

May 12, 2025

Antitrust Division U.S. DEPARTMENT OF JUSTICE 950 Pennsylvania Avenue NW Washington DC 20530

## Submitted via Federal Portal at www.regulations.gov

Re: Executive Order 14219 or Ensuring Lawful Governance and Implementing the President's "Department of Government Efficiency" Deregulatory Initiative

To Whom It May Concern:

The Cardinal Institute for West Virginia Policy appreciates the opportunity to provide comment in response to Executive Order 14219, *Ensuring Lawful Governance and Implementing the President's "Department of Government Efficiency" Deregulatory Initiative*. The Order's commitment to restoring constitutional governance and curbing unnecessary and overreaching regulation aligns with our mission to promote limited government and economic freedom.

Founded in 2014, the Cardinal Institute is a 501(c)(3) non-profit organization dedicated to researching, developing, and communicating effective free-market public policies for West Virginia. We envision a "West Virginia Miracle"—a transformational era of prosperity for the Mountain State—built upon the foundational pillars of economic freedom, education freedom, worker freedom, and a culture of liberty rooted in the state's motto: *Montani Semper Liberi* ("Mountaineers Are Always Free").

As part of our ongoing efforts to promote effective governance and remove barriers to innovation and entrepreneurship, we urge the Administration to include **Certificate of Need (CON) laws** in its deregulatory priorities under Section 2 of Executive Order 14219. While CON laws are now implemented at the state level, they were first justified and enforced by federal standards and funding mechanisms that have allowed for their continuation. These laws stand in direct contradiction to the spirit of Executive Order 14219—hindering innovation, restricting access to care, stifling small business entry, and protecting entrenched interests at the expense of patients and entrepreneurs.

In West Virginia, CON laws have long acted as a regulatory bottleneck in the health care sector, artificially limiting the supply of services and infrastructure under the guise of planning. In practice, these laws:

- Impose significant costs on private parties with little or no public benefit (EO 14219, Section 2(a)(v));
- Impede **technological and infrastructure development**, particularly in rural and underserved areas (Section 2(a)(vi));
- Create **barriers to entry** that disproportionately impact small providers and innovators (Section 2(a)(vii)).

We believe the federal government can—and should—take a stronger role in encouraging states to **repeal CON programs**, particularly where federal funding or administrative alignment is used to support or enforce them. The Centers for Medicare & Medicaid Services (CMS), the Department of Health and Human Services (HHS), and other relevant federal agencies should consider CON-related policies as part of their regulatory review obligations under this order. The Department of Justice (DOJ) could also play a critical role, issuing updated antitrust guidelines and pursuing proper enforcement actions against anticompetitive practices, providing further pressure from the federal government to drive needed reform.

Moreover, in alignment with Section 3 of EO 14219, agencies should de-prioritize any enforcement mechanisms or funding incentives that indirectly support these outdated and harmful state-level regulations.

The Cardinal Institute supports this Administration's effort to restore lawful governance and reduce regulatory overreach. To that end, we strongly recommend that federal agencies incorporate the repeal and disincentivizing of Certificate of Need laws into their deregulatory frameworks and coordination efforts with the states. By doing so, the federal government can help restore healthcare competition, improve patient access, and spur innovation—especially in states like West Virginia that have long borne the costs of overregulation.

We thank the Administration for its leadership on this issue and look forward to continued engagement in support of a freer, more prosperous America.

Sincerely,

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# Public Comment from the Cardinal Institute for West Virginia Policy Regarding Executive Order 14219: Ensuring Lawful Governance and Implementing the President's "Department of Government Efficiency" Deregulatory Initiative

## May 12, 2025

## I. Introduction

West Virginia suffers from some of the worst health outcomes in the nation.<sup>1</sup> With high rates of obesity, heart diseases, and chronic illness, the quality and accessibility of healthcare continues to be a rampant issue. These circumstances are compounded by limited access to health services, worsened by the state's maintenance of outdated, unproven Certificate of Need (CON) laws, even as neighboring states, and the federal government, have moved away from them.

