑ |
| S151 | | CSA Surgical Center, LLC | Columbia | BOONE | 26C0001151 | Central | ☑ |
| S170 | | Lake Regional Diagnostic and Surgery Center | Osage Beach | CAMDEN | 260186 | Central | ☐ |
| S009 | | CMMP Surgical Center, LLC | Jefferson City | COLE | 26C0001042 | Central | ☑ |
| S026 | | JCMG Surgery Center, Inc. | Jefferson City | COLE | 26C0001049 | Central | ☑ |
| S136 | | Mercy Hospital Lebanon Surgery Center Rolla | Rolla | PHELPS | 260059 | Central | ☑ |
| S135 | | Mercy Outpatient Surgery Center Washington | Washington | FRANKLIN | 260052 | Eastern | ☑ |
| S099 | | Washington Surgery Center, Inc | Washington | FRANKLIN | 26C0001106 | Eastern | ☑ |
| S113 | | Twin Cities Ambulatory Surgery Center, LP | Festus | JEFFERS | 26C0001117 | Eastern | ☑ |
| S045 | | Surgery Center of Farmington | Farmington | ST FRAN | 26C0001054 | Eastern | ☑ |
| S148 | | Ambulatory Surgery Center Shoal Creek Mosai | Kansas City | CLAY | 26c0001149 | KC Area | ☑ |
| S010 | | Creekwood Surgery Center, LP | Kansas City | CLAY | 26C0001021 | KC Area | ☑ |
| S091 | | Eye Surgery Center - Northland | Kansas City | CLAY | 26C0001118 | KC Area | ☐ |
| S063 | | Briarcliff Ambulatory Surgery Center, LP | Kansas City | CLAY | 26C0001069 | KC Area | ☑ |
| S095 | | The Endoscopy Center - Liberty | Kansas City | CLAY | 26C0001098 | KC Area | ☑ |
| S014 | | The Endoscopy Center - North | Kansas City | CLAY | 26C0001041 | KC Area | ☑ |
| S171 | | Total Joint Center of the Northland | Kansas City | CLAY | | KC Area | ☐ |
| S123 | | Surgery Center at Liberty Hospital | Liberty | CLAY | 26C0001126 | KC Area | ☑ |
| S108 | | Northland Eye Surgery Center, LLC | Liberty | CLAY | 26C0001113 | KC Area | ☑ |
| S075 | | Liberty Cataract Center, LLC | Liberty | CLAY | 26C0001078 | KC Area | ☑ |
| S061 | | Liberty Ambulatory Surgery Center, LP | Liberty | CLAY | 26C0001070 | KC Area | ☑ |
| S093 | | St Mary's Surgical Center | Blue Springs | JACKSON | 26C0001094 | KC Area | ☑ |
| S110 | | Centerpoint Ambulatory Surgery Center | Independence | JACKSON | 26C0001114 | KC Area | ☑ |
| S016 | | Eye Surgery Center - The Cliffs | Independence | JACKSON | 26C0001022 | KC Area | ☑ |
| S122 | | The Highlands Surgery Center | Independence | JACKSON | Licensed only | KC Area | ☑ |
| S013 | | The Endoscopy Center - East | Independence | JACKSON | 26C0001038 | KC Area | ☑ |
| S048 | | Surgicenter of Kansas City, L.L.C. | Kansas City | JACKSON | 26C0001002 | KC Area | ☑ |
| S019 | | Saint Luke's -G.I. Diagnostics, LLC | Kansas City | JACKSON | 26C0001028 | KC Area | ☑ |
| S164 | | Truman Medical Center, Incorporated Ambulato | Kansas City | JACKSON | 260048 | KC Area | ☑ |
| S065 | | Blue Ridge Surgical Center, LLC | Kansas City | JACKSON | 26C0001072 | KC Area | ☑ |
| S058 | | Midwest Digestive Health Center, LLC | Lee's Summit | JACKSON | 26C0001066 | KC Area | ☑ |
