IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF IOWA
CENTRAL DIVISION

DES MOINES MIDWIFE COLLECTIVE, CAITLIN HAINLEY, Plaintiffs, v. IOWA HEALTH FACILITIES COUNCIL, HAROLD MILLER, AARON DEJONG, KELLY BLACKFORD, and BRENDA PERRIN. Defendants.	Case No. 4:23-CV-00067-SMR-HCA **PLAINTIFFS' RESISTANCE TO DEFENDANTS' MOTION FOR SUMMARY JUDGMENT**

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INTRODUCTION

The government agrees that there are "many benefits" to freestanding birth centers. *See* Pls.' SUF ¶ 13.[1] Yet, the challenged Certificate of Need (CON) law has led to a complete lack of *any* birth center in the state. Relying solely on the deference afforded under the rational basis standard—and contrary to the evidence and the only expert testimony in this case—the government claims that this *de facto* ban is reasonable because it prevents those beneficial birth centers from opening unless they can overcome competitors' protests and prove a "need" for their services.

Rational basis is not so toothless. That's especially true here, where businesses that provide the exact same service as birth centers are exempted from CON requirements, so long as they do their work in a patently *less* safe environment like a home or hotel. How could such differential treatment possibly be rational? The government cannot say. Similarly, it is not rational to require birth centers to prove "need" while exempting hospitals that want to expand their birthing services with up to $1.5 million in annual capital expenditures. Instead, it's baldly protectionist. On one extreme, multimillion-dollar hospitals are exempted from proving need and overcoming the competitor's veto; on the other extreme, backroom hotel businesses are also exempted from these irrational requirements. In contrast, before Ms. Hainley can expend even one dollar on a freestanding and safe birth center, she must navigate the gauntlet of Iowa's CON requirement. Such absurdities in treatment undercut any rational basis for Iowa's CON law.

The government's arguments must be rejected. Ms. Hainley can plainly assert a due process challenge. She need not show it is impossible for her to obtain a CON; it's enough that the CON law places irrational burdens in the way of her exercising her right to earn a living. On the merits,

[1] "Pls.' SUF" refers to Plaintiffs' Statement of Undisputed Facts, Doc. 49-2. "Defs.' SOF" refers to Defendants' Statement of Material Facts, Doc. 51-2.

the government's *post hoc* justifications for these burdens stretch rational basis beyond its breaking point. And even if rational basis could eke out a plausible justification under due process, those same justifications are undercut by the differential treatment afforded hospitals and hotels. The CON law irrationally denies Ms. Hainley her right to equal protection of the laws.

The parties agree that there are no genuine disputes of material fact. Docs. 49, 49-1, 51, 51-1. However, it is Ms. Hainley, not the government, who is entitled to summary judgment.

ARGUMENT

I. Ms. Hainley Properly Asserts a Due Process Challenge

A. Ms. Hainley has protectable due process interests

The government argues that because Ms. Hainley has been actively working as a lactation consultant and midwife, "the CON requirement for birth centers hasn't prevented [her] from practicing a chosen profession." Defs.' Br. at 11. They claim that this raises "serious questions" as to whether Ms. Hainley can claim any due process[2] interests at all. *Id.* at 13. The government is incorrect. Iowa's CON law imposes significant burdens on Ms. Hainley's right to work in her chosen profession, even if it does not exclude her from the health industry altogether.

The Supreme Court recognized over a century ago that "the right to work for a living in the common occupations of the community is of the very essence of the personal freedom and opportunity that it was the purpose of the [Fourteenth] Amendment to secure." *Truax v. Raich*, 239 U.S. 33, 41 (1915); *see also Meyer v. Nebraska*, 262 U.S. 390, 399 (1923) (the term "liberty" in the Due Process Clause "denotes not merely freedom from bodily restraint but also the right … to engage in any of the common occupations of life"). Accordingly, there is a recognized liberty interest in "choos[ing] one's field of private employment." *Conn v. Gabbert*, 526 U.S. 286, 292

[2] The government does not specify which claims are relevant to this argument, but the cases and standard they cite are limited to federal due process claims. *See* Defs.' Br. at 11–12.

(1999) (citing *Truax*, 239 U.S. at 41). Here, Ms. Hainley has a liberty interest in establishing a birth center where women can give low-risk births in a non-hospital setting. The CON law infringes that interest because it prohibits her from doing so unless she successfully navigates an arbitrary and irrational process.

The government argues that there is no liberty interest at stake unless its regulation is a "complete prohibition" that excludes Ms. Hainley from the maternal health field entirely. Defs.' Br. at 11 (quoting *Conn*, 526 U.S. at 292). In other words, unless the CON law excludes Ms. Hainley from all work with women's health, the government believes that it need not justify the law at all, even under rational basis. That is incorrect. As discussed below, the cases on which the government relies concern *temporary* interruptions to an occupation. That is not what is happening here. Iowa's CON law is a permanent restriction on Ms. Hainley's right to earn a living in her chosen occupation.

In *Conn v. Gabbert*, the Supreme Court held that the plaintiff's right to work as an attorney was not infringed by execution of a search warrant that temporarily kept him from representing a client. 526 U.S. at 288–89. Enforcement of the warrant was not a "complete prohibition" on his work, but merely a "brief interruption," after which he was able to go right back to work. *Id.* at 292. Similarly, in *Castanon v. Cathey*, the Tenth Circuit held that a racehorse owner was not prevented from pursuing his occupation by the temporary disqualification of his horse, which kept it from running a single race. 976 F.3d 1136, 1142 (10th Cir. 2020). And in *Hu v. City of New York*, the Second Circuit found that enforcement actions against owners of a construction business did not infringe their right to occupational choice because the cost of enforcement actions did not prevent them from running their business. 927 F.3d 81, 102–03 (2d Cir. 2019). In each case, the

key consideration was whether the challenged action was a "brief interruption" of an occupation or a more permanent "complete prohibition."[3]

Here, Iowa's CON requirement is a "complete prohibition" on Ms. Hainley's ability to open and run what would be Iowa's *only* stand-alone birth center. The CON law does not merely cause a "brief interruption" that will shortly be remedied. As long as the challenged law remains in place, Ms. Hainley must obtain a CON to legally operate a birth center. Accordingly, the requirement infringes her occupational liberty interests.

