CONVICTING CON

Putting West Virginia's Certificate of Need Laws on Trial

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CARDINAL INSTITUTE
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AN INTRODUCTION FROM THE EXECUTIVE DIRECTOR

Friends,

What follows is the most comprehensive look into the various effects that certificate of need (CON) laws have on the healthcare system in West Virginia that has ever been produced.

Given the importance of health care in West Virginia, the Cardinal Institute felt it was critical to do a thorough dissection of the various distortions, unintended consequences, and negative side effects that CON laws create. Part research, part analysis, and part storytelling, this paper will give you an understanding of the pernicious effects of this archaic, outdated regulatory regime.

CON laws affect nearly all aspects of healthcare in West Virginia, from provision on the part of doctors, nurses, midwives, and hospitals to consumers looking to access life-saving procedures, hospital beds, and the latest technological innovations.

Thank you for taking the time to read through this analysis; the health of West Virginians depends on it.

Garrett Ballengee
Executive Director, Cardinal Institute for West Virginia Policy

CHAPTER ONE: CERTIFICATE OF NEED LAWS

What is Certificate of Need?

Certificate of Need (CON) laws are regulatory barriers instituted in thirty-five states that require health care providers to receive authorization from a state's health regulatory board to open a new or expand an existing health facility.

A CON is unlike familiar regulatory processes. Some health regulations ensure facilities meet quality standards for care and safety. CON programs determine a necessity for services based upon the anticipated investments of a prospective provider and possible commercial impact on existing regional providers. The health care markets in states with CON have made decisions contingent on state bureaucrats who have the authority to consent to or deny service, making investments costly and risky.

Eager providers must reason the need for their business to function or expand in a lengthy application to determine CON eligibility. Fees for the application to be considered vary, and determination of admissibility may take 60-105 days (dependent on whether a hearing before the state health board is called). The CON process also allows incumbent competitors to intervene in the application review activities by proposing arguments for why an application should be denied. [1]

In the case of a CON denial, in which boards are not required to indicate a reason, providers are forbidden from establishing or expanding any health care facility or service.

1 W. Va. Code R. § 65-32-8.25; § 65-32-8.26

History of Certificate of Need

The original enactment of CON programs claimed to be an effective means to reduce health care costs and promote equal access to care. Proponents of CON also alleged that these new guidelines would efficiently reduce mortality by protecting high-volume, skilled care facilities across the states.

In 1964, New York became the first state to endorse CON programs throughout their municipalities. In 1972, Section 1122 programs, a segment of the Social Security Act of 1935, encouraged a regulatory review process for large capital expenditures in the states. [2]

The Social Security Act allowed the federal government to withhold Medicare and Medicaid reimbursements for capital expenditures not approved by state planning agencies. [3] Therefore, states began to adopt various review methods over health care facilities so that reimbursement payments would still stream to states.

Then, in 1974, the National Health Planning and Resources Development Act passed and offered exclusive federal funds for health market review. [4] Early stages of this CON process permitted the assessment and regulation of expenses totaling more than $100,000, bed additions, and service expansions for hospitals and nursing homes. [5] By 1975, 46 states had opted into some form of a review program, either through Section 1122 or the National Health Planning and Resources Development Act. [6] By 1980, 49 states had fully enacted a CON process.

The Development Act dispensed nearly $150 million in annual funding for health planning in its prime. [7] Yet, in 1987, a bipartisan federal government repealed CON, confirming that the program failed to resolve the issues it sought to resolve. This federal repeal caused many states to eliminate or modify their review programs. Unfortunately, West Virginia chose to continue their CON program.

2 Sec. 1122. [42 U.S.C. 1320a–1].
3 U.S. Congress, Office of Technology Assessment. (1984). *Federal Policies and the Medical Devices Industry*. Washington, D.C.: U.S. Government Printing Office. (pages 142-151).
4 Simpson, James B. "State Certificate-of-Need Programs: The Current Status." *American Journal of Public Health*, vol. 75, no. 10, 1985, pp. 1225–1229., https://doi.org/10.2105/ajph.75.10.1225.
5 Ibid.
6 Ibid.
7 Ibid.

Health Care and Free Market Exceptionalism

Proponents of CON argue that health care is atypical, segregating it from traditional free-market principles due to physician determination of services rendered rather than patient selection. Therefore, arguments for review processes say health care is incapable of treatment similar to conventional market service.

"Uncertainty and the Welfare Economics of Medical Care [8]," a study published in 1963, directly challenged the free market's relationship with health care. The study documented claims that medical care markets are fundamentally assured to fail to satisfy conditions where market equilibrium is socially suitable. [9] With this perception, the author of the study, Kenneth Arrow, determined an issue of moral hazard for doctors and patients. [10]

The paper sustains the belief that the unguaranteeable receipt of health insurance is evidence that health care is not, and cannot be, a marketable commodity. [11] Thus, preventing free markets from attaining the ability to ensure health care is accessible to all. [12] However, in a critique of Arrow, an Austrian doctor, and researcher, Gilbert Berdine, MD, illuminates the inaccuracy of this claim, asserting that Arrow conflates insurance with a subsidy. [13]

To make his point, Berdine affirms that illness is unpredictable. We cannot predict when we will become sick or require care as modest as a bandage. Though unpredictability does not preclude the market from providing dozens of unique Band-Aids that can fit our needs, no matter the size or location of the cut, scrape, or blister at all times. [14] For this reason, it is excessive to assume the free market cannot function in health care due to uncertainty. On the contrary, markets work for uncertainty.

Arrow also argues that patients lack a significant understanding of health care, otherwise known as information asymmetry. [15] His simple claim implies that patients face an inherent disadvantage that presents exploitation in health care. Arrow's solution is third-party payment insurance sponsored by the government. [16] Yet, this solution worsens the problems Arrow claims to resolve—creating more distance between patients and price.

8 Arrow, Kenneth J. "Uncertainty and the Welfare Economics of Medical Care." *Uncertainty in Economics*, vol. 53, no. 5, Dec. 1963, pp. 941–973., https://doi.org/10.1016/b978-0-12-214850-7.50028-0.
9 Ibid.
10 Ibid.
11 Ibid.
12 Ibid.
13 Berdine, Gilbert. "Uncertainty and the Welfare Economics of Medical Care: An Austrian Rebuttal: Part One." *The Southwest Respiratory and Critical Care Chronicles*, vol. 4, no. 16, 15 Oct. 2016, pp. 56–60., https://doi.org/10.12746/swrccc2016.0416.221.
14 Ibid.
15 Arrow, Kenneth J. "Uncertainty and the Welfare Economics of Medical Care." pp. 941–973.
16 Ibid.

Arrow's research is regularly recycled in health care discussions today, deciding that health care cannot manage through markets. Instead, making the case that government should continue to regulate health-related services. Many of these advocates proclaim Arrow's point is absolute: Government regulation of healthcare is necessary to bridge the gaps in information and price. Yet, empirical reviews of health care in the United States provide data that says otherwise.

When Kenneth Arrow's research was published in 1963, 90% of senior citizens could pay their total health care costs out of pocket. Yet, after adjusting subsidies through various Medicare, Medicaid, and Affordable Care Act programs, almost no one can afford health care in the United States fifty years later. [17]

Market Perceptions and Certificate of Need

Kenneth Arrow's study was published just before CON practices were implemented nationwide. It was certainly no coincidence that entities began to believe price competition deteriorated healthcare quality.

States adopted CON to control health care costs by limiting growth (hoping to prevent expensive monopolies) and maintaining the quality of care through the extensive review processes. In addition, by implementing application reviews, CON boards are expected to provide access assistance to rural areas, ensuring the geographic distribution of potential health care facilities.

Carmel Shachar, Director of the Health Law Policy Center at Harvard Law, said, "If we let plants grow everywhere, sometimes they grow in ways that are unhealthy. So, Certificate of Need programs could be used to distinguish between care that is needed versus the care that might have a good return for investors but does not necessarily serve the community's best interests. [18]"

Rather than witnessing a large variety of institutions continuously open in high trafficked areas, CON supporters hoped that denial of service applications would encourage providers to go elsewhere —to a location in "need," praying to protect rural healthcare. [19] Yet, these regulations have only limited supply and provide more authority to bureaucrats and competitors who wish to remain dominant in the areas they operate within.

17 Arrow, Kenneth J. “Uncertainty and the Welfare Economics of Medical Care.” pp. 941–973.
18 Peace, Lauren. “Here's How Certificate of Need Laws Fit into the Conversation about Access to Care.” *Mountain State Spotlight*, 5 Mar. 2021, https://mountainstatespotlight.org/2021/03/05/many-west-virginians-still-struggle-to-access-health-care-heres-how-certificate-of-need-laws-fit-into-the-conversation/.
19 Simpson, James B. “State Certificate-of-Need Programs: The Current Status.” pp. 1225–1229.

