IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF KENTUCKY
LOUISVILLE DIVISION

DIPENDRA TIWARI, KISHOR SAPKOTA, and GRACE HOME CARE, INC., Plaintiffs, vs. ERIC FRIEDLANDER, in his official capacity as Secretary of the Kentucky Cabinet for Health and Family Services, and ADAM MATHER, in his official capacity as Inspector General of the Kentucky Cabinet for Health and Family Services, Defendants, and KENTUCKY HOSPITAL ASSOCIATION, Intervenor–Defendant.	Civil Action No. 3:19-cv-00884-GNS

PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

oral argument requested

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INTRODUCTION

Plaintiffs Dipendra Tiwari and Kishor Sapkota are Nepali-speaking entrepreneurs. They formed Plaintiff Grace Home Care so that Nepali-speaking refugees in Louisville could receive home health services in a language they understand. But Grace cannot provide those services because of Kentucky's certificate-of-need (CON) law. This law requires new medical businesses to prove their services meet an arbitrary definition of "need" before they can operate. For existing agencies, the law hands out golden tickets. CON in hand, existing agencies can expand while blocking new agencies from opening. They need only claim their own existing services are enough. It is hard to imagine incumbents wielding this kind of power in any other industry.

With no other options, Grace sued to protect its constitutional right to be free from protectionist laws. Then, in rejecting motions to dismiss, this Court recognized that the law may well be harming the public to benefit a specially connected few. *See* MTD Op. (Doc. 67). Grace now shows that Kentucky's CON law does just that. Speculation aside, the actual, undisputed facts show that the CON law is irrational. The law ignores why CONs were designed, it ignores the needs of Nepali speakers, it bans new home health agencies in almost the entire state, and it has prevented start-up agencies from opening for at least 20 years. It does all this without lowering cost, increasing access, or improving quality—the three interests it was supposed to serve. If anything, the law worsens the very problems it purports to fix. And that is saying nothing of its inexplicable exceptions.

Even in economic regulation, even in healthcare, the legislature's power is not unlimited. The Eastern District has struck down another Kentucky CON law on much less. The law keeping Grace out of business is not a debatable policy choice. It is unconstitutional protectionism. And this Court should grant summary judgment saying so.

BACKGROUND

I. GRACE WANTS TO PROVIDE HOME HEALTH CARE TO LOUISVILLE'S NEPALI SPEAKERS IN A LANGUAGE THEY UNDERSTAND.

Kentucky opens its arms to immigrants from all over the world —including the 2,000 to 3,000 Nepali speakers who call Louisville home. Hyman Rep. (Ex. 1) ¶ 21. Some came voluntarily from Nepal, but many are refugees, who were resettled in Louisville after terrible ethnic persecution expelled them from their native Bhutan. *See id.*; Tiwari Dec. ¶ 9.[1]

Like everyone else, these Nepali speakers require culturally competent healthcare, meaning care that "includes an understanding of beliefs, communications styles, and, crucially, language." Hyman Rep. ¶ 1. The takeaway from more than a dozen healthcare studies is that "language barriers … result in confusion, lower quality care, and worse outcomes." *Id.* ¶¶ 1, 15. Key players, from the federal government to the American Medical Association, all recognize the importance of linguistically appropriate care. *Id.* ¶¶ 9–18. Louisville's own health department recently interviewed Nepali speakers and other minority residents and reported that culture and language remain important barriers to care. *Id.* ¶¶ 12–13.

One growing form of care is home health. This is simply "health and health related services," prescribed by a physician, delivered "to a patient at his or her place of residence." 902 KAR 20:081 § 2. In Kentucky, home health agencies provide nursing services and at least some subset of physical, speech, or occupational therapy; medical social work; or home health aide services. *Id.* § 5(1). "Home health aide services" are help with basic tasks including bathing, using the bathroom, walking, taking medication, doing prescribed exercises, and incidental household chores. *See* KRS § 216.935(3). In one Defendant's words, "[a] home health visit is

[1] For background on "one of the most protracted and neglected refugee crises in the world," see, *e.g.*, Erika Shultz, *Bhutanese refugee crisis: a brief history*, The Seattle Times (Oct. 14, 2016), *available at* tinyurl.com/y4fcz5b7

typically an hour or less and an aide's job is to take vitals and provide basic therapies." KHA RFA Resps. (Ex. 2) at 13. In home health, with a provider coming into a patient's home, cultural and linguistic competence is important. Hyman Rep. (Ex. 1) ¶ 18; Sullivan Dep. (Ex. 3) at 115:7–11 (Defense expert "agree[ing] that language concordance in the delivery of home health care is important" because "obviously if you can't communicate with the patient, that poses a problem"). Unsurprisingly, Defendants' representatives admit that if they needed home health services, they would prefer care in English. Mather Dep. (Ex. 4) at 77:11–22; KHA Dep. (Ex. 5) at 213:20–23.

That brings the story to Plaintiffs: Dipendra, Kishor, and Grace.[2] Dipendra Tiwari left his native Nepal in 2008 and came to the United States hoping for a better education. Tiwari Dec. ¶¶ 2–4. He found it, earning an MBA and certification as a public accountant. *Id.* ¶¶ 5–6, 8; Ex. 6 (certification). One of his first jobs here was crunching the numbers at a home health agency. Tiwari Dec. ¶ 7. Eventually, Dipendra and his wife settled in Louisville, where he opened his own accounting practice focused on serving the Nepali-speaking community. *Id.* ¶¶ 8, 11. He became an American citizen earlier this year. *Id.* ¶ 30.

Kishor Sapkota immigrated directly to Louisville in 2012 to rejoin his wife, a Bhutanese refugee who had been resettled here with their daughter. Sapkota Dec. ¶ 4. Although he worked as a journalist in Nepal, here Kishor became a registered nurse aide, and he now works providing hands-on home health care. *Id.* ¶¶ 3, 5–6; Ex. 7 (registration). Kishor is an active member of the local Nepali-speaking community. Sapkota Dec. ¶ 7. He became a citizen in 2018. *Id.* ¶ 18.