| S094 | | Saint Luke's Surgicenter - Lee's Summit | Lee's Summit | JACKSON | 26C0001095 | KC Area | ☑ |
| S038 | | Skin & Mohs Surgery Center, Inc. | Lee's Summit | JACKSON | 26C0001115 | KC Area | ☑ |
| S116 | | Summit Plastic Surgery , Inc. | Lee's Summit | JACKSON | Licensed only | KC Area | ☐ |
| S163 | | Midwest Pain Management Center | Lee's Summit | JACKSON | 26C0001156 | KC Area | ☑ |
| S161 | | North Point Surgery Center, LLC | Kansas City | PLATTE | 26C0001155 | KC Area | ☑ |
| S032 | | Northeast Missouri Ambulatory Surgery Center, | Hannibal | MARION | 26C0001057 | Northeast | ☑ |
| S125 | | Physicians Surgery Center | Hannibal | MARION | 26C0001128 | Northeast | ☐ |
| S089 | | The Surgery Center of North Central Missouri | Moberly | RANDOLP | 26C0001102 | Northeast | ☐ |
| S069 | | Plastic Surgery Center of St. Joseph, Inc. | St. Joseph | BUCHANA | 26C0001081 | Northwest | ☑ |
| S070 | | St. Joseph Center for Outpatient Surgery | St. Joseph | BUCHANA | 26C0001075 | Northwest | ☐ |
| S031 | | Murphy Watson Burr Surgery Center, Inc. | St. Joseph | BUCHANA | 26C0001043 | Northwest | ☑ |
| S101 | | Mercury Surgery Center, LLC | St. Joseph | BUCHANA | 26C0001108 | Northwest | ☐ |
| S025 | | Surgery Center of St. Joseph | St. Joseph | BUCHANA | 26C0001012 | Northwest | ☐ |
| S004 | | Auburn Surgery Center, Inc. | Cape Girardeau | CAPE GIR | 26C0001048 | Southeast | ☑ |
| S034 | | Physicians Alliance Surgery Center | Cape Girardeau | CAPE GIR | 26C0001055 | Southeast | ☐ |
| S133 | | GA Endoscopy Center, LLC | Cape Girardeau | CAPE GIR | 26C0001137 | Southeast | ☑ |
| S012 | | Doctors' Park Surgery, Inc. | Cape Girardeau | CAPE GIR | 26C0001007 | Southeast | ☐ |
| S147 | | Midwest Surgery Center, LLC | Cape Girardeau | CAPE GIR | 26C0001147 | Southeast | ☑ |
| S037 | | Silver Springs Surgery Center, LLC | Cape Girardeau | CAPE GIR | 26C0001051 | Southeast | ☑ |
| S142 | | West Park Surgery Center | Cape Girardeau | CAPE GIR | Licensed only | Southeast | ☑ |
| S092 | | Mercy Surgery Center - National | Springfield | GREENE | 260065 | Southwest | ☑ |
| S078 | | The C. Rex Witherspoon Surgery Center, Inc. | Springfield | GREENE | 26C0001090 | Southwest | ☐ |





EXHIBIT 9

| FID | Fac Type | Facility Name | City | County | CMS Provider# | Region | Accred? |
|---|---|---|---|---|---|---|---|
| S028 | | Mattax-Neu-Prater Surgery Center, LLC | Springfield | GREENE | 26C0001029 | Southwest | ☑ |
| S055 | | Bradford Place Surgery & Laser Center, LLC | Springfield | GREENE | 26C0001064 | Southwest | ☐ |
| S100 | | West Plains Ambulatory Surgery Center, LLC | West Plains | HOWELL | 26C0001100 | Southwest | ☑ |
| S030 | | Freeman Midwest Surgery | Joplin | JASPER | 260137 | Southwest | ☑ |
| S018 | | Four States Surgery Center | Joplin | JASPER | 26C0001053 | Southwest | ☐ |
| S128 | | 32nd Street Surgery Center, LLC | Joplin | JASPER | 26C0001134 | Southwest | ☑ |