Certificate of Need Made Health Care Problems Worse

60% of the US population lives within a state that possesses CON regulations where there are 30% fewer hospitals per 100,000 residents. [20] The most frequently regulated services by CON requirements are nursing homes, psychiatric services, and hospitals. [21]

The Kaiser Family Foundation's most recent study found that states with CON laws in place have healthcare costs 11% higher than states without these policies. [22] Moreover, the Mercatus Center at George Mason University discovered a 5.5% higher mortality rate, [23] fewer hospital beds (131 fewer per 100,000), fewer MRI machines, and less access for CT scans. [24]

Hospital Compare, a database provided through Centers for Medicare and Medicaid Services (CMS), has allowed researchers to examine the healthcare markets in states with and without CON processes. Evidence has been statistically significant in exhibiting hospitals in non-CON states have lower mortality rates for pneumonia, heart failure, heart attacks, and surgical inpatients with treatable complications—controlled for unobservable factors such as culture and environment. [25]

The damaging impacts of CON have been well documented by the Federal Trade Commission (FTC) and the Department of Justice (DOJ). In a 2016 report, the two agreed that "it is apparent that CON laws can prevent the efficient functioning of health care markets." [26]

"By interfering with the market forces that normally determine the supply of facilities and services, CON laws can suppress supply, misallocate resources, and shield incumbent health care providers from competition from new entrants," they shared in a joint statement. [27]

The two cited the following chief issues with CON, high cost of entry and expansion due to added time, uncertainty, and fees, removal of competitive nature that incentivizes existing facilities to innovate, improve, and provide affordability, and outright prohibition to entry. [28]

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20 Mitchell, Matthew D., Anna Miller, and Elise Amez-Droz, "*Phasing Out Certificate-of-Need Laws: A Menu of Options*," Mercatus Center, Feb. 2020, https://mercatus.org/conlaws.
21 Mitchell, Matthew D., Anne Philpot, and Jessica McBirney, "*The State of Certificate-of-Need Laws in 2020*," Mercatus Center, Feb. 2021, https://mercatus.org/conlaws.
22 *"Health Care Expenditures per Capita by State of Residence."* KFF, 19 June 2017, https://www.kff.org/other/state-indicator/health-spending-per- capita/?currentTimeframe=0&sortModel=%7B%22colId%22%3A%22Location%22%2C%22sort%22%3A%22asc%22%7D.
23 Stratmann, Thomas, and David Wille. *"Certificate-of-Need Laws and Hospital Quality."* Mercatus Center, 22 Sept. 2020, www.mercatus.org/publications/corporate-welfare/certificate-need-laws-and-hospital-quality.
24 Koopman, Christopher, et al. *"Certificate-of-Need Laws: Implications for West Virginia."* Mercatus Center, 22 Sept. 2020, www.mercatus.org/publications/regulation/certificate-need-laws-implications-west-virginia.
25 Stratmann, Thomas, and David Wille. *"Certificate-of-Need Laws and Hospital Quality."*
27 U.S. FTC and DOJ. Joint Statement of the FTC and the Antitrust Division of the U.S. DOJ on Certificate-of-Need Laws and South Carolina House Bill 3250. January 2016, https://www.ftc.gov/system/files/documents/advocacy_documents/joint-statement-federal-trade-commission-antitrust-division-u.s.department-justice-certificate-need-laws-south-carolina-house-bill-3250/160111ftc-doj-sclaw.pdf.
28 Ibid.

Empirical evidence on health care competitiveness has shown that consumers continuously benefit from lower prices when providers are permitted to engage in a free market. [29]

The FTC and DOJ have recommended that states repeal their CON laws.

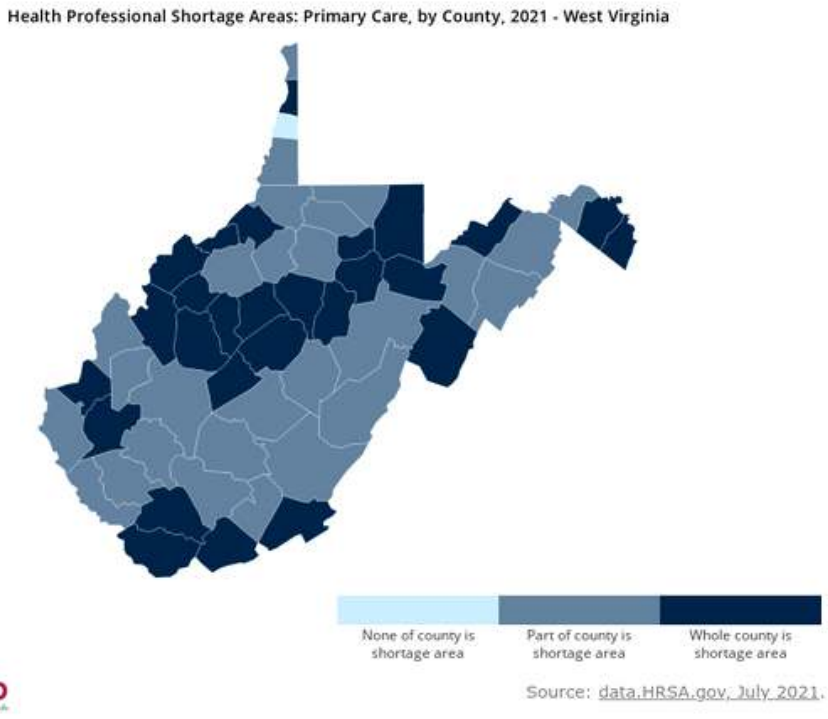
29 Gaynor, Martin & Robert J. Town, "Competition in Health Care Markets." *National Bureau of Economic Research*, 2011

CHAPTER TWO: WEST VIRGINIA'S HEALTH AND CON

Rural Health Care

For those who live within the Mountain State, it may be no surprise to hear of barriers to service for health needs. As a result, mountaineers must travel further distances to reach providers, face lengthier wait times, and pay more for care. [30] Unfortunately, obstructions worsen health complications in West Virginia, where we have the highest rate of obesity and the highest probability of suffering from a heart attack and coronary heart disease in the country. [31]

Today, 53 out of 55 counties in West Virginia face a health care shortage during national closure crises for rural hospitals. [32] In the face of such health failures, we must consider the effectiveness of standing regulations in healthcare.



30 Matthew C. Baker, Thomas Stratmann, "Barriers to entry in the healthcare markets: Winners and Losers from certificate-of-need laws," *Socio-Economic Planning Sciences*, Volume 77, 2021, 101007, ISSN 0038-0121, https://doi.org/10.1016/j.seps.2020.101007.
31 Ibid.
32 "Rural Health Information Hub." Map of Health Professional Shortage Areas: Primary Care, by County, 2021, 2021, https://www.ruralhealthinfo.org/charts/5?state=WV; Malcolm, Brock. "*Rural Hospital Closures Are on the Rise*." Bowles Rice, 25 Feb. 2n.d., https://www.bowlesrice.com/west-virginia-health-care-law-blog/rural-hospital-closures.

Rural CON proponents pursue the protection of the regulation, claiming that West Virginia is not like other states, citing the unique challenges and demographics of those who live in rural communities. Unfortunately, though, the existence of CON has guaranteed adverse health outcomes for West Virginia's rural scene.

Health Care Access for Rural Communities

Rural states seeking to protect CON believe that the parameter protects health services and community hospitals from competitors entering the market and consuming all available profits. Proponents welcome an undue fear that a flourishing market would generate devastating closures and reductions for rural health. These claims are misguided—this has never occurred in any other market.

States, including West Virginia, have used CON as a threat to ambulatory surgical centers (ASCs) in an attempt to clamp down on "hospital substitutes." [33] The objective behind such restrictions assumes that ASCs will enter the market to accept "profitable patients" who have more minor complications and are more likely to be insured. [34] Under this logic, CON proponents believe existing rural hospitals will be left for use only by uninsured, less profitable patients, envisioning CON necessary to protect incumbent hospital profits in rural communities. [35]

However, entry barriers due to CON have impacted the capability for nonhospitals and hospitals to compete and offer service variety, producing impairment for rural communities who desperately seek health care availability. [36] CON programs have effectively created fewer hospitals overall but significantly fewer rural hospitals, rural hospital substitutes, and rural hospice centers.

Research in 2016 from Thomas Stratmann and Christopher Koopman of the Mercatus Center tested this hypothesis: "Do CON programs protect hospitals from competition by regulating the entry and expansion of nonhospital providers? And do they protect access to rural care by controlling the entry and development of nonhospital providers?" [37]

33 Stratmann, Thomas, and Christopher Koopman. *"Entry Regulation and Rural Health Care."* Mercatus Center, Feb. 2016, www.mercatus.org/system/files/Stratmann-Rural-Health-Care-v1.pdf.
34 Ibid.
35 Ibid.
36 Ibid.
37 Ibid.

Their research inspected the number of community hospitals and ASCs per 100,000 people of state population from 1984 through 2011. [38] Stratmann and Koopman discovered a negative correlation in the number of rural hospitals per 100,000 and CON programs and a more substantial adverse effect on hospitals in rural areas than in the overall number of hospitals within the state. [39]

If CON laws were effective, as proponents claim, there would be more rural hospitals in the states that regulate ASC entry. [40] However, states without CON regulation have more community hospitals and more ASCs. This reality is in direct contradiction to claims that ASCs divert funding and threaten rural health providers. [41]

Certificate of Need Advocates Are Consistently Inconsistent

Cost of Care

CON laws have also been accredited as a cost-reducing regulation, making health care more affordable for those who live in states with the law. Yet, these regulations should remind us of basic economic fundamentals—supply restrictions lead to monopolistic behavior, limited access, and higher prices for consumers.

A Mercatus Center analysis of 19 peer-reviewed academic studies has revealed cost-reduction claims to be an illusion. Instead, CON is more commonly associated with higher per-unit costs and total expenditures. [42]

Quality of Care

Proponents of CON frequently assert the regulation preserves to high-quality care through the shelter of skilled care facilities.

In 2016, the Mercatus Center surveyed 23,152 hospitals in CON and non-CON states between the years 2011-2015. Their research established that nearly all quality measures were worse in CON states than in non-CON states. [43]

38 Stratmann, Thomas, and Christopher Koopman. *"Entry Regulation and Rural Health Care."*
39 Ibid.
40 Inid.
41 Malcolm, Brock. *"Rural Hospital Closures Are on the Rise."* Bowles Rice, 25 Feb. 2n.d., https://www.bowlesrice.com/west-virginia-health-care-law-blog/rural-hospital-closures.
42 Mitchaell, Matthew D. *"Do Certificate-of-Need Laws Limit Spending?"* Mercatus Center, 2016 Sept. https://www.mercatus.org/system/files/mercatus-mitchell-con-healthcare-spending-v1a.pdf.
43 Stratmann, Thomas, and David Wille. *"Certificate-of-Need Laws and Hospital Quality."*

Charity Care

Arguments for the protection of CON have assumed that through limited competition, incumbent healthcare providers earn more significant profits that are more likely to be used as a cross- subsidy to care for underserved patients. However, this claim fails to come to fruition, even in states that require charity care for CON providers, a free or discounted medically necessary health care service that hospitals offer to individuals who are unable to afford to pay. (West Virginia is one.)