Accordingly, West Virginians are prevented from accessing the care they need. CON laws block efforts for expansion and improvement, a barrier echoed across 35 states. This issue becomes more impactful on the national scale, accounting for the payer mix of West Virginia residents, nearly 50% of whom are on federal insurance programs.<sup>2</sup>

On behalf of the Cardinal Institute for West Virginia Policy, I submit this comment to highlight how the continued prevalence of CON undermines national goals of affordable, accessible care and healthier Americans. While federal mandates were removed, some states continue enforcement of CON, a disproven regulation, leading to higher costs, fewer providers, and rural neglect. Such circumstance demands federal action to dismantle systemic obstacles to a healthier people.

## II. Background

Originally enacted to improve rural healthcare and control Medicare and Medicaid costs, CON laws create significant obstacles. CON requires new and existing providers to receive approval from a state agency before a variety of services or facilities may open. The roots of CON laws trace back to 1964, when proponents claimed these laws would control healthcare costs and prevent overbuilding of healthcare facilities, ensuring access to quality care. By the early 1970s, the federal government incentivized CON laws by tying Medicaid and Medicare funding to their adoption.<sup>3</sup> The 1974 National Health Planning and Resources Development Act further supported CON with continued federal funding.<sup>4</sup>

 <sup>&</sup>lt;sup>1</sup> HealthChoice of Michigan. "West Virginia's Health Care Is the Worst in the Nation." *HealthChoice of Michigan*, 8 Dec. 2024, <u>www.healthchoiceofmichigan.com/industry/(b)/west-virginias-health-care-is-the-worst-in-the-nation</u>.
<sup>2</sup> Kaiser Family Foundation. "West Virginia." *Election 2024: State Health Care Snapshots*, 30 Sept. 2024, www.kff.org/statedata/election-state-fact-sheets/west-virginia/.

<sup>&</sup>lt;sup>3</sup> Dobrinsky, Jessica. *Convicting CON: DeCONstruction*. Cardinal Institute for West Virginia Policy, 2024, https://cardinalinstitute.com/wp-content/uploads/FINAL-CON-Paper-Rewrite\_v6.pdf.

<sup>&</sup>lt;sup>4</sup> United States, Congress. *National Health Planning and Resources Development Act of 1974*. S.2994, 93rd Cong., 2nd sess., 1974. Congress.gov, <u>https://www.congress.gov/bill/93rd-congress/senate-bill/2994</u>.

At the time, hospitals were reimbursed by Medicare on a retrospective "cost plus" basis.<sup>5</sup> In lay terms, hospitals were reimbursed for whatever they spent, incentivizing overspending. As such, there were slim incentives in place to control costs over the course of patient's care. Congress soon recognized the flaws in this system and passed legislation, including the Social Security Amendments Act of 1983 (P.L. 98-21), which fulfilled a prospective cost reimbursement scheme to Medicare that then incentivized hospitals to control costs when providing care.<sup>6</sup>

At its peak, 49 states had some form of CON regulation. By 1987, Congress recognized that the promise of CON laws—namely, reducing costs and improving access—had not been realized and withdrew the federal requirement.<sup>7</sup> This left the decision to maintain the regulation up to the states. Moreover, the Federal Trade Commission and Department of Justice have, since the Reagan Administration, recommended states repeal CON.<sup>8</sup> Yet, states like West Virginia continue to argue that CON protects resources.

State-based policy research allows us to compare quality, cost, and access between CON and non-CON states. These studies confirm what West Virginians experience everyday—CON doesn't work. Because state health policy contributes to the national healthcare market, CON laws inflate federal spending and limit care options for vulnerable patients.

#### III. Economics of Certificate of Need

The imposition of CON laws causes a shift in supply. More precisely, CON laws decrease the supply of healthcare. The result: higher prices and fewer services consumed by individuals in affected areas.