When Kishor met Dipendra four years ago, *id.* ¶ 10, an idea took shape. Both had seen the Nepali-speaking community's struggle to access culturally competent home health services,

[2] For convenience, "Grace" usually refers to all Plaintiffs.

especially home health services provided in Nepali. Sapkota Dec. ¶ 9[3]; Tiwari Dec. ¶ 12; *see also* Hyman Rep. (Ex. 1) ¶¶ 12–13, 23 (detecting the same problem). So, with their complementary talents and experiences in home health, Dipendra and Kishor incorporated a business to serve the Nepali-speaking community (and, of course, anyone else who needs home health care). *See* Sullivan Dep. (Ex. 3) at 119:12–20 (Defense expert admitting that "obviously you would—to the extent that you could, you would want to match up native speaking caregivers with patients … if that were practical").[4] Named for Dipendra's belief that the whole world exists because of grace, Grace Home Care was born. Tiwari Dec. ¶ 18. Everything was full steam ahead. Until Grace ran headlong into Kentucky's CON law.

II. THE CON LAW MAKES OPENING A NEW HOME HEALTH AGENCY IMPOSSIBLE.

This CON law forces new home health agencies to twice prove they are needed before they can operate. KRS §§ 216B.015(13), 216B.040(2)(a)(2), 216B.061(1)(a). Nominally, the law—which is separate from licensure for quality, *see* State Answer (Doc. 70) ¶ 24; 902 KAR 20:081—exists only to prevent the "proliferation of unnecessary health-care facilities, health services, and major medical equipment," KRS § 216B.010. As applied to home health, however, the CON law makes opening new businesses impossible. Getting a CON requires passing each of five statutory tests, KRS § 216B.040(2)(a)(2); State Answer ¶ 111, but the heart of the law is the first two: (1) compliance with a document called the state health plan and (2) proving "need."[5]

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[3] In deposition, Kishor named ten specific Nepali speakers who have had trouble with home health, and that is not an exhaustive record of every person in Louisville whom Plaintiffs could serve, Nepali speaking or otherwise. Sapkota Dec. ¶ 15; *see also* Tiwari Dec. ¶ 16, Hyman Rep. (Ex. 1) ¶ 21 (noting the thousands of Nepali speakers in Louisville).

[4] *See also* Ex. 8 (Grace CON application) at CHFS000031 (purpose); *id.* at CHFS000046 (incorporation).

[5] *See* Ex. 9 (database printout showing that 96 percent of CON denials cite noncompliance with the state health plan or lack of need); Sullivan Dep. 110:6–114:10 (Defense expert admitting that CON process focuses on need, that the other criteria overlap with need, that screening for only the other criteria would not make sense, and that he could not remember a time when an applicant that met the first two criteria was denied).

For home health agencies, here is how the state health plan has worked since at least 2010 (and probably since the mid-2000s). *See generally* Ex. 10 at Ex. 3 (compiling plan criteria since 2010).[6] First, the state calculates the statewide rates of how many people in given age groups (for example, ages 65–74 or 75–84) use home health care (averaged over the last two years). Ex. 10 at Ex. 3. This produces base rates that the state treats as the right amount of use.[7] Then, for each county, the state multiplies the statewide age-group rates by the county's projected population in each age group, adding up the results. *Id.* This produces an estimate of how many people in a county should be using home health care (assuming every county's population is medically identical to the statewide population except for age). Finally, the state subtracts from this estimate the number of patients in the county who did use home health care (again averaged over the last two years). *Id.* The resulting difference is the plan's calculation of "need." If it is 250 people or more in a county, new agencies satisfy the plan criterion. *Id.* If the need is less than 250, new agencies cannot open. *Id.* Nothing in the plan assesses whether a new agency would be better or cheaper or more accessible. *Id.* And, apparently, Defendants do not know why 250 is the proper threshold. Mather Dep. (Ex. 4) at 78:9–15; KHA Dep. (Ex. 5) at 123:23–124:1. But the number is the number.

At the same time, existing agencies play by different rules. For an existing agency to expand to a contiguous county requires half the need, just 125. Ex. 10 at Ex. 3.[8] This has allowed existing agencies to keep the need from reaching 250 by moving into counties before new agencies had the chance to open.[9] Indeed, even though demand for home health care is growing,

[6] *See also* State RFA Resps. (Ex. 11) at 24 (admitting compilation accuracy); Mather Dep. (Ex. 4) at 78:9–79:1.

[7] For an example of these calculations, see Ex. 12 (compiling the plan's need charts since 2010) at CHFS001700.

[8] There have been other differences, too, that have benefitted existing agencies. *E.g.*, Ex. 10 at Ex. 3, CHFS001648.

[9] For example, in the 2010s, calculated needs in Allen, Edmonson, Graves, and Logan counties were between 125 and 250 and mostly rising, but before they could reach 250, existing agencies moved in, and the need dropped off.

counties where only existing agencies can expand are suspiciously more likely to have the calculated need *decrease* below 125 over time than to increase enough for new agencies to open. Stratmann Rebuttal (Ex. 10) at 2–3 & Ex. 2 (tabulating need calculations).

The result is astonishing. In all of Kentucky's 120 counties, new home health agencies are allowed in only six. *Id.* at 2 & Ex. 1. There are only 17 counties where a new agency has been allowed for any year in the last decade. *Id.* In Louisville, the state has prohibited new agencies for at least 15 years. *Id.*; Sullivan Dep. (Ex. 3) at 40:16–20.

In the six counties where new agencies are not barred, these calculations are just the beginning. Regardless of the *plan's* calculation of need, a new agency still must satisfy the *separate* statutory need criterion in the daunting CON application process.[10] State Answer ¶ 90. That begins when a new agency pays at least $1,000, 900 KAR 6:02, and fills out a detailed 20-page, 3,500-word application, Ex. 17 (blank application). Applicants also typically submit 20 to 50 letters of support, although sometimes they gather 300 or 400, including letters from politicians. Sullivan Dep. 79:14–80:14. The more successful applicants hire a CON consultant, *id.* at 82:7–8, which costs around $15,000, *id.* at 73:21–25, 75:4–12.