The US Department of Health and Human Service released a joint report with the US Department of the Treasury and US Department of Labor in 2017 that showed safety-net hospitals are not financially stronger in CON states than non-CON states. [44] Further, they cited empirical evidence contradicting the impression that incumbents use market dominance to cross-subsidize charity care, finding a "complete lack of support" for the hypothesis. [45]

Stratmann and Russ were among the first to empirically test the relationship between CON and the likelihood of charity care. [46] They discovered that the effect of legislated charity care requirements has also failed to show an increase in charity care. [47]

Racial Disparities in Health

Literature reviews have historically publicized significant disparities in medical care access to racial and ethnic minorities across the country. Of the differences, limited access to cardio angiography for African Americans compared to white counterparts is most documented. [48]

In 1996, New Jersey sought to improve healthcare access, especially for underserved populations. The state legislature subsequently approved legislation to reform their CON process, no longer requiring hospitals to seek approval for diagnostic cardiac catheterization services within their facilities. [49]

A year after the reform was legislated, the number of licensed hospitals to provide cardiac angiography doubled. [50] More importantly, the disparity between African Americans and whites in New Jersey was eliminated for cardiac angiography. [51]

Many problems with health care accessibility fall back on CON.

44 "Reforming America's Healthcare System through Choice and ..." HHS.gov, 2017, www.hhs.gov/sites/default/files/Reforming-Americas-Healthcare-System-Through-Choice-and-Competition.pdf.
45 Ibid.
46 Stratmann, Thomas, and Jacob W. Russ. *"Do Certificate-of-Need Laws Increase Indigent Care?"* Mercatus Center, July 2014, www.mercatus.org/system/files/Stratmann-Certificate-Need.pdf.
47 Ibid.
48 DeLia, Derek, et al. "Effects of Regulation and Competition on Health Care Disparities: The Case of Cardiac Angiography in New Jersey." *Journal of Health Politics, Policy and Law,* vol. 34, no. 1, Duke University Press, 2009, pp. 63–91, https://doi.org/10.1215/03616878-2008-992.
49 Ibid.
50 Ibid.
51 Ibid.

Certificate of Need Regulations in West Virginia

West Virginia is among the most highly regulated CON states, chiefly compared to our Appalachian neighbors.

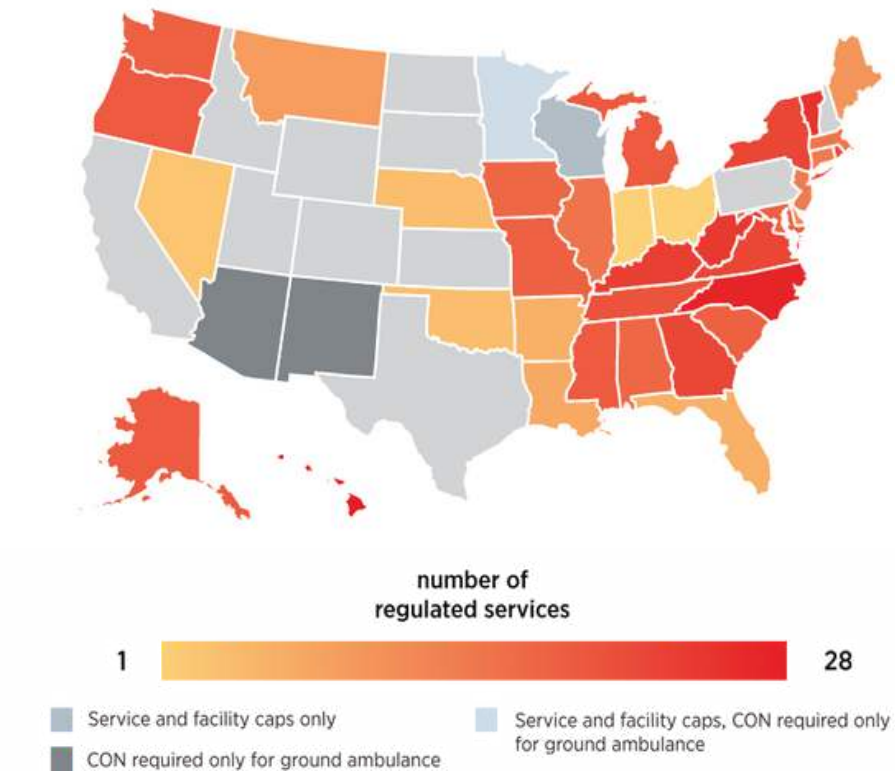


Table 1. Certificate-of-Need Laws in West Virginia and Surrounding States

STATE	NUMBER OF TECHNOLOGIES AND PROCEDURES REGULATED
West Virginia	24
Kentucky	23
Maryland	18
Ohio	1
Pennsylvania	0
Virginia	22
national average for CON-law states	15

Source: Matthew D. Mitchell, Anne Philpot, and Jessica McBirney, "The State of Certificate-of-Need Laws in 2020," Mercatus Center at George Mason University, February 19, 2021, https://www.mercatus.org/publications/healthcare/con-laws-2020-about-update.

The following facilities and services are currently regulated under our CON program: [52]

- Ambulatory surgical centers (ASCs)
- Cardiac catheterization
- Computed tomography (CT) scanners
- Home health
- Hospice
- Hospital beds
- Intermediate care facilities (ICFs) for individuals with intellectual disabilities
- Linear accelerator radiology
- Long-term acute care (LTAC)
- Magnetic-resonance imaging (MRI) scanners
- Mobile HI technology (CT/MRI/PET, etc.)
- Neonatal intensive care
- New hospitals or hospital-sized investments
- Nursing home beds/long-term care beds
- Obstetrics services
- Open-heart surgery
- Organ transplants
- Positron emission tomography (PET) scanners
- Psychiatric services
- Radiation therapy
- Rehabilitation
- Renal failure/dialysis
- Substance/drug abuse treatment
- Ultrasounds

CON solicitation is not straightforward; those who seek to provide care must follow strict guidelines outlined in State Code to make the case to start or expand their business.

Providers who desire to offer a CON-regulated service must first file a "Letter of Intent" 10 days before submitting their completed application to the West Virginia Health Care Authority (HCA) [53] The letter must contain "sufficient information to advise the Board of the nature, scope, cost and timing of the project, as well as the location and name of the proposed applicant." [54] It is habitually unclear what is considered "sufficient information."

52 W. Va. Code §16-2D-8.
53 W. Va. C.S.R. § 65-32-8.
54 Ibid.

Once a "Letter of Intent" is offered to the HCA, an application must be delivered. [55] Applications must be submitted with a fee based on expected capital expenditure. [56] (See below)

- Expenditures up to $1,500,000 a fee of $1,500
- Expenditures from $1,500,001 to $5,000,000 a fee of $5,000
- Expenditures from $5,000,001 to $25,000,000 a fee of $25,000
- Expenditures from $25,000,001 and above a fee of $35,000

W. Va. Code §16-2D-2(15) also stipulates a catch-all CON that requires expenditure minimums of $5,100,000 to obtain a CON. [57]

Once a CON application is formally submitted with appropriate supplements and fees, a CON may only be issued if the HCA determines the service is "found to be needed and consistent with the State Health Plan, unless there are emergency circumstances that pose a threat to public health." [58]

It is striking to notice that denied applications fail to specify the points for denial. (See below)

VIII. DECISION

The West Virginia Health Care Authority **DENIES** the application submitted by Appalachian Regional Healthcare, Inc. and ARH Tug Valley Services, Inc.

Certificate-of-Need Decision for Appalachian Regional Healthcare, Inc. (2015)

55 W. Va. C.S.R. § 65-32-8.
56 W.Va. Code § 16-2D-13(b)(2).
57 W. Va. Code §16-2D-2(15) states “Expenditure minimum” means the cost of acquisition, improvement, expansion of any facility, equipment, or services including the cost of any studies, surveys, designs, plans, working drawings, specifications, and other activities, including staff effort and consulting at and above $5 million.
58 W.Va. Code § 16-2D-12(a).

Another interesting suggestion of how "need" is determined by the HCA is through population projections prepared by the Regional Research Institute at West Virginia University. [59]

A unique feature of the CON process also allows for testimonies from witnesses during the CON application process through a formalized hearing held by the HCA Testimonies from current healthcare incumbents are welcomed with five minutes allotted to speak for or against the CON application.

Finally, if a provider is unsure if their service proposal is subject to CON laws, they must submit a "request for a determination of reviewability" to the HCA with a $100 fee for a determination. [60]

Those services and providers exempt from the CON review must submit an exemption application, where the HCA determines if the exemption is valid, accompanied by a $1,000 filing fee. [61]

59 The Regional Population Projection Models from West Virginia University (2020) states “projections are not predictions of what will actually happen but are hypothetical exercises that arithmetically establish the numerical impacts of assumptions made regarding expected patterns of fertility, mortality, and migration. The consequences that the projections identify are conditional on the assumptions being fulfilled.” https://researchrepository.wvu.edu/cgi/viewcontent.cgi?article=1014&context=rri-web-book.; West Virginia Health Care Authority. Frequently Asked Questions, hca.wv.gov/certificateofneed/Pages/FAQ.aspx.
60 W. Va. Code § 16-2D-7.
61 W.Va. C.S.R. § 65-29-1.

CHAPTER THREE: "OWN IT ALL"

The continuation of CON exterminates free-market competition within the healthcare industry, artificially picking winners and losers. The nature of the review requires anticipative providers to obtain authorization without clear, objective criteria throughout the approval process and allows competitors to comment on applications, effectively creating health cartels that fail to address care needs across the Mountain State.

Social Costs of Restricted Markets

For better or worse, government policy often influences market competition. CON laws tend to do the latter by discouraging new entrants from offering competition against incumbent hospitals.

Put simply, a monopoly occurs when a single seller of a product or service exists. Similarly, oligopolies occur when several sellers work together, so there is, functionally, only one seller.

The shared ownership of a market by a these select few encourages players to forgo competition with one another, raising profits. Each firm has the incentive to cheat by increasing supply, lowering prices, or both to gain more of a profit share. If there's no mechanism among the firms to punish the defector, the rational thing for everyone is to cheat.

These anticompetitive pacts illustrate that when an industry operates through personal market control, profits are artificially elevated through restricted outputs due to unnatural prices that rise above the competitive level. [62]

Oligopolies effectively remove a free market in which competition provides a fair price and ensures a variety of goods and services.