Even if Ms. Hainley had no liberty interests of her own at stake, she also raises claims regarding the right of birthing mothers to choose the manner and place of giving birth. *See* Amended Petition ¶¶ 48–51, 66. The Court has ruled that this right is not fundamental, (Doc. 44 at 7–10),[4] not that it is not a valid liberty interest. This interest of birthing mothers provides an independent basis for Ms. Hainley's due process claims, apart from her personal right to occupational choice.

B. Ms. Hainley need not apply for a CON to challenge the CON requirement

The government argues that the CON requirement "isn't preventing Hainley from opening a birth center" because she has not submitted a CON application. Defs.' Br. at 12–13. The government does not explain the purpose of this argument, but to the extent it is an argument that Ms. Hainley lacks standing, it has no merit.

[3] The government also cites cases concluding that it does not infringe due process to require would-be attorneys to pass the bar exam, *Raymond v. O'Connor*, 526 F. App'x 526, 528 (6th Cir. 2013) (unpublished), or to deny an attorney certification as a specialist, *Doe v. Fla. Bar*, 630 F.3d 1336, 1345 (11th Cir. 2011) (concluding that specialist certification "is not required to practice in any particular field of law"). The rejection of those unique claims does not show that Ms. Hainley lacks a liberty interest in seeking to establish a birth center.

[4] Ms. Hainley reserves the right to appeal the question of whether this is a fundamental right. *See* Pls.' MSJ Memo. at 10 n.8 (Doc. 49-1).

A plaintiff need not apply and be rejected to have standing to challenge an occupational barrier like Iowa's CON law. As the Supreme Court long ago held in a challenge to a similar need review law, a plaintiff "[i]s not obligated to apply for a certificate of convenience and necessity and submit to the administrative procedures incident thereto before bringing [an] action." *City of Chicago v. Atchison, Topeka & Santa Fe Ry. Co.*, 357 U.S. 77, 89 (1958). More recently, the district court in *Birchansky* rejected this exact argument, concluding that a plaintiff who "has never submitted a letter of intent to the Department, has never applied for a CON, [and] has never received a denial from the Council regarding a CON application" nonetheless had standing to challenge Iowa's CON law. *Birchansky v. Clabaugh*, 421 F. Supp. 3d 658, 672 (S.D. Iowa 2018); *see also, e.g.*, *Merrifield v. Lockyer*, 547 F.3d 978, 980 n.1 (9th Cir. 2008) (plaintiff had standing even though he never applied for a license because he could not "engage in his trade unless he first satisfies the current licensing requirement"); *Bruner v. Kentucky*, 997 F. Supp. 2d 691, 696–97 (E.D. Ky. 2014) (plaintiffs had standing even though they never applied for a certificate of need, "not because [they] would automatically be granted a Certificate [if they prevailed], but because the unconstitutional obstacle would be removed from their path").

Here, Ms. Hainley has standing to challenge Iowa's CON law because it burdens her and her patients' rights. She wants to open a birth center and has taken concrete steps toward that goal. *See* Defs.' SOF ¶¶ 59–63; Pls.' SUF ¶¶ 8–12. But she cannot do so unless she successfully navigates the arbitrary, irrational, expensive, and time-consuming CON process. Defs.' SOF ¶¶ 3, 8; Pls.' SUF ¶¶ 13, 16, 34. That barrier causes an injury widely recognized by federal courts, and the government does not dispute that the CON law causes her injury. *See* Pls.' SUF ¶ 36. Moreover, the Council is actively enforcing the CON law, and it rejected the only birth center CON application in the last ten years. *Id.* ¶¶ 48–57. Redressability is also straightforward. The injury

caused by the burdensome CON process will be remedied if Ms. Hainley is successful in this lawsuit—not because she would necessarily receive permission to establish a birth center, but because she could seek to do so without the burdens of proving need and facing a competitor's veto.

The government responds that the landscape has changed since the Council denied the Promise Birth Center (PBC) application in 2014, such that "it seems at least possible" that the Council would approve a birth center CON application now. Defs.' Br. at 12. They also point to a 2019 decision by the Council granting a CON to one hospital over another hospital's objection as evidence that the Council "does not simply adopt competitors' objections." *Id.* at 13. But the point isn't whether it is "possible" that Ms. Hainley could successfully prove a need for a birth center or overcome the inevitable objections from hospitals; the point is whether she must surmount these irrational and arbitrary obstacles to practice her profession. Because the CON process arbitrarily burdens her ability to establish a birth center, she has standing to challenge it.

II. The CON Scheme Violates Due Process

The deprivation of a non-fundamental right violates due process if it is not rationally related to a legitimate government interest. *Birchansky v. Clabaugh*, 955 F.3d 751, 757 (8th Cir. 2020).[5] The government asserts three interests, none of which are specific to birth centers and none of which are sufficiently plausible to survive rational basis review. Defs.' Br. at 16–18.

First, the government asserts "an interest in preserving the availability of comprehensive hospital care." Defs.' Br. at 16. That is essentially the same interest relied on in *Birchansky* to uphold Iowa's CON law against a due process challenge brought by an outpatient eye surgery

[5] As noted in Ms. Hainley's summary judgment brief, Iowa courts have interpreted the Iowa Constitution's due process and equal protection clauses similar to those in the federal Constitution, under a rational basis standard. *See* Pls.' MSJ Memo. at 24 & n.16.

provider, and the government places considerable weight on that decision. *See* Defs.' Br. at 2–3, 14, 17–18, 20.