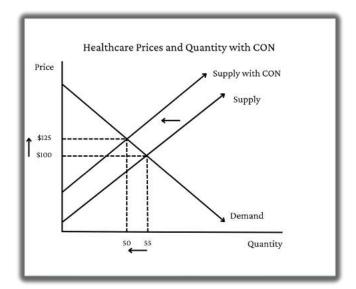
<sup>&</sup>lt;sup>5</sup> Guterman, Stuart, and Allen Dobson. "Impact of the Medicare Prospective Payment System for Hospitals." *Health Care Financing Review*, vol. 7, no. 3, Spring 1986, pp. 97–114. PubMed Central, https://pmc.ncbi.nlm.nih.gov/articles/PMC4191526/.

<sup>&</sup>lt;sup>6</sup> United States, Social Security Administration. "Compilation of the Social Security Laws. *Title 42—The Public Health and Welfare, Chapter 7—Social Security Act.*" Social Security Administration,. https://www.ssa.gov/OP Home/comp2/F098-021.html.

<sup>&</sup>lt;sup>7</sup> Dobrinsky, Jessica. *Convicting CON: DeCONstruction*. Cardinal Institute for West Virginia Policy, 2024, https://cardinalinstitute.com/wp-content/uploads/FINAL-CON-Paper-Rewrite v6.pdf.

<sup>&</sup>lt;sup>8</sup> Federal Trade Commission and U.S. Department of Justice. Improving Health Care: A Dose of Competition. Ch. 8, p. 2, 2004, <u>https://www.ftc.gov/reports/improving-health-care-dose-competition-report-federal-trade-commission-department-justice</u>; Federal Trade Commission and Antitrust Division, U.S. Department of Justice. Joint Statement

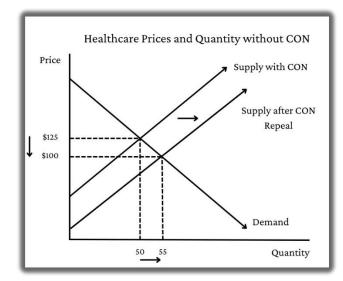
to the Virginia Certificate of Public Need Work Group. 26 Oct. 2015, <u>https://www.ftc.gov/policy/policy-actions/advocacy-filings/2015/10/joint-statement-federal-trade-commission-antitrust;</u> Antitrust Division, U.S. Department of Justice, and Federal Trade Commission. Joint Statement Before the Illinois Task Force on Health Planning Reform. 15 Sept. 2008, <u>http://www.justice.gov/atr/competition-health-care-and-certificates-need-joint-statement-antitrust-division-us-department;</u> Federal Trade Commission. FTC Staff Comment Before the Virginia Commission on Medical Care Facilities, Certificate of Public Need, Concerning Reform of Certificate of Public Need Regulation or Health Facilities. 6 Aug. 1987, <u>https://www.ftc.gov/policy/policy-actions/advocacy-filings/1987/08/ftc-staff-comment-virginia-commission-medical-care</u>.



## Figure 1: Market Effects of Certificate of Need (CON) Regulations on Healthcare Prices and Quantities

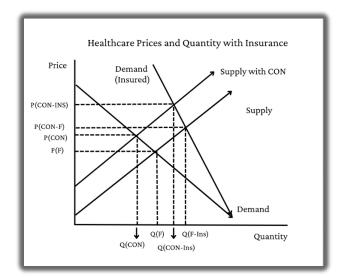
Figure 1 demonstrates the impact of CON. These laws decrease the total supply of healthcare services available, result in higher prices for healthcare services, and decrease the quantity of services consumed by individuals living in areas subject to these laws.

Conversely, the Figure 2 demonstrates the broad market effect of removing the supply restrictions imposed by CON laws. In this instance, removing CON results in an increase in the total supply of healthcare services available, lowers prices of those services, and increases the quantities of services consumed by individuals living in areas without CON laws. In a state like West Virginia, with a high number of services currently constrained by these regulations, this graph highlights how eliminating CON will lead to a greater number of healthcare providers and more affordable services.





With the inclusion of health insurance in the equation, supply restrictions enforced by CON regulations produce similar effects, as seen in Figure 3. Regardless of whether an individual is insured or not, CON laws remain restrictive on the supply of healthcare services available to consumers in the market. While the effects may be blunted for those with coverage, CON laws still clearly limit the healthcare market, reducing the availability and affordability of health services.