After the application is submitted, one or two (or more) "affected persons" typically intervene. KRS §§ 216B.085(1), 216B.015(3); Sullivan Dep. 86:18–25. In practice, "affected persons" are never potential patients. Instead, they are the applicant's future competitors. Payne Dep. (Ex. 18) at 44:7–9; Sullivan Dep. 92:17–93:11. These future competitors demand hearings, and, once demanded, hearings must be held. KRS § 216B.085(2). First, however, there is

See Ex. 10 at Ex. 2 (tabulating need calculations); CON applications 114-04-5486(2), 018-01-5316(4) (applications lowering need).

[10] A copy of Kentucky's CON application database is Exhibit 13. Exhibits 14–16 are typical decisions. Application records are also available at https://prdweb.chfs.ky.gov/CONOnline/SearchApplication.aspx

discovery, which can include document requests, interrogatories, requests for admissions, depositions, and motions to compel, and then the exchange of exhibit and witness lists, plus any motions in limine, all managed by the parties' lawyers. Sullivan Dep. (Ex. 3) at 89:8–17, 90:17–24, 92:11–16, 102:16–103:18.

The hearings then pit new businesses against their future competitors in full-blown trials.[11] While the typical federal trial takes one day,[12] CON hearings typically take two, and they can last up to five. Sullivan Dep. 94:6–21. Each party typically presents four or five witnesses, which can include executives, doctors, politicians, expert consultants (for another $11,000 or so, *id.* at 74:1–6), and the occasional statistician. *Id.* at 98:3–100:17. There are typically 25 to 50 exhibits, although the number can exceed 100. *Id.* at 101:25–102:6. As corporations cannot represent themselves, State Answer (Doc. 70) ¶ 110, each party typically brings one or two lawyers, Sullivan Dep. 95:14–19.

Once the hearing is over, there is post-hearing briefing. *Id.* at 108:14–16. Finally, a state staff attorney will rule on whether the applicant met its burden of proof, State Answer ¶ 108, although there are no standards to determine whether the application meets an identified need, Payne Dep. (Ex. 18) at 21:20–21, 41:3–10, 44:15–22; Mather Dep. (Ex. 4) at 63:24–64:2. The entire process—from deciding to apply to receiving a decision—usually takes half a year. Sullivan Dep. 180:23–181:1. But that is no guarantee: a dissatisfied competitor can always appeal the grant of a CON to the Franklin Circuit Court. *See* KRS § 216B.115.

[11] During the pandemic, the state is not conducting these hearings at all, so applicants just have to wait. Payne Dep. (Ex. 18) at 48:21–49:12, 50:15–51:4. As of August 2020, the state had not implemented virtual replacements. *Id.* at 49:13–21. Even Intervenor–Defendant agrees that the CON regime has not been flexible enough during the pandemic. KHA Dep. (Ex. 5) at 47:1–48:24.

[12] Federal Judicial Center, Table 6.5—U.S. District Courts–Combined Civil and Criminal Judicial Facts and Figures (September 30, 2019), https://www.uscourts.gov/statistics/table/65/judicial-facts-and-figures/2019/09/30.

In the end, after months and tens or hundreds of thousands of dollars, only one in four applications succeeds.[13] Stratmann Rebuttal (Ex. 10) at 3. And, again, this is the process in the six counties where new agencies are *allowed.* Between the sweeping ban in most of the state and the onerous process in the rest, the overall result is that, while a handful of agencies have fought their way in from out of state, no entirely new home health agency has opened in Kentucky for at least twenty years. *Id.* at 3–4. In Louisville, the last approved application was filed in 1995. *Id.* at 3.

III. BECAUSE OF THE LAW, GRACE CANNOT SERVE THE NEPALI-SPEAKING COMMUNITY.

For Grace, all this quickly became a nightmare. At the beginning, Dipendra assumed that Grace's niche focus on Nepali speakers would show enough need for the CON law. Tiwari Dec. ¶ 22; Ex. 20 (application supplement) at CHFS000001–02 (documenting focus). He spent more than a hundred hours researching the process and completing the application. Tiwari Dec. ¶ 21. Finally, in March 2018, Grace paid the $1,000 fee and submitted its application, projecting that it would serve 45 patients in its first year and 155 in its second. *See* Ex. 8 (application); *id.* at CHFS000030 (projections). Grace later submitted more information as requested. *See* Ex. 20.

Soon after, the Baptist Health conglomerate, which runs its own home health agency in Louisville, intervened. Five days before Christmas, it moved for summary judgment against Grace's application. *See* Ex. 21 (motion). One might think that a 3,500-patient incumbent, Ex. 22 at CHFS003895, had nothing to fear from the small business Grace was proposing. But even so, Baptist stressed that the state health plan calculated a need of negative 929 in Jefferson County,

[13] This figure includes withdrawn applications because withdrawals are usually caused by the burden of the process itself. Applicants typically withdraw based "on the reaction they get in terms of opposition," Sullivan Dep. (Ex. 3) at 83:11–85:16, or because they "anticipate their application being declined," Deloitte Rep. (Ex. 19) at CHFS000162.

so Grace was not allowed. On January 3, the staff attorney who would rule on the application gave Grace one week to respond. *See* Ex. 23 (scheduling order).

Dipendra was shocked. Other CPAs hadn't tried to shut down his accounting business. Tiwari Dec. ¶ 23. He scrambled to find an attorney, but everyone he contacted was conflicted out by relationships with existing players. *Id.* ¶ 24; *see* Ex. 24 (attorney emails). Lacking an attorney, Grace did not respond by the deadline. Ex. 25 (application denial) at CHFS000055. The next day, the staff attorney denied Grace's application as inconsistent with the plan. *Id.* at CHFS000057.

IV. THE CON LAW IS PROTECTED BY POWERFUL SPECIAL INTERESTS.

Why did all this happen? The answer, although unseemly, is simple. Entrenched players fight tooth-and-nail to keep CON laws in place. *See* MTD Op. 7; Stratmann Rep. (Ex. 26) at 7 n.15, 13 n.33; Sullivan Dep. (Ex. 3) at 51:3–16 (Defense expert admitting that incumbents' "own economic self-interest … obviously is a factor").