But *Birchansky* does not resolve this case. Just because a law survives rational basis scrutiny in one context does not mean it survives in every context. *Birchansky* was premised on the conclusion that "Iowa could rationally conclude that its full-service hospitals would be at risk" if competitors were allowed "to cherry pick more lucrative medical services like outpatient surgery." 955 F.3d at 757. Because outpatient surgeries are uniquely lucrative and profitable, and because hospitals are required to provide other costly medical services at a loss, it was at least rational in that context to think that applying Iowa's CON law to outpatient surgery centers could promote an interest in "maintaining full-service hospital viability." *Id.* at 758. The court did *not* hold that protecting hospitals from competition is by itself a legitimate end—and rightly so. *See, e.g.*, *Craigmiles v. Giles*, 312 F.3d 220, 224 (6th Cir. 2002) ("Courts have repeatedly recognized that protecting a discrete interest group from economic competition is not a legitimate governmental purpose."); *St. Joseph Abbey v. Castille*, 712 F.3d 215, 222 (5th Cir. 2013) ("[N]either precedent nor broader principles suggest that mere economic protection of a particular industry is a legitimate governmental purpose …."); *Tiwari v. Friedlander*, 26 F.4th 355, 367–68 (6th Cir. 2022) ("A law that serves protectionist ends and nothing else … does not satisfy rational-basis review."). Critically, *Birchansky* also did not hold that an interest in maintaining hospital viability will sustain Iowa's CON requirement for every kind of health facility or every healthcare service.

Here, the Court should decline to extend *Birchansky* to birth centers. It is not plausible to believe that competition for each and every service provided by a full-service hospital inevitably puts the hospital's financial viability at risk. Unlike outpatient surgeries, there is no basis for

concluding that birth services are so profitable that they subsidize other hospital services or that hospitals must be protected from competition from birth centers to maintain viability. *Birchansky* relied on evidence that outpatient surgeries are profitable enough to "keep rural hospitals financially afloat." 955 F.3d at 757. The government has not introduced any such evidence here or given any reason to conclude the same is true of birthing services.

Citing paragraph 47 of Defendants' Statement of Facts, the government broadly claims that "specialized medical facilities offering only a limited scope of healthcare services, without a demonstrated need for more of those services in the area, could result in a full-service hospital losing patients and, in turn, reducing certain programs and services, or even shutting down altogether." Defs.' Br. at 16–17 (citing Defs.' SOF ¶ 47). Not only is that speculative statement too general to support any conclusion about birth centers, but it also is not corroborated by the deposition testimony the government cites. *See* Pls.' Resp. to Defs.' SOF ¶ 47 (the testimony only addressed the "potential negative consequences from a hospital closing"). Even accepting that a hospital's closure has negative consequences, there is no evidence and no reason to believe that birth centers create or heighten a risk of hospital closure. *See also* Pls.' MSJ Memo. at 17–18 (Iowa's CON law as applied to birth centers does not ensure access or aid underserved communities).

Nor does the Council's 2014 decision rejecting PBC's application establish that the CON law furthers an interest in protecting rural Iowans' access to health services. *See* Defs.' Br. at 17 (claiming that the PBC denial was based in part on a concern about "depriv[ing] rural Iowans of, or mak[ing] it more difficult for them to access, the care they need"). The Council's assertion that the CON law serves a legitimate purpose does not make it so, and the Court should not accept the government's *ipse dixit* simply because it was included in a decision denying a CON. Rather than

establishing a rational basis, the Council's denial of PBC's well-supported application in the face of hospital opposition reveals its *actual* purpose of protecting incumbents from competition. As noted above, that is not a legitimate governmental interest. *See also* Pls.' MSJ Memo. at 13–14 (discussing the economic protectionism inherent in applying Iowa's CON law to birth centers).

Second, the government asserts an interest in "control[ling] health care costs for consumers by preventing duplication of services and eliminating excess capacity." Defs.' Br. at 17. But as proven with substantial evidence in Ms. Hainley's summary judgment brief, any claim that applying the CON law to birth centers controls costs is contradicted by basic economics, decades of research, the federal government, and the *only* expert testimony offered in this case. Pls.' MSJ Memo. 15–17. The principles of supply and demand are no less scientifically accepted than the law of gravity. And basic principles of supply and demand hold that restricting competition for birth services through a CON increases, rather than reduces, costs. The government has produced no evidence to contradict that basic truth. Congress itself recognized the folly of a federal CON mandate in 1986 when the evidence showed that CON programs *increased* health care costs. *See id.* (citing the federal government's repeated admonitions that CON laws lead to increased prices). And the only expert in this case, Dr. Bailey, issued a report concluding that Iowa's CON scheme raises prices—not to mention results in inferior healthcare services. Pls.' SUF ¶¶ 64–69.

Rather than controlling health care costs, applying Iowa's CON law to birth centers undermines that interest and is thus irrational. Even if legislators erroneously considered controlling costs to be a plausible justification when Iowa's CON law was enacted in 1977, the intervening decades of research and experience have entirely undermined any such justification. *Cf. United States v. Carolene Prods. Co.*, 304 U.S. 144, 153 (1938) ("[T]he constitutionality of a statute predicated upon the existence of a particular state of facts may be challenged by showing

to the court that those facts have ceased to exist."). The government's burden under the rational basis test is not heavy, but it cannot simply ignore all available evidence and blithely assert that restricting birth centers furthers an interest in controlling costs when the opposite has been shown to be true.

Third, the government asserts an interest in "discouraging the development of underutilized facilities, ensuring that practitioners have ample patient volume to generate necessary expertise." Defs.' Br. at 18. But the government does not even attempt to connect this general assertion with the regulation of birth centers or to show that freestanding birth centers threaten the expertise at existing facilities. Uncritically accepting this broad assertion as justification for a CON law would require the Court to uphold even baldly protectionist regulations, since *every* additional patient will increase "patient volume" and *every* repetition of a procedure can be said to promote "expertise" in that procedure. This interest would allow the government to apply a CON law to literally any industry or service for no other reason than to entrench incumbent businesses. "No sophisticated economic analysis is required" to see that it is pretextual and fails rational basis review. *Bruner*, 997 F. Supp. 2d at 701 (quoting *Craigmiles*, 312 F.3d at 229). In any event, birth centers are statutorily limited to deliveries that "follow[] a normal, uncomplicated, low-risk pregnancy." Iowa Code § 10A.711(3). By definition, they do not involve high-risk or unusual births requiring specialized expertise that can only be developed by channeling patients to existing providers. This asserted interest cannot justify the application of Iowa's CON law to birth centers.