| S140 | | Freeman Surgical Center, LLC | Joplin | JASPER | 26C0001142 | Southwest | ☑ |
| S036 | | Regional Surgery Center, PC | Joplin | NEWTON | 26C0001026 | Southwest | ☐ |
| S144 | | Citizens Memorial Hospital Ambulatory Surgery | Bolivar | POLK | Licensed only | Southwest | ☑ |
| S114 | | Surgery Center of Branson, LLC | Branson | TANEY | 26C0001120 | Southwest | ☐ |
| S082 | | Tri-Lakes Surgery Center, LLC | Branson | TANEY | 26C0001104 | Southwest | ☐ |
| S088 | | Mercy Hospital Endoscopy Center Lake St. Loui | Lake St. Louis | ST CHARL | 260020 | St L Area | ☑ |
| S143 | | St. Charles Surgery Center, LLC | St. Charles | ST CHARL | 26C0001144 | St L Area | ☑ |
| S042 | | St. Peter's Ambulatory Surgery Center | St. Peters | ST CHARL | 26C0001052 | St L Area | ☑ |
| S072 | | Mid Rivers Surgery Center | St. Peters | ST CHARL | 26C0001080 | St L Area | ☑ |
| S071 | | SSM St. Joseph Endoscopy Center, LLC | St. Peters | ST CHARL | 26C0001077 | St L Area | ☑ |
| S141 | | Mercy Outpatient Surgery Center Clayton at Cla | Ballwin | ST LOUIS | 260020 | St L Area | ☑ |
| S167 | | Premier Surgical Center, LLC | Bridgeton | ST LOUIS | pending | St L Area | ☐ |
| S127 | | MidAmerica Surgery Center, LLC | Chesterfield | ST LOUIS | 26C0001130 | St L Area | ☑ |
| S120 | | Barnes-Jewish Hospital Outpatient Orthopedic | Chesterfield | ST LOUIS | 260032 | St L Area | ☑ |
| S156 | | Orthopedic Ambulatory Surgery Center of Ches | Chesterfield | ST LOUIS | Licensed only | St L Area | ☐ |
| S064 | | Timberlake Surgery Center | Chesterfield | ST LOUIS | 26C0001071 | St L Area | ☑ |
| S138 | | Chesterfield ASC | Chesterfield | ST LOUIS | 26C0001143 | St L Area | ☑ |
| S103 | | Interventional Pain Center of Chesterfield | Chesterfield | ST LOUIS | 26C0001107 | St L Area | ☐ |
| S076 | | Chesterfield Surgery Center | Chesterfield | ST LOUIS | 26C0001082 | St L Area | ☑ |
| S158 | | HHC ASC, LLC | Creve Coeur | ST LOUIS | 26C0001153 | St L Area | ☑ |
| S150 | | Emerson Road Surgery Center, LLC | Creve Coeur | ST LOUIS | 26C0001148 | St L Area | ☑ |
| S087 | | St. Louis Surgical Center | Creve Coeur | ST LOUIS | 26C0001093 | St L Area | ☑ |
| S152 | | Total Joint Center Of St Louis | Creve Coeur | ST LOUIS | Licensed only | St L Area | ☑ |
| S086 | | Advanced Endoscopy Center, LLC | Creve Coeur | ST LOUIS | 26C0001091 | St L Area | ☑ |
| S153 | | Laser Spine Surgery Center of St Louis, LLC | Creve Coeur | ST LOUIS | Licensed only | St L Area | ☑ |
| S084 | | Advanced Surgical Care | Creve Coeur | ST LOUIS | 26C0001087 | St L Area | ☑ |
| S011 | | City Place Surgery Center | Creve Coeur | ST LOUIS | 26C0001033 | St L Area | ☑ |
| S118 | | Mercy Hospital Endoscopy Center Des Peres | Des Peres | ST LOUIS | 260020 | St L Area | ☑ |
| S121 | | St Louis Eye Surgery and Laser Center | Des Peres | ST LOUIS | 26C0001125 | St L Area | ☑ |
| S137 | | SSM St. Clare Surgical Center, LLC | Fenton | ST LOUIS | 26C0001141 | St L Area | ☑ |