62 Posner, Richard A. 1975. "The Social Costs of Monopoly and Regulation," *Journal of Political Economy*, vol 83(4), pages 807-827.

Anticompetitive Health Care

West Virginia is among the most highly regulated CON states, chiefly compared to our Appalachian neighbors.

WVU Medicine

In 2019, WVU Medicine and The Health Plan, a managed care insurance organization based in Wheeling, announced they would combine health care services, maintaining managed care and insurance options previously offered by The Health Plan. [63] The firms reported that they would become a "fully integrated healthcare delivery and financing system for the people of West Virginia," aiming to improve care quality, reduce cost, and focus on the health outcomes of Mountaineers through wellness. [64]

Shortly after, Charleston Area Medical Center (CAMC) informed The Health Plan that they would terminate their contract at the end of the year due to the partnership with WVU Medicine. This decision immediately threatened the accessibility of health care for parties who received care coverage through the Public Employees Insurance Agency (PEIA). [65]

Upon the notification, President of The Health Plan, Jim Pennington, shared that CAMC informed him that the contract was terminated due to the new attachment to WVU Medicine, who CAMC deemed as a "northern aggressor." [66]

In conversations with press across the state, CAMC stated that WVU Medicine had frequently opposed collaborative agreements, publicly suggesting that West Virginia should have one health care system: WVU Medicine. [67]

WVU Medicine presently owns nine hospitals in Morgantown, Martinsburg, Gassaway, Parkersburg, Ranson, Keyser, Glen Dale, Buckhannon, and Bridgeport, not including those that WVU Medicine manages or their special facilities for critical care, cancer, heart and vascular health, and neurosciences.

63 Post, David Beard/The Dominion, et al. "WVU Medicine Joining with the Health Plan to Integrate Health Care and Financing." *WV MetroNews*, 7 May 2019, wvmetronews.com/2019/05/07/wvu-medicine-joining-with-the-health-plan-to-integrate-health-care-and-financing/.
64 Ibid.
65 Jenkins, Jeff, et al. "WVU Medicine Deal Leads to Provider Contract Cancellation at CAMC." *WV MetroNews*, 30 Sept. 2019, wvmetronews.com/2019/09/30/wvu-medicine-deal-leads-to-provider-contract-cancellation-at-camc/.
66 Ibid.
67 Ibid.

Eight months after the merger announcement, the deal between WVU Medicine and The Health Plan was terminated. [68] However, soon after, CAMC and The Health Plan renewed their partnership. [69]

While the anticompetitive nature of WVU Medicine is alarming, it is far from unusual. CON artificially directs resources away from health care innovation and reallocates them to legal and lobbying efforts for operational challenges. [70] But, more importantly, CON inspires anticompetitive agreements that further create market domination and protect personal interests.

Court Challenges

United States v. Charleston Area Med. Ctr., Inc. (2006)

In February of 2002, West Virginia modified state standards for opening a cardiac-surgery center [71] The new rule relaxed CON qualifications for cardiac-surgery by lowering the minimum number of medical procedures a hospital needed to show it had or would perform. [72] In addition, the standards were structured to assume the Health Care Authority (HCA) would approve a new cardiac-surgery program in the southern region of the state. [73]

Charleston Area Medical Center, Inc. (CAMC) operated the most extensive cardiac-surgery program in West Virginia. At the time, the cardiac program at CAMC was its most profitable program, contributing $20 million to the facility's net profits each year. [74]

CAMC sought to prevent Raleigh General Hospital (RGH) from opening a cardiac-surgery program once they learned that establishing such would reduce CAMC's net profits by nearly half [75] Upon this discovery, CAMC began to fight aggressively to prevent the new cardiac-surgery option. [76]

68 Adams, Steven Allen. “Failed Health Care Merger Highlights Issues with 'Certificate of Need' Laws.” *The Intelligencer*, 1 Jan. 2020, https://www.theintelligencer.net/news/top-headlines/2020/01/failed-health-care-merger-highlights-issues-with-certificate-of-need-laws/.
69 Ibid.
70 U.S. FTC and DOJ. Joint Statement of the FTC and the Antitrust Division of the U.S. DOJ on Certificate-of-Need Laws and South Carolina House Bill 3250. January 2016, https://www.ftc.gov/system/files/documents/advocacy_documents/joint-statement-federal-trade-commission-antitrust-division-u.s.department-justice-certificate-need-laws-south-carolina-house-bill-3250/160111ftc-doj-sclaw.pdf.
71 United States v. Charleston Area Med. Ctr., Inc., No. 2:06-0091 (S.D. W.Va. 2006).
72 Ibid.
73 Ibid.
74 Ibid.
75 Ibid.
76 Ibid.

A presentation from CAMC termed "Cardiovascular Network Project Executive Steering Group Meeting" shared that the market strategy for the Raleigh County area was to "focus efforts on obtaining open-heart CON for Bluefield/Princeton and averting CON for Raleigh General Hospital." [77] A second document, originating after the meeting, said that the goal of CAMC was to prevent and delay new open-heart surgical programs while maintaining the configuration to offer exclusive open-heart services. [78] CAMC went as far as to add, "If Parkersburg becomes inevitable, support Bluefield; absolutely not Beckley." [79]

In the case that establishment of cardiac services at RGH was inevitable, a CAMC executive stated, [if RGH] were granted a certificate of need, we would be down there—it's only an hour away—we would be down there advertising and facilitating and probably even putting physicians down there to ensure that those patients came to Charleston instead of going to Raleigh General." [80]

To remedy this concern, CAMC directly contacted the HCA. The HCA informed CAMC that they sought help to develop a cardiac-surgery program at St. Joseph's Hospital (SJH) in Parkersburg [81] Consequently, CAMC entered an ideal scenario—if they aided the HCA in developing cardiac surgery at SJH, the HCA would be more inclined to abide by a memorandum of understanding (MOU). [82]

Through consultations, an MOU between CAMC and the HCA was produced, encouraging the HCA to reject any CON application for a cardiac-surgery program at RGH if CAMC would support the programs developing at SJH. [83] The MOU prevented the HCA from permitting the development of a cardiac-surgery program at RGH. [84] The HCA entered a commitment only to approve cardiac programs at Princeton Community Hospital or Bluefield Regional Medical Center, facilities at least 100 miles away rather than RGH's 50-mile distance. [85]

Intriguingly, this was not the first time RGH hoped to offer services for the region. In 1992, the hospital applied for a cardiac surgery CON that was denied in 1995. [86] The HCA said the hospital was "unable to show it would perform the minimum number of procedures required by the then existing state standard for granting cardiac-surgery CONS." [87] (The point of contention revised in the 2002 CON modification.)

77 United States v. Charleston Area Med. Ctr., Inc., No. 2:06-0091 (S.D. W.Va. 2006).
78 Ibid.
79 Ibid.
80 Ibid.
81 Ibid.
82 Ibid.
83 Ibid.
84 Ibid.
85 Ibid.
86 Ibid.
87 Ibid.

In the face of bureaucratic defeat, RGH attempted to offer these services a second time in 1999 through a joint venture with Princeton Community Hospital. [88] Upon receiving a CON, the hospitals were instructed that based on "market, geographical location, physician support, and referral patterns and clinical infrastructure and culture, Raleigh General Hospital is the recommended location for the cardiovascular surgical program." [89] However, the stringent approval failed to provide the two hospitals with enough autonomy to finalize a strategy to pursue the intended venture jointly. [90]

In 2006 RGH filed suit and asserted that CAMC was incentivized through current health market regulation to convince the HCA to enter into an anticompetitive agreement, preventing competition from local hospitals.

The plaintiffs requested that the Court side in their favor due to anti-competitive violations of Section 1 of the Sherman Act, 15 USC 1 through the creation of the MOU. [91]

The Court's final judgement determined "CAMC is enjoined from, in any manner, directly or indirectly, entering into, continuing, maintaining, or enforcing any agreement with a healthcare facility that (1) allocates any cardiac-surgery service, market, territory, or customer; (2) prohibits or restricts such healthcare facility from applying for a certificate of need to offer, maintain, or expand cardiac-surgery services; or (3) otherwise prohibits or restricts such healthcare facility from providing cardiac surgery. [92]"

United States v. Bluefield Regional Medical Center, Inc. (2005)

In 1999, Bluefield Regional Medical Center (BRMC) filed a CON application to develop a cardiac-surgery program in Mercer County. [93] Upon the application review process, Princeton Community Hospital (PCH) and St. Luke's Hospital in Bluefield challenged BRMC's request for a CON because "it did not provide a role" for PCH and St. Luke in anticipation of providing cardiac-surgery services. [94]

88 United States v. Charleston Area Med. Ctr., Inc., No. 2:06-0091 (S.D. W.Va. 2006).
89 Ibid.
90 Ibid.
91 United States Code, 2019 Edition. Title 15 - COMMERCE AND TRADE. CHAPTER 1 - MONOPOLIES AND COMBINATIONS IN RESTRAINT OF TRADE. Sec. 1 - Trusts, etc., in restraint of trade illegal; penalty. ; United States v. Charleston Area Med. Ctr., Inc., No. 2:06-0091 (S.D. W.Va. 2006).
93 United States v. Bluefield Reg'l Med. Ctr., Inc., No. 1:05-0234 (S.D. W.Va. 2005).
94 Ibid.

The HCA denied BRMC's application because PCH and St. Luke "failed to successfully negotiate with [BRMC] to reach a shared goal. The goal being to provide advanced cardiology services to the citizens of southern West Virginia and southwestern Virginia… [The WVHCA] would have preferred that the parties work together to present a project that could have been approved under the existing law. Instead, the parties fought among themselves, failed to resolve their differences, and in return, the citizens of southern West Virginia will be inconvenienced and suffer by not having a regional open-heart service provider."

In 2002, representatives from BRMC and PCH began to meet with individuals from the HCA who advised the two organizations to arrive at an agreement that would provide each facility the ability to submit applications that the HCA would be able to approve. [95]

In 2003, PCH entered into an agreement, "Cancer and Open-Heart Agreements," with BRMC.