CON laws became widespread in the 1960s and '70s, especially after the federal government encouraged states to adopt them. Stratmann Rep. at 3. At the time, Medicare reimbursed on a "cost-plus" basis, meaning it paid providers no matter how much capital they invested, even if the capital investments (like new but unused hospital beds) were excessive. *Id.* at 3–4. The idea of CONs was that limiting services to what was "needed" would reduce the resulting unnecessary costs. *Id.* at 4. But even then, experts were warning that "vested interests," including in home health, would use CON laws to "control their turf, limit competition, and consequently stifle innovation." *Id.* at 13 n.33, 15. A simpler solution was to just stop using cost-plus reimbursement, which Congress did in the '80s, when it switched to the current fee-for-

service model. *Id.* at 4. So the original rationale for CON laws has not been relevant for decades, *id.*, and most states no longer require CONs for home health.[14]

The federal government has opposed CONs ever since, continually warning of the risks of protectionism. *See* MTD Op. 16. That has included a 1988 FTC report concluding that CONs were likely raising hospital costs rather than lowering them; a 2004 FTC and DOJ report concluding that "CON programs are generally not successful in containing health care costs and … risk entrenching oligopolists and eroding consumer welfare"; a 2015 comment that "incumbent firms seeking to thwart or delay entry by new competitors may use CON laws to achieve that end"; and a 2018 HHS, Treasury, and Labor report concluding that "CON laws have failed to produce cost savings, higher quality healthcare, or greater access to care." Stratmann Rep. (Ex. 26) at 5–6.

Thanks to the oligopolists and incumbent firms, change is hard to come by in Kentucky. The Kentucky Hospital Association (KHA), which represents 95 percent of the hospitals in the state, has always had a CON committee, and one of its strategic objectives is to protect CON laws. KHA Dep. (Ex. 5) at 26:6–15, 28:18–24; Ex. 27 (objectives) at KHA004705. That could be with simple member guidance, as in 2005, when KHA reported that proposed higher calculated need thresholds in the state plan would not "negatively impact[]" hospitals, "since the plan is intended to protect existing providers." Ex. 28 at KHA000671.

Other times KHA runs to the battlements. For example, after the Affordable Care Act passed, Kentucky hired Deloitte Consulting for a major review of the state's healthcare system. Deloitte Rep. (Ex. 19) at CHFS000089. Calling home health "critically important" and "a central pillar," the review recommended that the state "consider suspending / discontinuing the CON

[14] *See* Emily Parento, *Certificate of Need in the Post-Affordable Care Act Era*, 105 Ky. L. J. 201, 257 (2017).

program for Home Health Agencies." *Id.* at CHFS000161, 168. In response, KHA quickly hired a consultant (its current expert in this case) to "prepare a position paper citing the value of Certificate of Need programs." Ex. 29 (KHA–consultant emails) at KHA000151; *see also* Ex. 30 (roughly $15,000 contract). Around the same time, knowing the state was considering loosening the CON restrictions on home health, Ex. 31, KHA also ran a working group with the express goal of "increas[ing] availability of home health services provided by hospitals without widely opening up the service," Ex. 32 at KHA000854. Ultimately, rather than listen to its own consultant, the state modified the health plan along the lines KHA, its "trusted adviser," KHA Dep. (Ex. 5) at 41:17–42:7, proposed.[15] The state has modified the plan as KHA wanted at least two more times, loosening requirements for hospitals' agencies and tightening them for others.[16]

Put simply, CONs are "an anti–competitive relic whose repeal is prevented by political inertia and entrenched incumbents." And that is according to someone who used to run Kentucky's CON program.[17]

V. GRACE SUED TO PROTECT ITS FOURTEENTH AMENDMENT RIGHTS.

If this history is any guide, the state will never let Grace provide home health services to the refugees that need them. So, with no other options, Grace filed this suit, alleging that, as applied to home health agencies, Kentucky's CON law violates the Due Process, Equal Protection, and Privileges or Immunities clauses of the Fourteenth Amendment.[18] Right on cue,

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[15] *Compare* Ex. 10 at Ex. 3, CHFS001323–24 (August 2013 standards) *with* Ex. 33 at KHA000830 (June 2014 KHA requests) *and* Ex. 10 at Ex. 3, CHFS001457–58 (May 2015 standards).

[16] *Compare* Ex. 10 at Ex. 3 (plan standards for home health) *with* Ex. 34 at KHA000632 (June 2015 KHA home health requests), Ex. 35 at KHA000654–55 (August 2017 requests), *and* Ex. 36 at KHA000663 (August 2018 requests). Defendant Inspector General Adam Mather also attended the deposition of KHA's representative and met with KHA attorneys to prepare for his own deposition. Mather Dep. (Ex. 4) at 17:1–10.

[17] Stratmann Rebuttal (Ex. 10) at 18 (quoting Parento, 105 Ky. L. J. at 255). *See also* Parento, 105 Ky. L. J. at 255–56 (describing CON laws as a "persistent nuisance" and the product of "entrenched healthcare interests").

[18] On equal protection, Grace challenges both the broader arbitrary distinction between CON holders and non-CON holders, and the narrower distinctions between similarly situated providers discussed in Part F, below.

KHA intervened "to protect its members' valuable property interests in their CONs." Doc. 23 at 7; *see also* MTD Op. 23–24 ("as if to prove the point"). The Court then denied Defendants' motions to dismiss. While appropriately acknowledging Grace's burden under the rational-basis test, the Court held that Grace had stated a claim[19] and that "there is every reason to think that Kentucky's law … protect[s] the pockets of rent-seeking incumbents at the expense of entrepreneurs who want to innovate and patients who want better home health care." MTD Op. 27. Because the undisputed facts now prove that is true, Grace moves for summary judgment.