## Figure 3: Persistent Supply Constraints Under CON Regulations, With or Without Health Insurance

## IV. Analysis

Overwhelming evidence shows that CON laws harm patients. For instance, studies have shown states without CON laws have a greater number of hospitals per capita, better access to

medical technologies such as MRI and CT scans, and lower mortality rates for common conditions like heart attacks and pneumonia. The Mercatus Center at George Mason University found a 5.5% higher mortality rate<sup>9</sup> in CON states. Acute care hospitals in CON states face 10%<sup>10</sup> higher variable costs, likely due to the restricted ability to expand or improve services. Hospitals charges tend to fall by 5.5%<sup>11</sup> after a state's repeal of CON, demonstrating the downward pressure on prices when competition is increased.

Further, CON states experience increased Medicaid costs for home health services,<sup>12</sup> due to the limited availability of care providers. Out of 52 empirical studies, 44%<sup>13</sup> link CON to increased overall spending. Hospital expenditures per capita are 20.6%<sup>14</sup> greater in CON states, and nursing home CONs are linked to higher expenditures per resident.<sup>15</sup>

When looking at access, 190 studies<sup>16</sup> have evaluated CON's effect. Over half—52%— linked CON to reduced access. Only 10% associated it with improved access.

Proponents also argue that these laws protect quality by limiting expansion to only the best providers. Yet, hospitals in non-CON states outperform those in CON states in key quality metrics such as mortality rates for heart attack, heart failure,<sup>17</sup> and pneumonia.<sup>18</sup> In fact, West Virginia's own CON application process does not assess provider or facility quality. Mortality rates for pneumonia and heart failure are estimated to be 1.7 to 3.2% higher<sup>19</sup> in CON states. Hospitals in CON states average six more deaths per 1,000 surgical discharges with

<sup>&</sup>lt;sup>9</sup> Stratmann, Thomas, and David Wille. "*Certificate-of-Need Laws and Hospital Quality*." Mercatus Center, 22 Sept. 2020, <u>www.mercatus.org/publications/corporate-welfare/certificate-need-laws-and-hospital-quality</u>.

<sup>&</sup>lt;sup>10</sup> Anderson, K. B. "*Regulation, Market Structure, and Hospital Costs: Comment.*" Southern Economic Journal, vol. 58, no. 2, 1991, pp. 528-534.

<sup>&</sup>lt;sup>11</sup> Bailey, J. "Can Health Spending Be Reined In through Supply Constraints? An Evaluation of Certificate-of-Need Laws." Mercatus Center at George Mason University, 2016, <u>www.mercatus.org/publications/certificate-need/canhealth-spending-be-reined-through-supply-constraints-evaluation</u>.

<sup>&</sup>lt;sup>12</sup> Custer, W., P. Ketscche, B. Sherman, et al. "*Report of Data Analyses to the Georgia Commission on the Efficacy of the CON Program.*" Georgia State University Andrew Young School of Policy Studies, Nov. 2006,

www.academia.edu/81395977/Report\_of\_Data\_Analyses\_to\_the\_Georgia\_Commission\_on\_the Efficacy\_of\_the\_C\_ON\_Program.

<sup>&</sup>lt;sup>13</sup> Mitchell, M. "Certificate of Need Laws in Health Care: A Comprehensive Review of the Literature." *Southern Economic Journal*, forthcoming.

<sup>&</sup>lt;sup>14</sup> Rivers, P. A., M. D. Fottler, and M. Z. Younis. "Does Certificate of Need Really Contain Hospital Costs in the United States?" *Health Education Journal*, vol. 66, no. 3, 2007, pp. 229-244.

<sup>&</sup>lt;sup>15</sup> Ettner, S. L., J. S. Zinn, H. Xu, et al. "Certificate of Need and the Cost of Competition in Home Healthcare Markets." *Home Health Care Services Quarterly*, vol. 39, no. 2, 2020, pp. 51-64.

<sup>&</sup>lt;sup>16</sup> Mitchell, M. D. "Certificate of Need Laws in Health Care: Past, Present, and Future." *INQUIRY: The Journal of Health Care Organization, Provision, and Financing*, vol. 61, 2024, <u>https://doi:10.1177/00469580241251937</u>.