The agreement affirmed "(1) BRMC would not apply, finance, encourage or participate in a CON to provide cancer services independently or with any provider that was not PCH (2) BRMC would not develop, finance, encourage, participate in, or support the development of a cancer service even if the state no longer required CON (3) BRMC would not "engage in, support, finance, encourage, or participate in the recruitment of any physician cancer specialists to BRMC's medical staff (4) BRMC would provide PCH information relating to cancer services provided (5) BRMC would not market that they had a cancer center (6) BRMC would not provide outpatient chemotherapy (7) BRMC would not lease existing or future medical office buildings to cancer specialists (8) BRMC would not squire, develop, offer, or provide new technology or modality for treatment or diagnosis shall it become available." [96]

A similar agreement was made restricting PCH from entering the market for cardiac-surgery services. [97] The terms of the "Cancer and Open-Heart Agreements" launched on January 30, 2003 and would conclude five years after the first open-heart surgery was performed at BRMC or the first cancer patient received at a PCH comprehensive cancer center.

In July of 2003, PCH and BRMC offered joint applications to the HCA. [98] The application proposed the transfer of BRMC's existing CON for radiation-therapy equipment to PCH. The HCA also provided BRMC with a cardiac surgery CON. [99]

95 United States v. Bluefield Reg'l Med. Ctr., Inc., No. 1:05-0234 (S.D. W.Va. 2005).
96 Ibid.
97 Ibid.
98 Ibid.
99 Ibid.

The pact between the two parties ensured protections from prospective competition. [100]

In 2005, a violation was filed against PCH and BRMC in court. The complaint stated: "Pursuant to the Cancer and Open-Heart Agreements, Defendants have refrained and will likely continue to refrain from competing to serve patients that need cancer and cardiac-surgery services. The Cancer and Open-Heart Agreements have had and will likely have the following harmful effects: (1) Managed-care purchasers, their enrollees and employees, and other patients in southern West Virginia and western Virginia have been denied and will be denied the benefits of price competition between PCH and BRMC; (2) The quality of services has decreased and will likely decrease in the absence of competition between PCH and BRMC to provide cancer and cardiac-surgery services; (3) Patients have lost and will lose the ability to choose between PCH and BRMC when selecting a hospital to provide cancer services; (4) Patients have lost and will lose the benefit of potential competition between PCH and BRMC in cardiac-surgery services; and (4) PCHs and BRMC's incentives to innovate or offer new cancer and cardiac-surgery services have been and will be decreased."

Plaintiffs requested that the Court declare the agreement to violate Section 1 of the Sherman Act, 15 USC § 1 and order the defendants to be forbidden from entering into contracts that prohibit or restrict health care facilities from obtaining a CON relating to cancer services or cardiac surgery [101]

In its final judgement, the Court ruled that BRMC and PCH were "enjoined from enforcing all or any part of the Cancer and Open-Heart Agreements…enjoined from, in any manner, directly or indirectly, entering into, continuing, maintaining, or enforcing any agreement to allocate any cancer or cardiac-surgery service, market, territory, or customer… enjoined from, in any manner, directly or indirectly, entering into, continuing, maintaining, or enforcing any other agreement that (1) prohibits or restricts a healthcare facility from obtaining a certificate of need relating to cancer services or cardiac surgery or (2) otherwise prohibits or restricts a healthcare facility from taking actions related to providing cancer services or cardiac surgery without prior notice to and prior written approval of the United States, which will not be withheld unreasonably… enjoined from, in any manner, directly or indirectly, entering into, continuing, maintaining, or enforcing any agreement with each other concerning cancer services or cardiac surgery without prior notice to and prior written approval of the United States, which will not be withheld unreasonably." [102]

100 United States v. Bluefield Reg'l Med. Ctr., Inc., No. 1:05-0234 (S.D. W.Va. 2005).
101 United States Code, 2019 Edition. Title 15 - COMMERCE AND TRADE. CHAPTER 1 - MONOPOLIES AND COMBINATIONS IN RESTRAINT OF TRADE. Sec. 1 - Trusts, etc., in restraint of trade illegal; penalty.; United States v. Bluefield Reg'l Med. Ctr., Inc., No. 1:05-0234 (S.D. W.Va. 2005).
102 Ibid.

CHAPTER FOUR: A COMMUNITY LEFT BEHIND

In January of 2020, the Hunt Club Urgent Care facility was forced to close its doors after 28 years of providing a vital service to a rural community in West Virginia.

The Hunt Club clinic averaged 30 visits per day and was responsible for treating various ailments. Their facility was not accused of offering poor care or engaging in medical malpractice. Instead, the facility had been operating without a CON. Upon notification from UPMC Western Maryland, who acquired the facility, that Hunt Club would need to obtain a CON to continue operating, Hunt Club became the subject of months of hearings and appeals for the clinic to remain open. The HCA allowed WVU Medicine to challenge the need for the decade's old facility continuously.

As the months passed, Hunt Club withdrew their application rather than be continuously exposed to egregious filing fees and lengthy applications. [103]

In August of that year, the facility was reopened by UPMC Western Maryland. Upon acquisition through the CON process, UPMC modified the services offered. [104]

"Beginning July 1, 2021, walk-in and appointment-based primary care will begin operation at Hunt Club, and urgent care services will no longer be offered," the UPMC press release announced. [105]

103 Glass, Brandon. "WMHS to Temporarily Close Hunt Club Urgent Care Facility." *Cumberland Times News*, 23 Jan. 2020, https://www.times-news.com/news/local_news/wmhs-to-temporarily-close-hunt-club-urgent-care-facility/article_d4539bd7-6972-552d-aeff-b084724f2706.html.
104 Cumberland Times Staff. "Hunt Club Transitioning to Primary Care Facility." *Cumberland Times News*, 16 May 2021, www.times-news.com/news/business/hunt-club-transitioning-to-primary-care-facility/article_2ed2246a-b32f-11eb-9c2f-db625cd89cf6.html.
105 Ibid.

"The transition of our Hunt Club location to a primary care model that accepts walk-ins will be a better alternative for our patients in West Virginia," said President of UPMC Western Maryland, Michele Martz. [106] "Primary care is an identified need in that portion of our service area and will provide patients with continuity of care, along with comprehensive care that includes medication management, prevention, time savings, and behavioral health resources." [107]

The closest urgent care for those in Short Gap is now across state lines.

106 Cumberland Times Staff. "Hunt Club Transitioning to Primary Care Facility." Cumberland Times News, 16 May 2021, www.times-news.com/news/business/hunt-club-transitioning-to-primary-care-facility/article_2ed2246a-b32f-11eb-9c2f-db625cd89cf6.html.
107 Ibid.

CHAPTER FIVE: MENTAL HEALTH

West Virginia securely ranks among states with the highest proportion of people suffering from mental health problems, including concerns of depression, anxiety, and bipolar disorder. [108] In 2020, 19% of adults reported their mental health as "not good" for two weeks or more each month [109] The state maintains one of the nation's most significant death rates by despair. Amid a mental health calamity, hospitals in West Virginia are closing their doors.

For over 100 years, the Ohio Valley Medical Center was accessible to residents of Wheeling. In 2018, two years after a California-based company hoped to revitalize the facility, the Ohio Valley Medical Center closed. The closure resulted in one less emergency room available within 5 miles from downtown Wheeling. The facility was one of the largest inpatient psychiatric care in the Northern Panhandle. [110] The closest inpatient psychiatric care option is now 18 miles away—in Steubenville, Ohio.

Delays and Denials for Mental Health

Iowa has seen similar issues with mental health accessibility plague its state.

In 2017, Strategic Behavioral Health (SBH) applied for a CON in Iowa to build a 72-bed inpatient mental health facility. [111] Upon submission of SBH's application, two rival companies, Genesis Health System (GHS) and UnityPoint Health-Trinity (UPHT), vocally opposed the establishment of the facility to the Iowa CON Board. [112] The facilities joined in asserting that the new beds were not needed as there was an alleged existing plan to mitigate the shortages for mental health services in the region. [113] The efforts of GHS and UPHT delayed a decision for SBH's CON application for roughly two years. [114] In the meantime, residents of Iowa suffered.

108 2020 Adult Data." Mental Health America, https://mhanational.org/issues/2020/mental-health-america-adult-data.
109 Mulligan, Casey B. "Deaths of despair and the incidence of excess mortality in 2020." *National Bureau of Economic Research*. Working Paper 28303, 2020. https://www.nber.org/papers/w28303
110 Peace, Lauren. "When a W.va. Community Lost Its Mental Health Services, the Results Were a Matter of Life and Death." *Mountain State Spotlight*, 21 Oct. 2020, mountainstatespotlight.org/2020/10/15/this-place-helps-us-stay-alive-when-a-west-virginia-community-lost-its-mental-health-services-the-results-were-a-matter-of-life-and-death/.
111 Flatten, Mark. *"Con Job: Certificate of Need Laws Used to Delay, Deny Expansion of Mental Health Options."* Goldwater Institute, 28 Feb. 2020, goldwaterinstitute.org/article/con-job-certificate-of-need-laws-used-to-delay-deny-expansion-of-mental-health-options/.
112 Ibid.
113 Ibid.
114 Ibid.

JARED'S STORY
from the Goldwater Institute

Jared was violent and dangerous.

But he was not a criminal.

He was sick.

Not the kind of sick that can be treated in a hospital emergency room. His was a mental illness. And because of that, there was no place to take him for the crisis care he needed.

Jared (not his real name) was big and strong; in his early 20s, autistic, and intellectually challenged with an IQ of 54. He lived with his mother, who struggled to deal with a full-grown man who had the mind of a troubled child.

Then one day, for no apparent reason, Jared assaulted her.

Police were called. Jared was arrested.

That's when his nightmare began.

He was taken in front of Richard Vander Mey, a magistrate judge in Tama County, Iowa. It was clear from the start that the man was not criminally responsible for what he had done, Vander Mey said in an interview with the Goldwater Institute. He needed treatment, not punishment.

Frantic calls went out from county officials trying to find an inpatient mental health facility that would take Jared. None was available. Not in the entire state of Iowa.

That left Vander Mey in a bind. He knew he could not release Jared, who would have no place to go except back home with his mother. If that happened, there was a high risk he would harm himself or attack his mother again, perhaps causing serious injury.