ARGUMENT

I. LEGAL STANDARD

Summary judgment is required when "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). "[A] party may not avoid summary judgment by resorting to speculation, conjecture, or fantasy." *K.V.G. Props., Inc. v. Westfield Ins. Co.*, 900 F.3d 818, 823 (6th Cir. 2018) (internal quotation omitted). That is because "[t]rials exist to resolve concrete factual disputes, not to satiate the endless imagination of trial lawyers." *Id.*

Grace's substantive due process and equal protection claims are governed by the rational-basis test. Under that test, Grace must show that, either as applied in home health generally or to Grace specifically, Kentucky's CON law is not rationally related to a legitimate state interest. MTD Op. 11. The test is "a high bar," but it is "not a rubber stamp." *Id.* Courts at every level invalidate economic regulations under it. *See id.* at 11 & n.67 (collecting Supreme Court cases); Pls.' Resp. KHA MTD (Doc. 46) at 8 nn. 2–3 (circuit and district cases). The test does not

[19] Except on the admittedly foreclosed privileges or immunities claim, which Grace seeks to preserve for appellate review. MTD Op. 1; *see also* Am. Compl. (Doc. 15) ¶¶ 210–14.

prevent plaintiffs from using evidence to "negate a seemingly plausible basis for [a] law." MTD Op. 12 n.71 (quoting *St. Joseph Abbey v. Castille*, 712 F.3d 215, 223 (5th Cir. 2013)).[20] Nor does it make courts "rationalize away … irrational decisions" or "accept nonsensical explanations." *Id.* at 12 n.73, 21 n.121 (quoting *Seal v. Morgan*, 229 F.3d 567, 579 (6th Cir. 2000), then *St. Joseph Abbey*, 712 F.3d at 226–27).

II. THE CON LAW IS NOT RATIONALLY RELATED TO THE INTERESTS IT SUPPOSEDLY SERVES.

Under that test, Grace has already stated a claim. The official explanation for the CON law is that it lowers cost, increases access, and improves quality. *Id.* at 14 (citing KRS § 216B.010). This Court has held that the law is irrational if it plainly fails to do any of those things. *Id.* at 12, 27. On the undisputed record, the evidence of that failure is staggering.

In Part A, Grace notes that CON laws make no sense for home health agencies, even as conjecture. In Part B, Grace presents the overwhelming evidence that CON laws fail to lower costs. In Part C, Grace explains how a law that exists to limit service does, in fact, limit access to service. In Part D, Grace proves that the CON law worsens quality. In Part E, Grace discusses the CON law's exceptions, which are baffling under Defendants' theories but easily explained by protectionism. Finally, in Part F, Grace shows that courts strike down CON laws on much less evidence than what Grace presents here.

A. CON laws make no sense in home health.

To begin, there are two reasons that CON laws do not even hypothetically improve home health care. First, CON laws were enacted to address a problem in healthcare finance that Congress fixed decades ago. As the federal government has put it, "the original reason for …

[20] *See also United States v. Carolene Prods. Co.*, 304 U.S. 144, 153–54 (1938) (explaining the appropriateness of facts in rational-basis cases); *Craigmiles v. Giles*, 312 F.3d 220, 224 (6th Cir. 2002) (striking down an economic regulation because of evidence).

CON laws is no longer valid." Stratmann Rep. (Ex. 26) at 4. So the CON law here cannot be fixing a problem that does not exist. And the rational-basis test "does not demand judicial blindness to the history of a challenged rule or the context of its adoption." MTD Op. 21 n.121 (quoting *St. Joseph Abbey*, 712 F.3d at 226–27). Rather, "a statute predicated upon the existence of a particular state of facts" may be unconstitutional if "those facts have ceased to exist." *Carolene Prods.*, 304 U.S. at 153.

Second, CON laws also do not make sense in home health because home health is a low-capital industry. CON laws are supposed to regulate major investments like hospital beds and MRI machines. MTD Op. 18, 25; Stratmann Rep. (Ex. 26) at 2, 13. At least in theory, a small town could suffer the "costly duplication," KRS § 216B.010, of having two half-empty hospitals instead of one full one, or expensive scanners sitting around unused. But home health does not require large investments because it is based almost entirely on labor. Stratmann Rep. 14–15; Mather Dep. (Ex. 4) at 159:2–6. Unless agencies pay people to stand around, there is no such thing as a half-empty home health agency. *See* Stratmann Rep. 15 n.36 ("[N]urses tend to work at full capacity even in small scale agencies.").

And the record here does confirm that home health agencies need only small capital investments. Unlike eight-figure hospitals, Grace planned to invest $80,000, Ex. 8 (application) at CHFS000033. One older estimate of the average investment is around $40,000. Stratmann Rep. 15. And nearly every Kentucky home-health application reports capital investments under $400,000. State RFA Resps. (Ex. 11) at 36. These amounts are a tiny fraction of the investment size the CON law explicitly cares about, around $3,400,000.[21] Against that backdrop, experts

[21] For investments that do not need a CON based on category, Kentucky generally still requires a CON if the investment exceeds $3,423,684. *See* KRS §§ 216B.061(1)(b), (f); 216B.015(8), (17); Ex. 37 (2020 threshold).

have long recognized that, in home health, "there is no reason to expect an effect of CON on expenditures, costs, procedure volume, or mortality." Stratmann Rep. (Ex. 26) at 14 (quoting expert views from 2014); *see also id.* at 15 (expert views from 1980).

B. The CON law is not rationally related to reducing cost.

The real-world evidence proves that CON laws do not work in home health. Start with cost. This Court has held that "Plaintiffs may be on to something when they say Certificate of Need laws raise costs." MTD Op. 15–16. The undisputed evidence proves that correct. Self-interested parties aside, everyone—experts, federal agencies, courts—*everyone* knows that CON laws are not lowering costs.

First is the empirical research. In 2016, a meta-analysis of 20 peer-reviewed studies spanning 40 years of academic scrutiny found that "[t]he overwhelming weight of evidence suggests that CON laws are associated with both higher per unit costs and higher total expenditures." Stratmann Rep. 7. Defendants' expert agrees that is what the studies say. Sullivan Dep. (Ex. 3) at 148:12–18. And the failure is mainly among institutions such as hospitals for which CONs were designed.