<sup>&</sup>lt;sup>17</sup> Chiu, K. "The Impact of Certificate of Need Laws on Heart Attack Mortality: Evidence from County Borders." *Journal of Health Economics*, vol. 79, 2021, 102518, <u>https://doi.org/10.1016/j.jhealeco.2021.102518</u>.

<sup>&</sup>lt;sup>18</sup> Stratmann, T. "The Effects of Certificate-of-Need Laws on the Quality of Hospital Medical Services." *Journal of Risk and Financial Management*, vol. 15, no. 6, 2022, 272.

<sup>&</sup>lt;sup>19</sup> Stratmann, T. "The Effects of Certificate-of-Need Laws on the Quality of Hospital Medical Services." *Journal of Risk and Financial Management*, vol. 15, no. 6, 2022, 272.

complications.<sup>20</sup> Additional evidence links CON to increased mortality risks for conditions such as septicemia, diabetes, Alzheimer's, and COVID-19,<sup>21</sup> as well as increased physical force incidents in nursing homes.<sup>22</sup>

Overall, the existence of CON leaves patients with 30% to 48% fewer hospitals,<sup>23</sup> 30% fewer rural hospitals, 13% fewer rural ambulatory surgery centers,<sup>24</sup> 25% fewer open-heart surgery programs,<sup>25</sup> 20% fewer psychiatric care facilities,<sup>26</sup> fewer dialysis clinics and reduced capacity,<sup>27</sup> and fewer imaging devices.<sup>28</sup>

CON laws also empower incumbent healthcare providers, by enabling them to block competitors during the approval process. Between 2017 and 2020, nearly \$44 million in healthcare investment was withdrawn<sup>29</sup> in West Virginia following opposition from competing providers. This regulatory structure incentivized incumbents to underutilize their existing health services to block new entrants, preserving market dominance.<sup>30</sup>

Independent doctors struggle under CON, facing delays and systemic pressure to merge into larger systems. As a result, patients suffer the consequences of longer waits, higher costs, and fewer care options. Rather than fostering competition, CON laws foster monopolies that increase per-unit costs and inflate overall spending.

<sup>&</sup>lt;sup>20</sup> Stratmann, T. "The Effects of Certificate-of-Need Laws on the Quality of Hospital Medical Services." *Journal of Risk and Financial Management*, vol. 15, no. 6, 2022, 272.

<sup>&</sup>lt;sup>21</sup> Roy Choudhury, A., S. Ghosh, and A. Plemmons. "Certificate of Need Laws and Health Care Use During the COVID-19 Pandemic." *Journal of Risk and Financial Management*, vol. 15, no. 2, 2022, 76, https://doi.org/10.3390/irfm15020076

https://doi.org/10.3390/jrfm15020076. <sup>22</sup> Zinn, J. S. "Market Competition and the Quality of Nursing Home Care." *Journal of Health Politics, Policy and Law*, vol. 19, no. 3, 1994, pp. 555-582.

<sup>&</sup>lt;sup>23</sup> Stratmann, T., and C. Koopman. "Entry Regulation and Rural Health Care: Certificate-of-Need Laws, Ambulatory Surgical Centers, and Community." *Mercatus Center at George Mason University*, 2016, www.mercatus.org/research/working-papers/entry-regulation-and-rural-health-care-certificate-need-laws-ambulatory

<sup>&</sup>lt;sup>24</sup> Stratmann, T., and C. Koopman. "Entry Regulation and Rural Health Care: Certificate-of-Need Laws, Ambulatory Surgical Centers, and Community." *Mercatus Center at George Mason University*, 2016, www.mercatus.org/research/working-papers/entry-regulation-and-rural-health-care-certificate-need-laws-ambulatory.

<sup>&</sup>lt;sup>25</sup> Robinson, J. L., D. B. Nash, E. Moxey, and J. P. O'Connor. "Certificate of Need and the Quality of Cardiac Surgery." *American Journal of Medical Quality*, vol. 16, no. 5, 2001, pp. 155-160.