To buy time, Vander Mey encouraged police to file criminal charges so Jared could be held safely in jail as the search for the coveted bed in a mental health hospital could continue.

The search went on for days. Not a single bed could be found.

JARED'S STORY
from the Goldwater Institute

Jared's case soon reached a county district court judge, who ordered the criminal charges dropped and that he get appropriate mental health treatment.

Still, there were no mental health beds available in the state.

Finally, Libby Reekers, the county's mental health advocate, told Vander Mey that he would either have to find someplace that would take Jared or let him go. Together, they devised a plan to send him to the medical hospital at the University of Iowa, 75 miles away, which also had a psychiatric unit. Once he was in the hospital's emergency room, the facility would have no choice but to admit Jared for psychiatric treatment, they reasoned.

They were wrong. Hospital officials said there was no room in its mental health unit, and Jared would not be admitted.

A standoff ensued. The hospital refused to admit Jared, and the judge refused to take him back into custody.

Days continued to pass as county officials and hospital staff called psychiatric hospitals and mental health wards across Iowa begging them to take Jared. Because he was not getting the mental health treatment he needed, he remained dangerous and volatile. The only way to protect his safety and that of others was to shackle him to a hospital bed and station a sheriff's deputy in his room all day, every day.

"He sat in the Tama County jail for five days—five days for this kid with mental retardation and autism, sitting in a jail because there was not one hospital bed available," Vander Mey said in recounting the story last year during a hearing to assess whether a new inpatient mental health hospital would be allowed in eastern Iowa. "That young man sat in the emergency room at the University of Iowa hospital for three days and three nights chained to a bed in the emergency room because there was not a psychiatric hospital in the state that was willing to take him."

Eventually, Vander Mey and Reekers enlisted the aid of state legislators to pressure the state mental hospital to admit Jared into its psychiatric ward. The strong-arming worked, and, after more than a week locked in jail or chained to a hospital bed, he finally began receiving the treatment he needed.

JARED'S STORY
from the Goldwater Institute

"What we are doing now to the mentally ill, to the mentally impaired people, the people who are the most vulnerable and the least able to protect themselves, what we are doing to them is criminal," Vander Mey said. "It is criminal. We as a state ought to be ashamed of ourselves."

Jared's case is not unusual. It was one of a litany of horror stories described by a parade of witnesses who testified last year about the dire shortage of inpatient mental health facilities in the area of eastern Iowa around Davenport.

Emergency room doctors, social workers, and mental health advocates described deranged and dangerous patients being forced to sit untreated in hospital emergency rooms for hours, days, and sometimes more than a week because there were no psychiatric hospital beds available in the entire state.

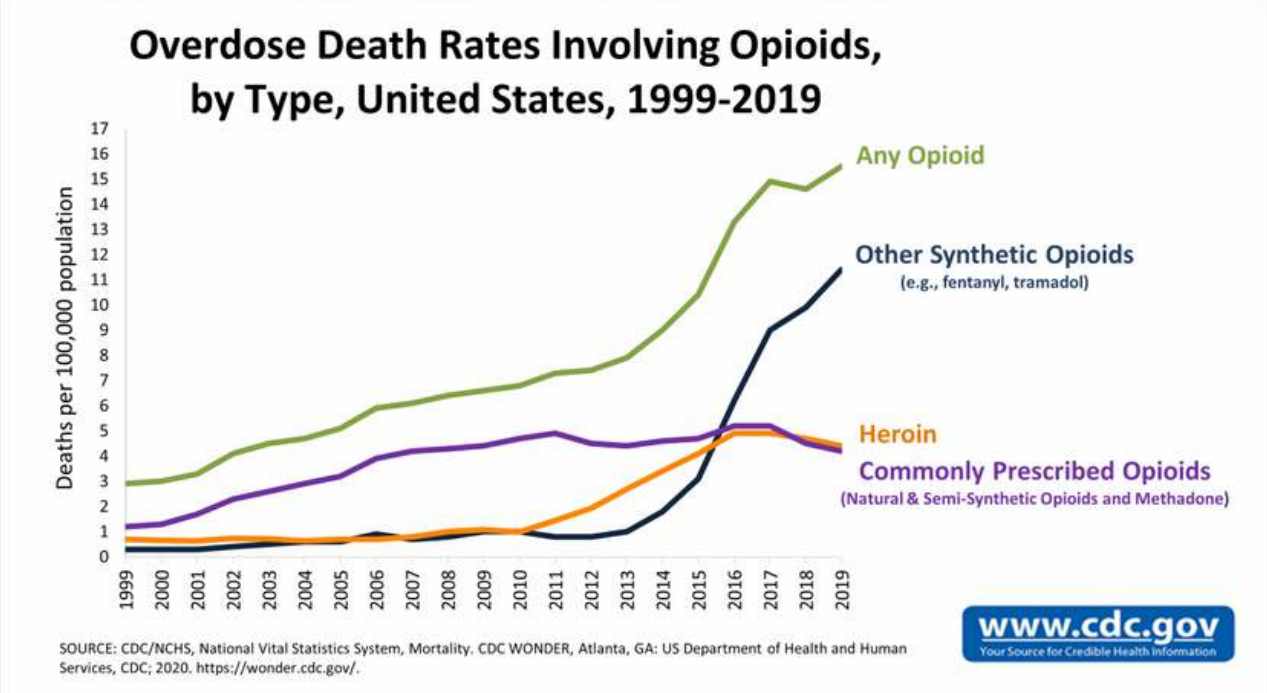
Sheriffs described having their deputies crisscrossing the state, routinely driving four and five hours or more, to deliver inmates in psychological crises to far-flung mental health facilities that had a single open inpatient bed available. They talked about having to assign deputies to sit with patients for days at a time in emergency room corridors or hospital cubicles because no psychiatric hospital would accept those having mental health emergencies.

Yet the existing providers of mental health services in the area insisted there was no crisis, that there were plenty of psychiatric beds, and that if there was a problem, they were the ones to fix it.

CHAPTER SIX: OPIOID TREATMENT

The opioid epidemic has permeated into every hill and valley of the Mountain State. Over the last decade, the rate of deaths and illnesses due to opioids has risen across the country. Sadly, West Virginia has unfailingly upheld the highest overdose rate in the nation.

In 2015, the state reported an average of 41.5 deaths per 100,000 individuals from addiction. [115] Between 2015 and 2016, there was a 20% increase in overdose occurences, making it the sixth leading cause of death in West Virginia. [116]



115 *"2016 West Virginia Overdose Fatality Analysis."* WVDHHR, 2016, dhhr.wv.gov/bph/Documents/ODCP%20Reports%202017/2016%20West%20Virginia%20Overdose%20Fatality%20Analysis_004302018.pdf.
116 Ibid.

Given the overdose rates, drug treatment in West Virginia should be among our top priorities. Yet, West Virginias CON protectionism has continued to fail our most vulnerable populations. National studies have shown that less than half of those who need addiction treatment receive it. [117]

Shortcomings in West Virginia State Code

According to W. Va. Code § 16-2D-11(b)(8), there is a concerning quantity of remaining statutory basis for prohibiting new opioid treatment programs and facilities. Effective June 10, 2016, the legislature enacted a moratorium on certificate of need regarding the licensure of new opioid treatment programs which do not have a certificate of need as of the effective date. [118] Said differently, no new opioid treatment centers may be established unless they had acquired a certificate of need before June 10, 2016, until the legislature determines otherwise. [119]

Additionally, in 2018, W. Va. Code § 16-2D-9 states that relevant authorities may NOT issue an opioid treatment program certificate of need. Similarly, in 2020, an exemption from the certificate of need process was created for alcohol or drug treatment facilities and drug and alcohol treatment services—unless the establishment is an opioid treatment facility. W. Va. Code § 16-2D-11(b)(24) (citing W. Va. Code, § 16-2D-9(4)).

In light of these statutes, it appears there is statutory basis for the prohibition of new treatment facilities. As a result of these statutory provisions, West Virginia is currently perpetuating the fallacious policy of CON

Certificate of Need Denial

Beckley Area Medical Clinic: Office-Based Medication-Assisted Treatment

In 2017, Beckley Area Medical Clinic (BAMC) applied for a CON exemption for an Office-Based Medication Assisted Treatment (OBMAT) program.

OBMAT programs are outpatient treatment services clinicians provide to individuals with opioid use disorder (OUD). OBMAT facilities typically involve opportunities to meet with a physician, prescribe buprenorphine or naltrexone, [120] and receive medical or psychosocial interventions to assist in OUD recovery, [121] a cumulation of methods that have been shown to increase a patient's ability to retain treatment and reduce the likelihood of relapse.

117 Vestal, Christine. *"Waiting Lists Grow for Medicine to Fight Opioid Addiction."* The Pew Charitable Trusts, 2016, www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2016/02/11/waiting-lists-grow-for-medicine-to-fight-opioid-addiction.
118 W. Va. Code § 16-5Y-12.
119 Ibid.
120 The US Food and Drug Administration (FDA) has found that the most effective treatments for OUD are methadone, buprenorphine, and naltrexone.
121 WVDHHR. *"Office-Based Medication-Assisted Treatment FAQs."* WVDHHR Office of Health Facility Licensure & Certification.

When BAMC filed for an exemption from CON requirements, they were a standing practice that provided treatment for OUD patients with buprenorphine prescriptions. However, the passage of new legislation stipulated a new prerequisite for OBMAT facilities—they had to obtain a CON [122] irrespective of previous operational services. Accordingly, BAMC filed their exemption with a $1,000 filing fee to the HCA:

> *"Beckley Area Medical Clinic is an existing practice. We have been treating patients by prescribing buprenorphine products for substance abuse. Since the passing of the above-mentioned bill (W. Va. Code $16-2d -11 (c) (21) and 516-2d-11 (c) (26), we are now required to register with the state of WV as an OBMAT facility and as a part of the application process are to require an exemption from the Certificate of Need. I feel that as we are not making any significant chances regarding our capital expenditure as we will not incur a substantial change to the currently provided health care services, I feel that an exemption is justified."*

On April 18, 2017, BAMC received a notice from the HCA. The message rejected BAMC's request to keep their OBMAT facility open, citing failure to "address behavioral services that would be provided" and "written designation from the CEO" that the application was valid.