In sum, none of the government's asserted interests are sufficient, and there is no "conceivable" basis that rationally supports the application of Iowa's CON requirement to birth centers. *Birchansky*, 955 F.3d at 757.[6]

III. The CON Scheme Violates Equal Protection

"[E]ven in the ordinary equal protection case calling for the most deferential of standards, we insist on knowing the relation between the classification adopted and the object to be attained." *Romer v. Evans*, 517 U.S. 620, 632 (1996). That is because a state "may not rely on a classification whose relationship to an asserted goal is so attenuated as to render the distinction arbitrary or irrational." *City of Cleburne v. Cleburne Living Ctr.*, 473 U.S. 432, 446 (1985). Here, even if the government had identified a plausible interest for purposes of due process, it fails to establish any rational relationship between the state's asserted goals and its decision to treat birth centers differently from other out-of-hospital birth service providers and from existing maternity care providers that want to expand their services by up to $1.5 million annually. *See* Pls.' MSJ Memo. at 20–23; *see also Merrifield*, 547 F.3d at 988–992 (striking down on equal protection grounds a classification that satisfied rational basis for purposes of due process).

The arbitrariness of these distinctions is highlighted by the fact that Iowa exempts not only businesses supporting births in patient homes, but also businesses that advertise and provide birth

[6] The government notes that the Iowa legislature has periodically convened working groups to evaluate the CON law and that those working groups have recommended some changes. Defs.' Br. at 15–16. But periodic review of, or even tweaks to, an irrational law does not make it rational. The government also cites two outlier CON studies, neither of which establishes a rational basis for applying Iowa's law to birth centers. *Id.* at 15 n.2. The first analyzed "Coronary Artery Bypass Graft Surgeries," a specialized procedure unrelated to birthing services. *Id.* The second likewise did not address birthing services and additionally failed to "control for the possibility that the observed differences could be caused by many other differences between states without CON laws, such as market and environmental characteristics." Emily Whelan Parento, *Certificate of Need in the Post-Affordable Care Act Era*, 105 Ky. L.J. 201, 227 (2017).

services in the business owners' homes or in hotel rooms. Pls.' SUF ¶¶ 17–18; *see also id.* ¶ 19 (the Council was unable to say whether an Airbnb designated for birthing services would require a CON). Even though these all provide the exact same service using the same providers and equipment as a freestanding birth center, only the birth center is subject to the CON requirement. Because they are similarly situated, the government can only satisfy equal protection if it rationally justifies the distinction.

It fails to do so. The government suggests that there is a regulatory "continuum" with hospitals at one end and home births on the other. Defs.' Br. at 18–19. It calls birth centers a "medium" option, subject to the "medium" regulation of a CON. *Id.* at 19. But this just begs the question. The government fails to explain *why* it is rational to regulate birth centers as a "medium" option and to treat them differently from similarly situated businesses. Such circular reasoning is necessarily irrational. *See Merrifield*, 547 F.3d at 991 ("[T]his type of singling out, in connection with a rationale so weak that it undercuts the principle of non-contradiction, fails to meet the relatively easy standard of rational basis review.").

The government's only response is that "birth centers offer healthcare" and "it would be irrational if the State constitutionally *could not* regulate a healthcare business." Defs.' Br. at 19. But no one argues that birth centers ought to be free from all regulation. Moreover, home birth businesses and hospitals seeking to expand their birthing operations also "offer healthcare," yet are exempt from the irrational competitor's veto and need requirements of Iowa's CON law. Ms. Hainley seeks to be treated in a similar fashion. The government even recognizes that home birth

services "are unregulated" by the state, *id.* at 18,[7] yet they offer the same healthcare services as a birth center. It is irrational to require a CON for one but not the other.

In any event, Iowa's CON requirement is not a healthcare regulation—such as a regulation for dispersing medicines, testing newborns for disease, or treating biological waste—but an *economic* regulation, geared toward reducing unwanted competition for existing health facilities. Ms. Hainley does not challenge any valid health or safety regulation, and the government does not identify any health or safety concern underlying the CON requirement, let alone a concern that justifies imposing it only on birth centers but not similarly situated businesses.[8] If the *lack* of CON regulation for businesses supporting home births is rational (as Ms. Hainley agrees it is), then Iowa must do more than simply claim that birth centers require CON regulation because they "offer healthcare." Because there is no rational justification for Iowa's singling out of birth centers, its CON law violates equal protection as applied to them.

IV. Whether Iowa's CON Law Violates Ms. Hainley's Constitutional Rights Is Not a Question for the Legislature

The government argues that the rational basis standard means that the CON requirement should be upheld regardless of the "current efficacy of CON programs" and despite all evidence and expert analysis undermining the government's claimed rationales. Defs.' Br. at 20. Whether to apply the CON program to birth centers, it argues, is "a matter for the Iowa General Assembly and not this Court." *Id.* But the Court has an important role in evaluating whether Iowa's law

[7] The lack of regulation for home births distinguishes the Sixth Circuit decision in *Tiwari*, 26 F.4th 355. *Tiwari* was based on the service at issue being "heavily regulated," including through governmental cost controls. *Id.* at 364; *see also id.* at 368 (referring to the "intensely regulated market" at issue in that case). In contrast, the government concedes it does not regulate birthing services unless they take place in specific kinds of facilities.

[8] The unrebutted expert testimony from Dr. Bailey also shows that CON laws like Iowa's *reduce* the quality and availability of services—in this case, the very healthcare services that the government considers important. *See* Pls.' SUF ¶¶ 64–69.

survives constitutional standards. Although undoubtedly lenient, the rational basis test "is not toothless." *Kansas City Taxi Cab Drivers Ass'n v. City of Kansas City*, 742 F.3d 807, 810 (8th Cir. 2013). And although legislatures have broad discretion in enacting economic regulation, they may not unconstitutionally infringe protected rights with arbitrary and irrational regulation, or burden birth centers with CON requirements while exempting similarly situated businesses without rational justification. *See, e.g.*, *Merrifield*, 547 F.3d at 988–92; *Craigmiles*, 312 F.3d at 227–29; *St. Joseph Abbey*, 712 F.3d at 226; *Bruner*, 997 F. Supp. 2d at 700.