Lowered costs are even less likely in home health, and the research bears that out too. Studies of home health CON laws routinely conclude that "CON regulation appears to be associated with higher costs" and that "[p]ermitting free entry by home health agencies … most likely would *lower* [costs]" and that "[r]emoving entry regulations for home health would have negligible system wide effects on health care costs." Stratmann Rep. 16–22. One of Grace's experts—a PhD economist and leading CON researcher—reviewed every academic study of home health CON laws and concluded that "the literature specific to home health shows that CONs at best fail to improve the system, and more likely make healthcare worse." *Id.* at 23.

The federal government agrees, and it has been sounding the alarm since the 1980s. Through Republican and Democratic administrations, five separate agencies—the Department of Justice, the Department of Labor, the Department of Health and Human Services, the Department of the Treasury, and the Federal Trade Commission—have warned that CON laws do not lower costs. *Id.* at 5–6.

Nor is this basic economics lost on the courts. The Fourth Circuit, holding that a CON law violated the Dormant Commerce Clause, accepted the obvious point that blocking competitors does not lead to lower prices:

> [R]estricting market entry does nothing to insure that services are provided at reasonable prices. Without rate regulation, higher rather than lower prices will more likely result from limiting competition. [The state's] goal of providing universal service at reasonable rates may well be a legitimate state purpose, but restricting market entry does not serve that purpose.

Medigen of Ky., Inc. v. Pub. Serv. Comm'n of W. Va., 985 F.2d 164, 167 (4th Cir. 1993).

Indeed, the CON law fails even on its own terms. If "unnecessary" home health capacity were harming the system, then it would harm Louisville now because, according to the plan, Jefferson County has by far the most negative need in the state, which should mean the most unnecessary duplication of services. *See* Ex. 10 at Ex. 2. Yet Defendants' expert admitted that "[he doesn't] see problems that need to be addressed in Jefferson County" of any kind, Sullivan Dep. (Ex. 3) at 236:6–23, even though Jefferson County is precisely where the CON law predicts cost, access, and quality would be worst. Indeed, he rejected that a calculated negative need shows an oversupply at all, *id.* at 239:1–4, even though that is the bedrock assumption of the plan.

In earlier briefing, Defendants have suggested that, by limiting agencies, CON laws at least promote economies of scale—that banning new businesses is worthwhile because one billing department is cheaper than two. This is wrong in theory and practice. Even in theory,

strict pursuit of scale is absurd: there would be *one* home health agency, just as there would be one restaurant, one university, one law firm, and one CON consultant. *See* MTD Op. 2–3, 26.[22] In practice, not only are these supposed efficiencies not lowering cost overall, there is specific research finding "no evidence that CON regulation contributes to efficiency in the realization of scale economies." Stratmann Rep. (Ex. 26) at 16–18.

Put simply, the CON law is clearly not lowering costs. It is likely raising them.

C. The CON law is not rationally related to increasing access.

As with cost, the law of the case is that Grace "may be right that Kentucky's Certificate of Need regime reduces access to care." *See* MTD Op. 17–18. That is dead-on. Again, the law exists to restrict "the proliferation of … health services" when the state deems them "unnecessary." KRS § 216B.010. That means less access by definition. "Restricting market entry … necessarily limits the available service because it limits the number of [providers] from which a [customer] can seek service." *Medigen*, 985 F.2d at 167.

That reduced access is not limited to the Nepali speakers ignored by the state plan. Again, in 114 counties, new agencies are banned by law, and in every county, they have been banned in practice for decades. Stratmann Rebuttal (Ex. 10) at 2–4. That is mostly because of an arbitrary formula that even Defendants' expert admits is painting with "too broad a brush." Sullivan Dep. (Ex. 3) at 57:11–16; *see also* Mather Dep. (Ex. 4) at 73:12–75:14 (state admitting that its only evidence of the formula's correctness is a lack of complaints).

The evidence bears out that these restrictions are just the beginning. As the Court has observed, MTD Op. 17–18, CON states (undisputedly) have fewer hospital beds, fewer hospitals

[22] *See also* Mather Dep. (Ex. 4) at 160:11–24 (state admitting that "there's diminishing returns on scale, so as you get too large, your returns diminish and you become less efficient and productive"); Sullivan Dep. (Ex. 3) at 156:8–157:2 (Defense expert admitting "that patient choice is an issue" and that "you [don't] want to have one home health agency in each county").

with MRI machines, fewer medical imaging providers, and lower utilization of medical imaging, Stratmann Rep. (Ex. 26) at 11–12. CON states have about half as many home health agencies per Medicare beneficiary, and they have less competitive home health markets.[23]

Those deficiencies extend to the most vulnerable populations. Consider rural Kentucky. Defendants have suggested that the CON law encourages home health agencies to open in underserved rural areas. But CON laws are (undisputedly) associated with less rural care: fewer rural hospitals, fewer rural surgery centers, and less access to rural hospice care. Stratmann Rep. 9–10; MTD Op. 17–18. Which makes sense because, again, CON laws *prohibit* care. There is no rational reason that a law prohibiting agencies from opening in one place would encourage them to open in other, financially unattractive places. Stratmann Rebuttal (Ex. 10) at 15; Sullivan Dep. (Ex. 3) at 175:9–176:9 ("I'm not sure you could do that through CON."); *see also Walgreen Co. v. Rullan*, 405 F.3d 50, 60 (1st Cir. 2005) (holding that pharmacy CON law "cannot reasonably be thought to advance" purpose of ensuring pharmacies in underserved areas). Nor does the state have any evidence that this hypothetical reshuffling ever actually happens. Mather Dep. (Ex. 4) at 117:16–22 ("Q. Do you have evidence that an agency that can't open where it isn't needed under the plan would open somewhere it is needed? … A. I do not. That would be their decision to make."); *see also* Sullivan Dep. 169:18–170:12 (same).