IV. DECISION

Accordingly, it is ***ORDERED*** that the proposal by Beckley Area Medical Clinic, Inc. for the development of an Office Based Medication Assisted Treatment (OBMAT) program and behavioral health services ***IS DENIED***.

Certificate-of-Need Decision for Beckley Area Medical Clinic, Inc. (2017)

When this was published, BAMC still had a closed OBMAT facility.

Currently, no clinics in the Beckley region offer OUD treatment with buprenorphine, further constraining options for West Virginia's OUD patients.

122 W. Va. Code $16-2d -11 (c) (21) and 516-2d-11 (c) (26).

CHAPTER SEVEN: COVID-19

In 2020, existing healthcare shortages and access issues were worsened in the face of the coronavirus (COVID-19) pandemic. Many hospitals became, and are still, overwhelmed with COVID-19 case—hospitals are continuously running short on beds.

Desperate times call for desperate measures.

In Washington state, a local hospital did not have an intensive care unit (ICU) available to patients [123] As a result, in response to surges for care, the facility began to transfer patients to other hospitals—some patients as far away as eastern Idaho, 600 miles away. [124] Remarkably, Idaho does not have CON; Washington does.

Early COVID-19 Acceleration in Certificate of Need States

At the time of writing this paper, nearly 46 million cases and 754,000 deaths had been reported due to the COVID-19 pandemic.

At the beginning of 2020, COVID-19 began to sweep through the nation, disproportionately impacting communities of color and immunocompromised/high-risk populations. [125] Over the year, researchers began to study correlations between the rates of infection and variables such as state protocols, incidents of COVID-19 generally, and the like.

Cyrus M. Kosar, MA, and Momotazur Rahman, Ph.D., pursued answers to one of these questions: Is there an association between county average nursing home bed size and presence of CON laws, which influence nursing home sizes, with county-level COVID-19 prevalence over time? [126]

123 The Associated Press. "Many Hospitals with No Beds Left Are Forced to Send Covid Patients to Cities Far Away." *NPR*, 19 Aug. 2021, https://www.npr.org/2021/08/19/1029378744/hospital-beds-shortage-covid-coronavirus-states.
124 Ibid.
125 Kosar, Cyrus M., and Momotazur Rahman. *"Early Acceleration of Covid-19 in Areas with Larger Nursing Homes and Certificate of Need Laws."* Journal of General Internal Medicine, vol. 36, no. 4, 28 Jan. 2021, pp. 990–997., https://doi.org/10.1007/s11606-020-06518-2.
126 Ibid.

The pair hypothesized that "A nursing home's size is perceptibly connected to local population density. However, federal and state policies are potential contributing factors. For example, in some states, Medicaid reimbursement and staffing levels are tied to bed size thresholds. Under federal law, nursing homes with 121 or more beds must staff a licensed social worker full-time. Certificate of Need (CON) laws, another state-level policy, also indirectly impact nursing home size through placing a ceiling on the supply of nursing home beds."

Their study examined, specifically, the association between the average nursing home bed sizes with COVID-19 prevalence from March 11, 2020, through June 12, 2020.[127]

Through an analysis of 2,883 counties across the country, Kosar and Rahman discovered that counties with larger nursing homes had (1) more residents, (2) were more densely populated, (3) more likely to be metropolitan, and (4) located in the South or Northeast.

Figure 1 (shown below) demonstrates the relationship between the size of nursing homes and CON laws.

Figure 1

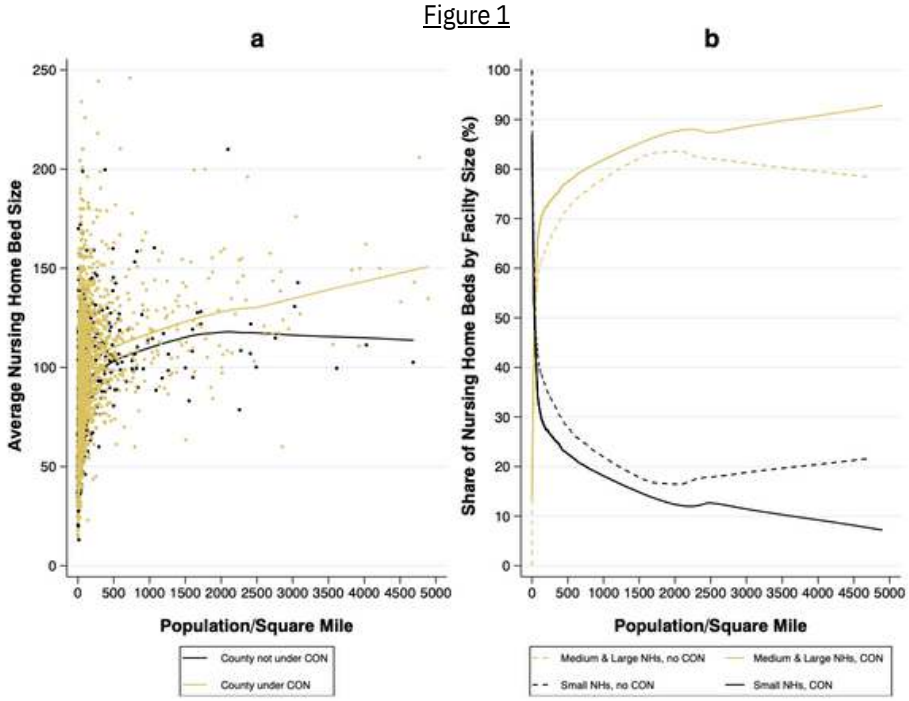


Figure 1 Nursing home size in counties located in states with and without certificate of need laws. (a) Average nursing home size. (b) Proportion of beds in small, medium, and large nursing homes. Notes: NH= Nursing home; CON= certificate of need law. Small nursing homes are defined as those with less than 90 beds. Large nursing homes are defined as those with greater than 120 beds. Trend lines were estimated via locally weighted scatterplot smoothing (local linear regression). To improve visual clarity, 11 counties with population densities greater than 5,000 were excluded from the plot.

127 Journal of General Internal Medicine, vol. 36, no. 4, 28 Jan. 2021, pp. 990–997., https://doi.org/10.1007/s11606-020-06518-2.

Table A shows the average nursing home size difference between counties located in states with and without CON laws. [128] Table B shows the proportion of all nursing home beds that are in medium and large (≥ 90 bed) versus small (< 90 bed) facilities for counties with and without CON (based on population density level). [129]

This data revealed that the size of nursing homes was generally more prominent in CON affected counties, and the proportion of all nursing home beds located in medium and large facilities was more significant in CON affected counties. [130] The proportion of nursing home beds in small facilities was higher in non-CON regions. [131]

"A between-county difference in average nursing home size equal to 1 bed was associated with 3.92 additional [COVID-19] cases… on average, and counties subject to CON laws had 104.53 additional [COVID-19] cases… on average," they stated. [132]

The study noticed that the average size of nursing homes was more significant in states with CON, and these states had a greater frequency of COVID-19 cases (shown in Figure 2 below). [133] This finding also indicated an important role in nursing home infections being accelerants for community infection rates. [134]

128 Kosar, Cyrus M., and Momotazur Rahman. "Early Acceleration of Covid-19 in Areas with Larger Nursing Homes and Certificate of Need Laws." *Journal of General Internal Medicine*, vol. 36, no. 4, 28 Jan. 2021, pp. 990–997., https://doi.org/10.1007/s11606-020-06518-2.
129 Ibid.
130 Ibid.
131 Ibid.
132 Ibid.
133 Ibid.
134 Ibid.

Figure 2

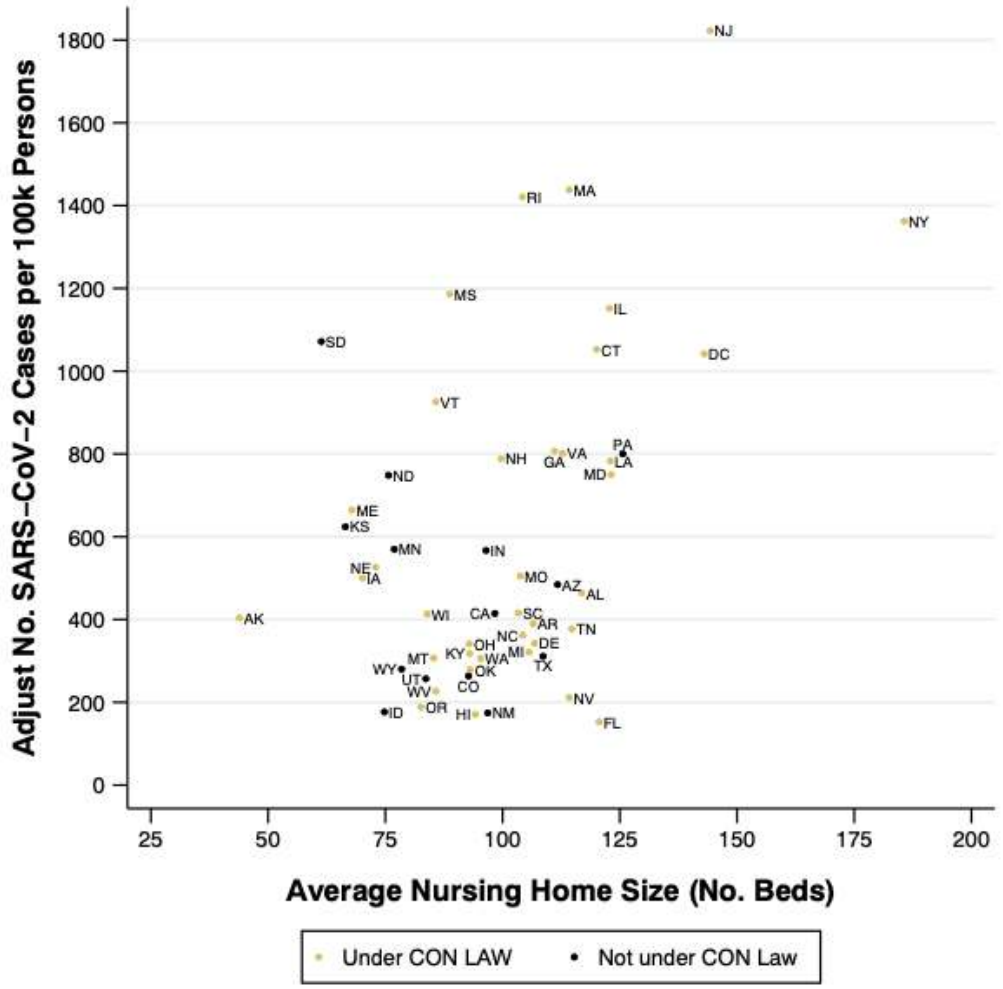


Figure 2 State-level adjusted SARS-CoV-2 prevalence on June 12 by average nursing home size and certificate of need law presence. Notes: SARS-CoV-2, severe acute respiratory syndrome coronavirus 2; No., number of; CON, certificate of need law. Prevalence estimates were derived from a Poisson regression model including robust standard errors. The set of covariates were population size, population density (persons per square land mile), metropolitan versus rural county status, census region, % of residents aged 65 and over, % female, % Black, % college educated, median household income, the poverty rate, nursing home bed supply, bed supply of small-, medium-, and large-sized hospitals, number of home health agencies, number of medical doctors, number of housing units, and date of the first SARS-CoV-2 case.