| S146 | | Fresenius Vascular Care St. Louis LLC | Florissant | ST LOUIS | Pending | St L Area | ☑ |
| S172 | | Fresenius Vascular Care St. Louis ASC, LLC | Florissant | ST LOUIS | Licensed only | St L Area | ☐ |
| S149 | | Florissant Surgery Center | Florissant | ST LOUIS | 26C0001146 | St L Area | ☑ |
| S106 | | Frontenac Surgery and Spine Care Center | Frontenac | ST LOUIS | 26C0001112 | St L Area | ☑ |
| S090 | | The Endoscopy and Colonoscopy Center | Hazelwood | ST LOUIS | 26C0001097 | St L Area | ☑ |
| S162 | | St. Louis Specialty Surgical Center, LLC | Kirkwood | ST LOUIS | 26C0001158 | St L Area | ☑ |
| S155 | | MidAmerica Spine Center, LLC | ST Louis | ST LOUIS | 26C0001154 | St L Area | ☑ |
| S073 | | Mid County Surgery Center | St Louis | ST LOUIS | Licensed only | St L Area | ☑ |
| S098 | | Manchester Surgery Center | St. Louis | ST LOUIS | 26C0001099 | St L Area | ☑ |
| S131 | | South County Surgical Center | St. Louis | ST LOUIS | 26C0001132 | St L Area | ☑ |
| S169 | | Missouri Commons Surgery Center, LLC | St. Louis | ST LOUIS | Licensed Only | St L Area | ☐ |
| S166 | | Barnes-Jewish Hospital Center for Advanced M | St. Louis | ST LOUIS | 260032 | St L Area | ☐ |
| S168 | | Central West End Endoscopy, LLC | St. Louis | ST LOUIS | Pending | St L Area | ☐ |
| S134 | | Seven Oaks Surgery Center, L.L.C. | St. Louis | ST LOUIS | 26C0001139 | St L Area | ☐ |
| S109 | | Gateway Endoscopy Center | St. Louis | ST LOUIS | 26C0001116 | St L Area | ☑ |
| S074 | | St. Louis Multispecialty Surgery Center | St. Louis | ST LOUIS | 26C0001079 | St L Area | ☑ |
| S007 | | Woodcrest Surgery Center | St. Louis | ST LOUIS | 26C0001006 | St L Area | ☑ |
| S046 | | South County Outpatient Endoscopy Services, | St. Louis | ST LOUIS | 26C0001060 | St L Area | ☐ |
| S067 | | Advanced Surgery Center | St. Louis | ST LOUIS | 26C0001074 | St L Area | ☐ |
| S066 | | North Campus Surgery Center | St. Louis | ST LOUIS | 26C0001076 | St L Area | ☑ |
| S051 | | Des Peres Square Surgery Center | St. Louis | ST LOUIS | 26C0001061 | St L Area | ☑ |
| S035 | | Old Tesson Surgery Center, L.P. | St. Louis | ST LOUIS | 26C0001138 | St L Area | ☑ |
| S105 | | Landmark Surgery Center | St. Louis | ST LOUIS | 26C0001109 | St L Area | ☑ |

| FID | Fac Type | Facility Name | City | County | CMS Provider# | Region | Accred? |
|---|---|---|---|---|---|---|---|
| S157 | | Children's Speciality Care Center | Town & Country | ST LOUIS | 263301 | St L Area | ☑ |
| S126 | | St Louis Spine & Orthopedic Surgery Center | Town and Count | ST LOUIS | 26C0001133 | St L Area | ☑ |
| S096 | | Cedar Oaks Surgery Center | Warrensburg | JOHNSON | 26C0001103 | Western | ☑ |
| S017 | | Eye Surgery Center of Warrensburg | Warrensburg | JOHNSON | 26C0001044 | Western | ☐ |
| S057 | | Sedalia Surgery Center, LLC | Sedalia | PETTIS | 26C0001065 | Western | ☐ |