<sup>&</sup>lt;sup>26</sup> Bailey, J., and E. Lewin. "Certificate of Need and Inpatient Psychiatric Services." *Journal of Health Economics*, vol. 24, no. 4, 2021, pp. 117-124.

<sup>&</sup>lt;sup>27</sup> Ford, J. M., and D. L. Kaserman. "Certificate-of-Need Regulation and Entry: Evidence from the Dialysis Industry." *Southern Economic Journal*, vol. 59, no. 4, 1993, pp. 783-791.

<sup>&</sup>lt;sup>28</sup> Stratmann, T., and J. Russ. "Do Certificate-of-Need Laws Increase Indigent Care?" *Mercatus Center at George Mason University*, 2014, <u>www.mercatus.org/students/research/working-papers/do-certificate-need-laws-increase-indigent-care</u>.

<sup>&</sup>lt;sup>29</sup> Schmidt, Kevin, and Thomas Kimbrell. *Permission to Care: How West Virginia's Certificate of Need Laws Harm Patients and Stifle Health Care Innovation*. Americans for Prosperity Foundation, Sept. 2022,

https://americansforprosperity.org/wp-content/uploads/2022/09/AFPF\_WV\_PermissionToCare\_Final-4.pdf. <sup>30</sup> Mitchell, M. D. "Certificate of Need Laws in Health Care: Past, Present, and Future." *INQUIRY: The Journal of Health Care Organization, Provision, and Financing*, vol. 61, 2024, doi:10.1177/00469580241251937.

#### V. Rural Health

In West Virginia, CON delays force rural patients to travel long distances for care—a burden for those with urgent needs. The state already faces a severe provider shortage and high rates of chronic diseases.

Despite these challenges, CON laws persist under the guise of protecting rural healthcare services. Yet evidence shows that states without CON laws have more rural hospitals and ambulatory surgical centers (ASC). Research from the Cato Institute examined six states that repealed ASC CON laws between 1991 and 2019, observing a 44–47% increase in ASCs statewide, with a notable 92–112% increase in rural areas.<sup>31</sup> Several studies also highlight that CON laws contribute to longer wait times<sup>32</sup>, greater travel distances<sup>33</sup>, and increased reliance on out-of-state care<sup>34</sup>, all of which exacerbate challenges in accessing timely, life-saving healthcare.

The claim that CON protects rural healthcare is not supported by evidence.

## VI. West Virginia

The real-world application of CON programs has shown that they can—and often do—serve as tools for incumbent providers to suppress any competition, even at the expense of public health. A clear example of this is a case involving Charleston Area Medical Center (CAMC) and Raleigh General Hospital (RGH) in West Virginia, as documented in *United States v. Charleston Area Med. Ctr., Inc.* 

In 2002, West Virginia modified state standards for opening a cardiac-surgery center,<sup>35</sup> lowering the procedural threshold for hospitals to establish cardiac surgery programs. The changes were made to assume the state's Health Care Authority (HCA) would approve a new cardiac-surgery program in the southern region of the state, an underserved region. RGH, a hospital in southern West Virginia, saw this as an opportunity to bring life-saving cardiac services closer to the population it served.

Rather than welcome competition that could increase access and reduce travel burdens, CAMC—whose cardiac program was its most profitable service—launched an aggressive campaign to block the RGH application. Internal documents reveal a clear strategy: prevent or delay RGH from entering the market to protect CAMC's financial interests.

<sup>&</sup>lt;sup>31</sup> *Cato Institute*. "Certificate of Need and Ambulatory Surgical Centers." *Cato Regulation*, Fall 2024, www.cato.org/regulation/fall-2024/con-ambulatory-surgical-centers.

<sup>&</sup>lt;sup>32</sup> Myers, M., and K. Sheehan. "The Impact of Certificate of Need Laws on Emergency Department Wait Times." *Journal of Private Enterprise*, vol. 35, no. 1, 2020, pp. 59-75.