At the conclusion of the study, Kosar and Rahman found a "one bed between-county difference in average nursing home size was associated with nearly four additional [COVID-19] cases." [135] States that are subject to CON laws had roughly 104 more [COVID-19] cases than those not subject to CON with an association between the average size of nursing homes and [COVID-19] related mortality. [136]

135 Early Acceleration of Covid-19 in Areas with Larger Nursing Homes and Certificate of Need Lawsstates that "A; Kosar, Cyrus M., and Momotazur Rahman. "Early Acceleration of Covid-19 in Areas with Larger Nursing Homes and Certificate of Need Laws." *Journal of General Internal Medicine*, vol. 36, no. 4, 28 Jan. 2021, pp. 990–997., https://doi.org/10.1007/s11606-020-06518-2.
136 Ibid.

"Consistent with prior reports, we show that the size of nursing homes depends in part on long-term care policies, and particularly CON laws. New York State, for instance, has a CON law, and its nursing homes are over 1.5 times the size of those in California, a non-CON state with comparable population density. CON laws for nursing homes have been in place for several decades in 37 states and were initially established to limit state Medicaid spending on long-term care by placing a cap on the supply of nursing home beds. However, high nursing home capital costs combined with bed supply ceilings has led to fewer nursing home operators and larger facilities in states with CON." [137]

A deadly combination in the face of COVID-19.

137 Kosar, Cyrus M., and Momotazur Rahman. "Early Acceleration of Covid-19 in Areas with Larger Nursing Homes and Certificate of Need Laws." *Journal of General Internal Medicine*, vol. 36, no. 4, 28 Jan. 2021, pp. 990–997., https://doi.org/10.1007/s11606-020-06518-2.

CHAPTER EIGHT: THE END IS IN SIGHT

The evidence is abundantly clear there is no justification for the continuation of CON.

West Virginians would greatly benefit from the elimination of this egregious health market regulation. Yet, self-interested bureaucrats maintain willful ignorance and force Mountaineers to make do in an environment motivated by large profits that protect a prejudicial status quo. West Virginia cannot stifle investment by keeping regulatory shackles on industries that have a real ability to grow and thrive in our state.

Government-instituted hurdles create an inefficient market that cannot familiarize with innovations in healthcare. Conversations centered on support for CON are habitually about insurance and profits instead of need, care, or quality of health. West Virginia is 36 years behind the nation.

It's time to catch up and provide the health services that Mountaineers not only need but deserve.

Reform Options

Full Repeal

Full CON repeal would increase the access to affordable, high-quality health care. After the federal government's CON repeal in the 1980s, many states repealed their CON laws too. Arkansas and Colorado had previously adopted a provision that committed the states to repeal the regulation in the case that the federal mandate was eliminated. [138]

138 Mitchell, Matthew D., et al. *"Phasing out Certificate-of-Need Laws: A Menu of Options."*

Pennsylvania

In 1992, Pennsylvania modified statutes that permitted a sunset clause, allowing the CON system to automatically cease in four years. [139] In 1996, the state eliminated CON. Yet, special interests have worked to yield power through licensing provisions. [140]

New Hampshire

New Hampshire passed a sunset provision in 2012 that fully repealed its CON law in 2015. [141]

Phased Repeals Across the U.S.

Florida

Florida's CON program, like West Virginia's, is administered by the Agency for Health Care Administration (AHCA). [142] The AHCA has issued CONs based on the determination of need in a geographic region, known as the "fixed need pool." [143] The program in Florida applied to facilities such as hospitals, nursing homes, and intermediate care services. In 2019, the AHCA had "only approved 16 of the 32 CON applications submitted from 2014 to 2018." [144]

Florida enacted a phased repeal of some CON restrictions just ahead of the pandemic. [145] In July 2019, HB 21 was approved, repealing CON program requirements for (1) general hospitals, (2) comprehensive rehabilitation, and (3) "tertiary" health services. [146] Yet, the bill also had provisions for further repeals. In July 2021 the following specialty services were also exempt from CON requirements (1) Class II hospitals, including children's and women's hospitals, (2) Class III hospitals, including specialty medical, rehabilitation, and psychiatric and substance abuse hospitals, and (3) Class IV hospitals, which are specialty hospitals restricted to offering Intensive Residential Treatment Facility Services for Children. [147] Therefore, those seeking to establish pone of these facilities in Florida will no longer need to demonstrate a need for a geographical region. [148] This also means that existing providers will not be permitted to interfere with the ability of a new provider to open business. [149]

Florida became the fifth state with a partial CON program, requiring review only for nursing homes and hospice centers. [150]

139 Mitchell, Matthew D., et al. *"Phasing out Certificate-of-Need Laws: A Menu of Options."*
140 Ibid.
141 Ibid.
142 Davis, Gary Scott, et al. "Florida Repeals Significant Portions of Certificate of Need Law." *The National Law Review,* 1 July 2019, www.natlawreview.com/article/florida-repeals-significant-portions-certificate-need-law.
143 Ibid.
144 Ibid.
145 Ibid.
146 Ibid.
147 Ibid.
148 Ibid.
149 Ibid.
150 Ibid.

Tennessee

Tennessee enacted Public Chapter 557 which codified the Health Services and Planning Act of 2021. [151] Effective October 2021, Tennessee's legislation made the following changes to CON approvals:

- A CON will not be granted unless three modified criteria are met:
  - the action proposed must be necessary to provide needed healthcare in the area to be served, the applicant must provide healthcare services that meet appropriate quality standards, and
  - "the effects attributed to competition or duplication [must] be positive for the consumers." [152] (The law previously required four criteria: need, orderly development, economic feasibility, and adequate quality.) [153]
- A CON is not required for mental health hospitals and other psychiatric services. [154]
- A nursing home does not need a CON if it increases its total number of licensed beds by the lesser of 10 beds or 10% of its licensed capacity. [155]
- A provider seeking to reopen a closed hospital in a rural or distressed county may do so without applying for CON if the hospital operated within the previous 15 years. [156]
- A CON is not required "for any action that would otherwise require a CON in counties having no actively licensed hospital that are designated as "distressed eligible" by the state Department of Economic and Community Development as of January 1, 2021." [157]
- The Health Authority head may provide an exemption from CON to relocate a facility if:
  - "at least 75% of the patients to be served are reasonably, expected to reside in the same zip codes as the facility's existing patient base," [158] and
  - relocation would not reduce access to consumers. [159]
- "Use It or Lose It" language that makes an issued CON void "if the actions it authorizes have not been performed for a continuous period of one year after its implementation." [160]
- A CON is not required to establish limited-purpose agencies such as:
  - "a home health agency to provide services under the federal Energy Employees Occupational Illness Compensation Program Act of 2000 (EEOICPA)" [161]
  - "a home care organization or residential hospice to provide hospice services to patients under the care of a healthcare research institution." [162]

151 Brent, Michael D, et al. "Tennessee Makes Major Changes to CON Law." *The National Law Review*, 21 June 2021, www.natlawreview.com/article/tennessee-makes-major-changes-to-con-law.
152 Ibid.
153 Ibid.
154 Ibid.
155 Ibid.
156 Ibid.
157 Ibid.
158 Ibid.
159 Ibid.
160 Ibid.
161 Ibid.
162 Ibid.

- A CON is not required for hospital-operated nonresidential substitution-based treatment centers. [163]
- A CON is not required for PET and MRI services in "urban counties" including Davidson, Hamilton, Knox, Rutherford, Shelby, and Williamson. [164]
- A CON is not required to replace or relocate medical equipment. [165]

There were also procedural changes to streamline the CON approval process. [166]

Montana

Montana CON previously required a minimum six-month review process and a fee of $500 or .03% of the project's capital expenditures, whichever is greater, to receive a CON. [167] Yet, with the passage of HB 231, October 2021 marked significant changes to their CON program. Montana now only requires a CON for long-term care facilities and swing beds. [168]

West Virginia

West Virginia has also had successes with scaling back CON laws in recent years. In 2017, legislators eliminated CON for telehealth, remedial care, ambulatory health facilities, and imaging services. [169]

A Final Note

In a state where 53 out of 55 counties experience health care shortages, we must recognize that CON laws leave states unprepared.

West Virginia has the opportunity to set the way with forward-thinking policies that put Mountaineers first. Ending CON laws is another step to make this happen by allowing the free, open market to bring competition to health care.

163 Brent, Michael D, et al. "Tennessee Makes Major Changes to CON Law." *The National Law Review*, 21 June 2021, www.natlawreview.com/article/tennessee-makes-major-changes-to-con-law.
164 Ibid.
165 Ibid.
166 Ibid.
167 *"Certificate of Need Program."* Office of Inspector General Montana, 2021, dphhs.mt.gov/qad/Licensure/HealthCareFacilityLicensure/CertificateofNeed/#688807855-how-does-the-process-work.
168 Ibid.
169 Mitchell, Matthew D., et al. *"Phasing out Certificate-of-Need Laws: A Menu of Options."*