Indigent populations fare no better. Defendants have said that the CON law encourages agencies to serve Medicaid and uninsured patients. But (undisputed) research shows that CON laws are not increasing charity care or leading to cross-subsidization of Medicaid patients. Stratmann Rep. 10–11; Stratmann Rebuttal 14; KHA Dep. (Ex. 5) at 179:4–18, 197:19–24 (no

[23] Daniel Polsky et al., *The Effect of Entry Regulation in the Health Care Sector: the Case of Home Health*, 110 J. Public Econ. 1 (2014).

contrary evidence); Sullivan Dep. (Ex. 3) at 169:22–170:12 ("I wasn't asking about envisioning, though. I was asking about can you point me to an actual example of that? A. I cannot."). Some existing agencies ignore these patients now, despite having CONs. *E.g.*, Ex. 33 at KHA000824. And the state itself definitively rejects that the CON law promotes indigent care:

> Q. [D]oes the CON program ensure that home health agencies serve Medicaid or underinsured populations?
>
> [Objection]
>
> A. It does not—it is not a requirement to receive your CON.

Mather Dep. (Ex. 4) at 124:5–12.

Things might be different in "speculation, conjecture, or fantasy," *K.V.G. Props.*, 900 F.3d at 823, but in the real world, laws that block new services decrease access to service.

D. The CON law is not rationally related to improving quality.

Things are the same for the last of the law's nominal justifications. It is already "plausible that [CON programs] diminish quality in the context of home health." MTD Op. 18–20. And this is, in fact, true. It is easiest to see for Louisville's Nepali speakers, who receive worse care (or no care) because of cultural and linguistic mismatch.

But the problem goes far beyond that. Whether it is deaths from heart failure, heart attack, pneumonia, or complications of surgery, CON states undisputedly do worse (and that is controlling for the health of the patient population). Stratmann Rep. (Ex. 26) at 9. In states with the most CON regulation, patients are less likely to rate hospitals highly. *Id.* Put simply, "in states where CON laws regulate provider entry into healthcare markets, incumbents tend to provide lower-quality services." *Id.* (quoting a 2016 study). Which the federal government has been saying for decades. *Id.* at 6 (quoting federal view that "CON laws have failed to produce cost savings, higher quality healthcare, or greater access to care, whether in underserved

communities or in underserved areas."); *see also Craigmiles*, 312 F.3d at 226 (noting that competition tends to improve quality).

This failure extends to home health specifically. Three studies have examined whether CON regulation improves home health care, and not one of them finds that it does. Stratmann Rep. (Ex. 26) at 18–21. The first, from 2014, finds that "[r]emoving entry regulations for home health would have negligible system wide effects on health care costs and quality." *Id.* at 19. The second, also from 2014, finds that CON laws are not associated with meaningfully improved quality, and that, in the most competitive markets, there is "a more rapid deterioration of quality when entry is restricted by CON." *Id.* at 18–19. The third study, from 2018, finds that CON laws are linked to more low-quality and fewer high-quality home health agencies. *Id.* at 20–21.

Defendants have supposed otherwise, but supposition does not trump the record.[24] There is no evidence that Kentucky's CON law leads to home health agencies with more qualified staff, KHA Dep. (Ex. 5) at 182:16–19, or better technology, Sullivan Dep. (Ex. 3) at 183:6–9, or more specialized services, *id.* at 183:10–13. Indeed, the most common argument that CON regulation boosts quality is entirely absent from this case. One theory is that, by concentrating particular surgeries like coronary artery bypass grafts at fewer hospitals, CON laws lead to more practiced surgery wings, and thus better outcomes.[25] But even if "practice makes perfect" were a rational reason to ban new hospitals, the Court has held that "the issue here isn't the constitutionality of a Certificate of Need law for heart surgeons, or for any medical providers outside the context of home health." MTD Op. 19–20. And a home health visit, in which an aide "take[s] vitals and

[24] At least for hospital-owned agencies, KHA has opposed quality standards in the plan, calling them "onerous." Ex. 35 (2017 KHA requests for plan) at KHA000654.

[25] The actual evidence is mixed. Newer studies find that this relationship does not exist. Stratmann Rep. (Ex. 26) at 8 n.18.

provide[s] basic therapies," KHA RFA Resps. (Ex. 2) at 13, is not heart surgery, KHA Dep. (Ex. 5) at 174:9–14; Sullivan Dep. (Ex. 3) at 181:6–11. There is simply "no evidence of a volume–outcome relationship" in home health. Stratmann Rep. (Ex. 26) at 14; *see also* Sullivan Dep. 181:2–5 ("I've not seen it."). Sure, Defendants' attorneys speculate that there could be, *see* KHA Dep. 158:10–15, 187:6–7 (discussing KHA interrogatory responses), but when asked under oath, the hospitals (who would know) disagreed:

> A. Well, this is, I don't believe, directed necessarily at home health care. There are certain services under CON that are volume sensitive. I think I've talked about those, you know heart procedures, open heart surgery, cardiac cath. … So it's not necessarily, you know, for every service that's out there …"

Id. at 187:6–24.[26]

In the same way, Defendants have suggested that the CON law decreases hospital readmissions. (The idea is that if a hospital can discharge patients to its own agency, care will be better, and there will be fewer readmissions, which are punished by Medicare.) Of course, the CON law does not limit home health services to hospital-owned agencies; it limits them to incumbents. The theory is doubtful when "[m]any hospitals are not interested in" having a home agency at all, KHA Dep. 64:9–13, and it's even more doubtful when the state health plan used to reward home health agencies with below-average hospital admission rates, Ex. 10 at Ex. 3, CHFS027724, until KHA *opposed* that exception and the state removed it, *id.* at CHFS001648; Ex. 36 at KHA000663. In any event, this is not the evidence. Home health CON laws do not decrease hospital readmissions. Stratmann Rep. 19; *see also* KHA Dep. 97:17–98:7 (no contrary evidence). Rather, hospitals in CON states appear to be 50 percent *more likely* to be penalized by

[26] Even if there were a volume–quality relationship in home health, it would not matter because "nurses tend to work at full capacity even in small scale agencies." So "there is little rationale for concentrating volume at a small number of agencies through entry restrictions." Stratmann Rep. 15 n.36 (quoting a 2014 study).