This case is not about whether Iowa's CON law is not a good idea,[9] or whether it has failed to have the beneficial effects that the legislature reasonably anticipated. Instead, the evidence and expert analysis show that there is no rational connection between Iowa's CON law and the government's *post hoc* justifications for applying it to birth centers. Because the undisputed facts show that Iowa's CON law violates Ms. Hainley's constitutional rights, this Court should enjoin it.

[9] The government falsely claim that Ms. Hainley's expert "acknowledged" that CON laws "'made more sense' in the past." Defs.' Br. at 20. To the contrary, Dr. Bailey testified that he was "not convinced that the laws made sense even before 1983." Pls.' Response to Defs.' SOF ¶ 71. Even if CON laws "*arguably* made more sense" at that time because "Medicare operated in a very different manner," it has been more than 40 years since Medicare changed its approach to reimbursement. *Id.* None of Dr. Bailey's testimony or opinions support the government's argument that it is rational to apply Iowa's CON law to birth centers today. *See also* Pls.' SUF ¶ 74 (Dr. Bailey testified that he "do[es] not see any rational basis for Iowa's CON law" being applied to birth centers).

CONCLUSION

The Court should deny the government's motion for summary judgment and instead grant Ms. Hainley's motion for summary judgment.

DATED August 26, 2024.

Respectfully submitted,

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CERTIFICATE OF SERVICE

The foregoing document has been filed with the court's ECF system on August 26, 2024, and notice of service has been provided to the following:

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DES MOINES MIDWIFE COLLECTIVE, and CAITLIN HAINLEY, Plaintiffs, v. IOWA HEALTH FACILITIES COUNCIL, HAROLD MILLER, AARON DEJONG, KELLY BLACKFORD, and BRENDA PERRIN. Defendants.	Case No. 4:23-CV-00067-SMR-HCA **PLAINTIFFS' RESPONSES TO DEFENDANTS' STATEMENT OF FACTS IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT**

Pursuant to LR 56(b), Plaintiffs Caitlin Hainley and Des Moines Midwife Collective hereby respond to Defendants' "Statement of Undisputed Material Facts in Support of Motion for Summary Judgement." (Doc. 51-2.)

1. The Iowa General Assembly first established Iowa's certificate-of-need (CON) framework in 1977. 1977 Iowa Acts, ch. 75.

Response: Admitted.

2. The 1977 enactment included a preamble expressly stating the law and CON framework were enacted to ensure new health facilities and services in Iowa are developed "in a manner which is orderly, economical and consistent with a goal of providing the necessary and adequate institutional health services to all of the people of this state while avoiding unnecessary duplication in institutional health services and

preventing or controlling increases in the cost of delivering the services[.]" 1977 Iowa Acts, ch. 75, preamble.

Response: Admitted.

3. The CON requirement applies to institutional health facilities providing institutional health services. Iowa Code §§ 10A.711(13)–(14), 10A.713(1).

Response: Admitted.

4. The Health Facilities Council (the Council) makes final decisions with respect to each CON application. Iowa Code § 10A.712(2)(*e*).

Response: Admitted.

5. The Council is within the Iowa Department of Inspections, Appeals, and Licensing (the Department). Iowa Code §§ 10A.101(2), 10A.712(1).

Response: Admitted.

6. The Department administers the CON statute and provides administrative support to the Council. Iowa Code §§ 10A.101(2), 10A.712(1), 10A.715–.716, 10A.719; 2023 Iowa Acts ch. 19, §§ 1429, 1443.

Response: Admitted.

7. Rebecca Swift is the CON Program Manager within the Department who provides support to the Council. (Swift 30(b)(6) Dep'n, pp. 8:23–9:23, 22:1–23:24; Summary Judgment Appendix [MSJ App.] at 004–005, 010–011.)

Response: Admitted.

8. A birth center is an institutional health facility. Iowa Code § 10A.711(13)(*f*).

Response: Admitted.

9. Beyond the front-end CON requirement, a birth center facility is not otherwise subject to licensure requirements or ongoing State oversight. (Swift Dep'n, 42:9–43:9; MSJ App. 044–045.)

Response: Denied. The cited testimony stated only that "if a CON requirement didn't apply to a birth center," the Department 30(b)(6) representative was not "aware" of "other oversight that would apply to it" and that the birth center would not require a license from the Department. Swift Dep'n 42:9–43:13, Defs.' MSJ App. 44–45. Under Iowa law, birth center facilities are subject to oversight and health and safety regulation by state and local entities. *See, e.g.*, Iowa Admin. Code r. 641-3.7 (newborn hearing screening requirements for birth centers); *id.* r. 441-77.27 (eligibility of birth centers to participate in the Medicaid program); *id.* r. 441-79.3(2)(d)(15) (recordkeeping requirements for birthing centers). And Defendants admit that birth centers may be accredited by national organizations and that a birth center's staff are subject to regulation by professional licensing boards. Defs.' Br. at 19.

10. To begin the CON process, the sponsor of a proposed new institutional health service submits a letter of intent to the Department describing its proposed project. Iowa Code § 10A.715.

Response: Admitted.

11. After thirty days elapse, the sponsor may then file a CON application containing information about the project, the need for the proposed service, and the project's financial feasibility. Iowa Code §§ 10A.713(1), 10A.714, 10A.715(1).

Response: Admitted.

12. The sponsor must also pay an application fee equal to three tenths of one percent (0.3%) of the anticipated cost of the project, with a floor of $600 and a ceiling of $21,000. Iowa Code § 10A.713(1).

Response: Admitted.

13. The application fee range has not changed since 1977. (Swift 30(b)(6) Dep'n, 110:12–110:21; MSJ App. 036.)

Response: Plaintiffs are not aware of evidence that would contradict this statement.

14. Iowa birth center application fees have generally been between $600 and $1,000. (Swift 30(b)(6) Dep'n, 110:12–111:15; MSJ App. 036–037.)

Response: Plaintiffs are not aware of evidence that would contradict this statement.

15. The fee for the most recent birth center CON application in 2014 was roughly $749. (Swift Dep'n, 25:2–25:17; MSJ App. 040.)

Response: Plaintiffs are not aware of evidence that would contradict this statement.

16. The Department's acceptance of a CON application begins the "formal review" process for the application. *See* Iowa Code § 10A.716(1), (3).

Response: Admitted.

17. The formal review process includes notification to all affected persons of the affected person's right to comment on the application. Iowa Code § 10A.716(2).

Response: Admitted.

18. Any person who meets the definition of an affected person may comment on the CON application. (Swift 30(b)(6) Dep'n 18:7–19:9, 50:19–53:14, 111:24–112:8; MSJ App. 006–007, 018–021, 037–038.)

Response: Admitted.

19. The Council's review of CON applications also includes a public hearing at which the applicant and any affected persons may provide testimony. Iowa Code § 10A.716(4); Iowa Admin. Code r. 641–202.6(3).

Response: Admitted.

20. Before the public hearing, the Department reviews each application and may request additional information from the applicants. (Swift 30(b)(6) Dep'n, 18:7–19:9, 20:8–21:21; MSJ App. 006–009.)

Response: Admitted.

21. The Department also prepares a summary of each application and sends the application, the summary, and any affected party letters to the Council members. (Swift 30(b)(6) Dep'n, 20:8–21:21, 61:10–63:7; MSJ App. 008–009, 023–025.)

Response: Admitted.

22. The Council members review applications, summaries, and letters in preparation for the public hearing, but do not confer with each other or reach any tentative decision beforehand. (Swift 30(b)(6) Dep'n, 90:2–91:16; MSJ App. 028–029.)

Response: Plaintiffs admit that the cited testimony establishes that Council members receive and are "expected" to review application materials but deny that it establishes that they actually do review those materials. (Swift 30(b)(6) Dep'n, 90:5–7, 19–21; Defs.' MSJ App. 28.) Plaintiffs admit that the Council members do not confer with each other or reach any tentative decision beforehand.

23. The Council's formal review of each CON application evaluates the application and hearing testimony against statutory criteria. Iowa Code § 10A.716(3)(a).

Response: Admitted.

24. There are eighteen qualitative statutory criteria that probe the need for a proposed project. Iowa Code § 10A.714(1).

Response: Plaintiffs admit that there are eighteen statutory criteria that the Council is to consider but deny that all of the criteria "probe the need for a proposed project." *See* Iowa Code § 10A-714(1).

25. Each individual Council member decides what weight they personally afford each statutory criterion in deciding whether to vote to grant a CON application. (Swift 30(b)(6) Dep'n, 62:17–63:3, 67:5–68:16; MSJ App. 024–027.)

Response: Admitted.

26. On top of considering the eighteen qualitative criteria in the statute, the Council may grant a CON only if it makes a written finding that each of four specific mandatory criteria have been satisfied. Iowa Code § 10A.714(2).

Response: Admitted.

27. The first finding required for the Council to grant a CON is that "[l]ess costly, more efficient, or more appropriate alternatives to the proposed institutional health service are not available and the development of such alternatives is not practicable." Iowa Code § 10A.714(2)(*a*).

Response: Admitted.

28. The second finding required for the Council to grant a CON is that "[a]ny existing facilities providing institutional health services similar to those proposed are being used in an appropriate and efficient manner." Iowa Code § 10A.714(2)(*b*).

Response: Admitted.

29. The third finding required for the Council to grant a CON is that if a project involves new construction, "alternatives including but not limited to modernization or sharing arrangements have been considered and have been implemented to the maximum extent practicable." Iowa Code § 10A.714(2)(*c*).

Response: Admitted.

30. The fourth finding required for the Council to grant a CON is that "[p]atients will experience serious problems in obtaining care of the type which will be furnished by the proposed new institutional health service or changed institutional health service, in the absence of that proposed new service." Iowa Code § 10A.714(2)(*d*).

Response: Admitted.

31. During the public hearing on a CON application, applicants receive time to present testimony about their proposed project. Iowa Admin. Code r. 641–202.6(3).

Response: Admitted.

32. Council members may ask questions of the applicant and of any affected parties providing testimony. Iowa Admin. Code r. 641–202.6(5); Swift 30(b)(6) Dep'n, 53:15–54:18, 90:2–90:21, 93:17–94:13 [MSJ App. 021–022, 028, 030–031.]

Response: Admitted.

33. At the end of the public hearing, the Council may deliberate in open session and votes orally to approve or deny the CON application. Iowa Admin. Code r. 641–202.6(1); Swift 30(b)(6) Dep'n, 94:14–95:2 [MSJ App. 031–032.]

Response: Admitted.

34. The Council follows its oral vote by issuing a written decision stating the basis for the approval or denial of the application. *See* Iowa Code § 10A.719.

Response: Admitted.

35. The applicant or any affected party may request rehearing or may seek judicial review in state court under the Iowa Administrative Procedure Act. Iowa Code § 10A.720; Iowa Admin. Code r. 641–202.9.

Response: Admitted.

36. From letter of intent to a written decision, the application process takes four to five months. (Swift Dep'n, 25:2–25:17; MSJ App. 040.)

Response: Denied, in that the cited testimony does not establish the overall period of time for a decision to be made on a CON application and does not mention "four to five months." Swift Dep'n, 25:2–25:17; Defs.' MSJ App. 40. There is no fixed time in which the Council must draft and approve a final written decision. *See* Swift 30(b)(6) Dep'n 94:22–95:17, Defs.' MSJ App. 32. And once the formal review process concludes, dissatisfied parties can request a rehearing or appeal the decision, launching a lengthy legal process. *See* Pls.' Statement of Undisputed Facts ¶ 33.

37. An application follows thirty days after a letter of intent; the Department takes six to eight weeks after accepting the application to collect and review materials, accept input from affected persons, and allow Council members time to prepare for the public hearing; and time elapses after the public hearing in which the Department drafts and the Council approves the written decision. (Swift Dep'n, 27:5–27:21; MSJ App. 041.)

Response: Admitted.

38. Applicants may begin a project upon the Council's oral approval of a CON without a written decision. (Swift Dep'n, 27:5–27:21; MSJ App. 041.)

Response: Plaintiffs are not aware of evidence that would contradict this statement.

39. If a party offers a new institutional health service without first obtaining a CON, or if a sponsor violates the terms of an approved application, the party may be subject to a financial penalty and the Department can seek injunctive relief. Iowa Code § 10A.723.

Response: Admitted.