Medicare. MTD Op. 19; *see also* KHA Dep. (Ex. 5) at 110:10–16 ("Q. Readmission penalties aren't related to Certificate of Need? A. No.").[27]

And even if none of this were true, forcing businesses to fight like gladiators for the prize of operating still would not rationally relate to ensuring quality, because there is a separate licensure system for that. As the state admitted, a CON "just allows you to open the operation, and licensing ensures that you're providing the appropriate level of service." Mather Dep. (Ex. 4) at 42:7–13. *See Craigmiles*, 312 F.3d at 226 (recognizing protectionism where another law protected the hypothetical state interest).

E. The CON law has inexplicable exceptions.

Not only is the law irrational because of what it does, it is also irrational because of what it does not do. If the law were really concerned with, say, maximizing economies of scale, it would cover similarly situated healthcare providers. But it does not do that. Instead, because of plain politics, some providers are more equal than others. *See Loesel v. City of Frankenmuth*, 692 F.3d 452, 462 (6th Cir. 2012) (recognizing Equal Protection violation where the state irrationally distinguished between similarly situated groups).

Take an example the Court has noted: continuing-care retirement communities, which do not need a CON to provide home health services to their residents. *See* MTD Op. 24 (citing KRS § 216B.020(1)). The services are the same as any another agency's. Mather Dep. (Ex. 4) at 146:1–8. Indeed, home health services in a retirement community serve just a handful of patients, which would seem to heighten any concerns about volume or economies of scale. Sullivan Dep. (Ex. 3) at 214:7–215:2. Yet those supposed concerns did not stop the Legislature from loosening the CON at retirement communities to try to promote a new model of care. *Id.* at

[27] The Court has noted that CON laws may be particularly harmful during the pandemic. MTD Op. 27. Early evidence suggests that CON-law suspensions have saved lives. Stratmann Rebuttal (Ex. 10) at 12.

213:17–214:06. (Apparently, the state's theory of CONs is that they encourage more home health care, except when they prevent businesses from providing home health care.) Tape-cutting like this can happen—when there is no serious opposition from incumbents, which think that the exception is narrow and does not affect them. *Id.* at 215:22–23 217:17–218:03.

Or take everyday doctors' offices, which are also exempt. KRS § 216B.020(2)(a). Doctors' offices are subject to economies of scale. Sullivan Dep. (Ex. 3) at 210:2–5. Doctors might have a volume–quality relationship. *Id. at* 209:12–20. If total spending, rather than capital investments, matters, that amount is seven times higher for doctors and clinics than for home health. *Id.* at 211:10–13; *see also* Ex. 38 (chart of healthcare spending). And yet doctors have never been covered by CON laws. Sullivan Dep. 207:8–9. One reason is that "there's a need for more primary care physicians." KHA Dep. (Ex. 5) at 139:2–10. (Again, apparently the state thinks CON laws increase access, except for all the times they block access.) Another explanation comes from Defendants' expert: "obviously there's probably a political aspect to it." Sullivan Dep. 208:1–15.

F. Courts reject protectionism like this as illegitimate.

Politics, in the end, is all this is. In the Sixth Circuit's words, "[n]o sophisticated economic analysis is required to see the pretextual nature of the state's proffered explanations." *Craigmiles*, 312 F.3d at 229. (Although, as this Court predicted, the sophisticated economic analysis supports Grace too.) Given the overwhelming evidence that the CON law has zero public benefit, only the obvious, if unpleasant, explanation remains: the law is a "naked attempt to … privilege certain businessmen over others at the expense of consumers." *Id.* And that triggers a "virtually *per se* rule of invalidity." MTD Op. 22.

Indeed, courts have invalidated CON laws that were more sensible or less burdensome. The Supreme Court of North Carolina has struck down a CON requirement for hospitals. *In re*

Certificate of Need for Aston Park Hosp., Inc., 193 S.E.2d 729, 736 (N.C. 1973) ("The Constitution of this State does not … permit the Legislature to grant to the Medical Care Commission authority to exclude Aston Park from this field of service in order to protect existing hospitals from competition otherwise legitimate.").[28] And the Eastern District has invalidated a Kentucky CON law far less burdensome than the CON law here. *See* MTD Op. 22–23 (relying on *Bruner v. Zawacki*, 997 F. Supp. 2d 691 (E.D. Ky. 2014)).

That case, *Bruner*, addressed a similar CON application process. Kentucky made moving companies get certificates of public convenience and necessity, which meant proving that "existing transportation [was] inadequate." Then, "any person having interest" could trigger a hearing on need, but this was always future competitors, never members of the public. New businesses could never succeed over protest. *Id.* at 693–95. On those facts, then-Judge Reeves had no trouble granting summary judgment and concluding that existing companies were "'veto[ing]' competitors from entering the … business." *Id.* at 700.

Under that ruling, the answer here is clear. In 114 counties in Kentucky, new home health agencies are banned outright. They cannot even undergo the process that was unconstitutional in *Bruner*. It is only in five percent of counties that a new business can get a foot in the door—and onto the minefield that Judge Reeves found unlawful all by itself. If the CON law was irrational in *Bruner*, then the CON law here is irrational too.

CONCLUSION

As applied to home health agencies, Kentucky's CON law fails so completely that it is unconstitutional. It relies on a theory that does not apply to solve a problem that no longer exists.

[28] Other courts have upheld CON requirements for surgery centers and imaging devices, but this Court has distinguished those cases. MTD Op. 24–26 (declining to follow *Birchansky v. Clabaugh*, 955 F.3d 751 (8th Cir. 2020), and *Colon Health Centers of America, LLC v. Hazel*, 733 F.3d 535 (4th Cir. 2013)).

It harms the system that it purports to fix. And it does so because entrenched players dig in their heels. As deferential as the rational-basis test may be, insiders cannot exclude newcomers through raw political power.

Grace is entitled to summary judgment.

DATED this 13th day of November, 2020 /s/ Andrew Ward

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