40. The Department more broadly, and not specifically the Council, undertakes CON enforcement. (Swift 30(b)(6) Dep'n, 31:7–32:5, 37:11–38:12; MSJ App. 013–016.)

Response: Admitted.

41. The Council has not received any CON applications for a birth center since 2014. (Swift 30(b)(6) Dep'n, 103:2–103:8.; MSJ App. 035.)

Response: Plaintiffs are not aware of evidence that would contradict this statement.

42. The Council denied the 2014 application, for a facility called Promise Birth Center in Sioux Center, Iowa. (Promise Birth Center Decision at 1–7, MSJ App. 166–172.)

Response: Admitted.

43. In 2014, two birth centers were operating in Iowa—one in Corydon and one in Des Moines. (Promise Birth Center Decision at 2, MSJ App. 167.)

Response: Admitted.

44. In 2014, the Promise Birth Center CON application generated 72 letters in opposition and 100 letters in support. (Promise Birth Center Decision at 5, MSJ App. 171.)

Response: Admitted.

45. In denying the Promise Birth Center application in 2014, the Council found that more efficient and appropriate alternatives to the birth center existed, because local full-service hospitals provided birthing services and had ample capacity for additional birthing patients. (Promise Birth Center Decision at 6, MSJ App. 171.)

Response: Admitted.

46. In denying the Promise Birth Center application in 2014, the Council also found that a standalone birth center could negatively affect local full-service hospitals by damaging their ability to recruit family physicians, which in turn could negatively affect rural Iowans' access to a full array of health services. (Promise Birth Center Decision at 6, MSJ App. 171.)

Response: Denied as phrased. The cited decision does not refer to "rural Iowans" or "a full array of health services," but to "residents of these communities" and "the full array of their health care needs." Promise Birth Center Decision at 6, Defs.' MSJ App. 171.

47. In general, if an institutional health facility opens but is not needed based on local patient load for those services, a full-service hospital could be forced to reduce programs, reduce services, or even close entirely. (Swift Dep'n, 44:4–45:1, MSJ App. 046–047.)

Response: Denied, as the cited testimony does not support this assertion. Instead, the deponent was only asked about the "potential negative consequences from a hospital closing." *See* Swift Dep'n 44:4–6, Defs.' MSJ App. 46. She said nothing about the effects of opening an institutional health facility that is "not needed based on local patient load for those services," including any effect that would have on hospitals. Furthermore, the unrebutted testimony of Plaintiffs' expert is that rather than assuring or increasing

access, CON laws like Iowa's result in *decreased* access, including in rural areas. Pls.' Statement of Undisputed Facts ¶¶ 64–69.

48. The Council has approved many other birth center applications it has received. (Swift 30(b)(6) Dep'n, 42:8–42:10; MSJ App. 017.)

Response: Denied as phrased. The cited testimony does not support the claim that the Council has approved "many" other birth centers; instead, the deponent simply agreed that "in the abstract, the Council has approved birth centers in the past." Swift 30(b)(6) Dep'n 42:8–10, Defs.' MSJ App. 17.

49. Specifically, the Council approved CONs for birth centers in Des Moines in 1984, 2003, and 2011; in Corydon in 2006; and in Bettendorf in 1997. (Birth Center Decisions, MSJ App. 128–130, 137–139, 149–165.)

Response: Admitted.

50. Until recently, the birth center approved in 2011 and located in Des Moines was the only remaining birth center in the state. (Swift Dep'n, 38:22–39:4, MSJ App. 042–043.)

Response: Admitted.

51. That birth center has now closed for reasons unknown to the parties; there are no currently operating birth centers in Iowa. (Swift Dep'n, 38:22–39:4, MSJ App. 042–043.)

Response: Admitted.

52. Plaintiff Caitlin Hainley is a certified nurse midwife. (Hainley Dep'n, 5:8–6:21, MSJ App. 049–050.)

Response: Admitted.

53. Hainley owns the Des Moines Midwife Collective. (Hainley Dep'n, 8:19–9:4, MSJ App. 051–052.)

Response: Admitted.

54. Hainley has practiced in the maternal health field in Iowa since 2012, first as a lactation consultant, then as a certified nurse midwife. (Hainley Dep'n, 13:6–13:22, MSJ App. 053.)

Response: Admitted.

55. The Midwife Collective operates a lactation, prenatal, and women's health clinic in Des Moines. (Hainley Dep'n, 14:3–19:15, MSJ App. 054–059.)

Response: Admitted.

56. Hainley also practices as a nurse midwife and attends births in homes or other locations outside the hospital setting. (Hainley Dep'n, 14:3–14:12, MSJ App. 054.)

Response: Admitted.

57. Hainley estimates that combined between them, she and her staff at the Collective attended 100 home births outside the hospital setting in 2023. (Hainley Dep'n, 24:6–25:17, 62:15–62:24, MSJ App. 060–061, 078.)

Response: Admitted.

58. Hainley's home birth practice focuses on low-risk pregnancies with zero or few complications. (Hainley Dep'n, 31:20–32:22, MSJ App. 062–063.)

Response: Admitted.

59. Hainley wants to open a standalone birth center in Des Moines, and estimates that such a facility would add around fifteen to twenty births per month to her existing home-birth and clinic business. (Hainley Dep'n, 51:4–51:15, MSJ App. 069.)

Response: Admitted.

60. Hainley's intended clientele at a birth center would continue to be low-risk pregnancies. (Hainley Dep'n, 31:20–32:8, MSJ App. 062–063.)

Response: Admitted.

61. Hainley has undertaken some preparations toward opening a birth center, including scouting locations in central Des Moines, near where she lives. (Hainley Dep'n, 41:3–42:3, MSJ App. 064–065.)

Response: Admitted.

62. Hainley has budgeted between $500,000 and $1.5 million for the costs of acquiring property for a birth center, renovating the property, and increasing staffing. (Hainley Dep'n, 42:21–45:2, MSJ App. 065–068.)

Response: Admitted.

63. Hainley has also worked out a five-year financial projection and business plan that includes financing from a local lender and a grant she has received. (Hainley Dep'n, 52:8–54:18, MSJ App. 070–072.)

Response: Admitted.

64. Hainley has not applied for a CON. (Hainley Dep'n, 56:5–56:10, MSJ App. 073.)

Response: Admitted.

65. One reason Hainley has not applied is that the Promise Birth Center did not receive a CON in 2014. (Hainley Dep'n, 56:11–57:12, MSJ App.073–074.)

Response: Admitted.

66. Hainley believes the Promise Birth Center application fee approached the maximum and that an application fee for her intended birth center would too. (Hainley Dep'n, 57:22–58:12, MSJ App. 074–075.)

Response: Denied as to the Promise Birth Center application fee; Ms. Hainley testified that she did not know what Promise Birth Center's application fee was. Hainley Dep'n, 57:13–15, Defs.' MSJ App. 74. Admitted that Ms. Hainley testified that she thought her fee would be $20,000. *See id.* 58:9–12, Defs.' MSJ App. 75.

67. Hainley also has not applied for a CON because she believes the State is doggedly determined not to grant certificates for birth centers. (Hainley Dep'n, 58:9–59:23, MSJ App. 077–078.)

Response: Admitted.

68. Nevertheless, Hainley feels she meets all the statutory criteria necessary to obtain a certificate of need for a birth center in the Des Moines area. (Hainley Dep'n, 61:24–62:8, MSJ App. 077–078.)

Response: Admitted.

69. Professor James Bailey, an economics professor, provided an expert report and opinion asserting that CON requirements are poor economic policy. (Bailey Report, MSJ App. 091–127.)

Response: Admitted that Dr. Bailey submitted an expert report and opinion, although they do not merely "assert[] that CON requirements are poor economic policy," but specifically

address the application of Iowa's CON law to birth centers. *See generally* Bailey Report.

70. Bailey's report and opinion about CON laws are not specific either to Iowa or to birth centers. (Bailey Dep'n, 39:19–44:25, MSJ App. 085–090.)

Response: Denied. Dr. Bailey's report and opinion are specifically directed at both Iowa and birth centers. He testified at his deposition that his "bottom-line opinion" is that there is not "an economic justification for certificate of need laws to restrict the opening of birth centers." Bailey Dep'n, 16:16–21, Defs.' MSJ App. 80. He further testified that his report and opinion were based in part on articles analyzing the effects of CON laws in Iowa. Bailey Dep'n, 39:19–40:4, Defs.' MSJ App. 85–86.

Furthermore, Dr. Bailey's expert report and the declaration he filed in support of Plaintiffs' motion for summary judgment confirm his focus on both Iowa and birth centers. *See* Bailey Decl. ¶ 14, Pls.' App. 9 ("Both economic theory and the empirical evidence in the studies that I reviewed suggest that Iowa's CON requirement for healthcare service providers does not serve consumers or the general economic interest."); *id.* ¶ 16 ("I do not see any rational basis for Iowa's CON law."); Bailey Report at 2, Pls.' App. 13; *id.* at 18–19, Pls.' App. 29–30 (discussing Iowa's inclusion in the empirical research reviewed by Dr. Bailey); *id.* at 24, Pls.' App. 35 ("After considering a variety of potential rationales, I can find no valid economic argument for a state to require a Certificate of Need for birth centers.").

71. Bailey agrees that notwithstanding his current opinion that CON laws are economically unjustified, CON laws made more sense before 1983. (Bailey Dep'n, 16:16–18:8, 19:5–20:18; MSJ App. 080–084.)

Response: Denied. This misrepresents Dr. Bailey's testimony. He testified that there is no economic justification for applying Iowa's CON law to birth centers, Bailey Dep'n, 16:16–21, Defs.' MSJ App. 80, and disagreed that there has been any economic justification for at least the past ten years, *id.* 17:6–12, Defs.' MSJ App. 81. As for the situation prior to 1983, Dr. Bailey stated that CON laws "*arguably* made more sense prior to 1983" because at that time, "Medicare operated in a very different manner," reimbursing on a cost-plus basis rather than paying a flat fee. *Id.* 17:19–18:4, Defs.' MSJ App. 81–82 (emphasis added). But Dr. Bailey stated that he was "not convinced that the laws made sense even before 1983," *id.* at 20:3–4, Defs.' MSJ App. 84, and that the 1983 change may have been less relevant for birth centers than for other types of services. *Id.* at 18:5–8, Defs.' MSJ App. 82. Dr. Bailey also testified that although the federal government encouraged CON laws in the 1970s, "by 1986, they … completely switched sides" and encouraged states to repeal all such laws. *Id.* at 19:12–24, Defs.' MSJ App. 83.

72. Bailey also testified that legislators before 1983 could have believed, and indeed "would not be crazy" to believe, a CON program would reduce healthcare costs. (Bailey Dep'n, 19:25–20:18, MSJ App. 083–084.)

Response: Denied. This misrepresents Dr. Bailey's testimony and is not based on relevant, admissible evidence. Defendants' questions about what legislators prior to 1983 "could have believed" were speculative and called for legal conclusions, and Plaintiffs'

counsel rightly objected to them. Bailey Dep'n 20:6–16, Defs.' MSJ App. 84. Even if the questions were not objectionable, when asked whether a legislator prior to 1983 "could have believed that the certificate of need program would reduce costs," Dr. Bailey stated the obvious: legislators "could believe all sorts of things," and "that's one of them." *Id.* at 20:6–12. When then asked whether it would be "reasonable to believe that," he responded that it "depends what you mean by reasonable" and that "[i]t would not be crazy." *Id.* at 19:5–20:18, Defs.' MSJ App. 83–84.

73. The Iowa Legislature convened a workgroup in the 1990s to evaluate the CON program, which resulted in some changes to the program's coverage and operation. (Swift 30(b)(6) Dep'n, 97:2–98:19, MSJ App. 033–034.)

Response: Admitted.

74. The Iowa Legislature sees periodic legislative proposals to amend the scope of the CON program, including adjustments to the capital expenditure threshold. (Swift 30(b)(6) Dep'n, 30:6–31:6, MSJ App. 012–013.)

Response: Admitted.

DATED August 26, 2024.

Respectfully submitted,

/s/ Glenn E. Roper

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CERTIFICATE OF SERVICE

The foregoing document has been filed with the court's ECF system on August 26, 2024, and notice of service has been provided to the following:

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