<sup>&</sup>lt;sup>33</sup> Carlson, M. D., E. H. Bradley, Q. Du, and R. S. Morrison. "Geographic Access to Hospice in the United States." *Journal of Palliative Medicine*, vol. 13, no. 11, 2010, pp. 1331-1338.

<sup>&</sup>lt;sup>34</sup> Baker, Matthew C., and Thomas Stratmann. "Barriers to Entry in the Healthcare Markets: Winners and Losers from Certificate-of-Need Laws." *Socio-Economic Planning Sciences*, vol. 77, 2021, <u>https://doi.org/10.1016/j.seps.2020.101007</u>.

<sup>&</sup>lt;sup>35</sup> United States v. Charleston Area Med. Ctr., Inc., No. 2:06-0091 (S.D. W.Va. 2006).

CAMC went as far as entering into a *memorandum of understanding* with the HCA, promising support for a more distant hospital's program in exchange for HCA's commitment to deny RGH's application. As a result, residents in the RGH service area were denied access to timely cardiac surgery within a reasonable distance because an established provider used CON laws as a weapon.

A similar pattern also emerged, in 2019, when WVU Medicine and The Health Plan (THP), a managed care insurance organization, announced their intent to merge.<sup>36</sup> The entities 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. However, CAMC moved to protect its market position, terminating its contract with THP, citing its new affiliation with WVU Medicine.<sup>37</sup>

This decision immediately threatened healthcare access for thousands of individuals, including public employees covered by the Public Employees Insurance Agency (PEIA). CAMC's leadership labeled WVU Medicine a "northern aggressor" and criticized its vision of a unified statewide healthcare system. Though the WVU and THP merger ultimately dissolved, the aftermath highlights how entrenched systems can leverage both CON laws and contractual threats to stifle competition, destabilize patient access, and maintain monopolistic control.

While WVU Medicine's rapid expansion raises important questions about market dominance, the broader issue remains that CON laws enable and incentivize this type of turf war.

Beyond large institutional conflicts, CON harms individual physicians who try to expand access and provide high-quality care. At the start of 2025, an independent ambulatory surgery center contacted the Cardinal Institute about their difficulty to open and operate in Huntington, West Virginia. The physician behind the project, a specialist in interventional pain management, sought to bring opioid-free pain treatment options to a region serving approximately 130,000 West Virginians.

Despite the clear public benefit of this facility, the CON process has been cumbersome. After submitting their CON application in September 2024, the physician incurred substantial legal and consulting fees and faced opposition from established providers. These entities contested the application, not based on quality of care or patient need, but to limit competition.

The process involved both pre-hearings and formal hearings, diverting critical time and resources away from patient care, a clear demonstration of how existing systems empower entrenched players to act as gatekeepers, using their status as "affected parties," permitted within

<sup>&</sup>lt;sup>36</sup> 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, <u>www.wvmetronews.com/2019/05/07/wvu-medicine-joining-with-the-health-plan-to-integrate-health-care-and-financing/</u>.

<sup>&</sup>lt;sup>37</sup> Jenkins, Jeff, et al. "WVU Medicine Deal Leads to Provider Contract Cancellation at CAMC." WV MetroNews, 30 Sept. 2019, <u>www.wvmetronews.com/2019/09/30/wvumedicine-deal-leads-to-provider-contract-cancellation-at-cancel.</u>

West Virginia State Code, to delay, challenge, or block new entrants regardless of community need or provider qualifications.

The physician who spearheaded this venture relocated to West Virginia over a decade ago with a commitment to improving care in a rural state. But, as they shared, the regulatory environment has made it difficult—if not punitive—for independent providers to bring much-needed services to patients. This is the disorder of healthcare in a state that upholds CON.

These three cases paint a troubling picture of CON in practice, in addition to the previously explained data on quality, access, and cost.

### VII. Recommendation

The Cardinal Institute for West Virginia Policy recommends that the federal government step in to correct the damage caused by decades of failed CON policies. Specifically, the federal government should tie Medicare and Medicaid funding to state-level reforms that increase provider supply and eliminate restrictive CON requirements. Non-CON states demonstrate superior outcomes in access and cost-effectiveness, providing a proven blueprint for reform.

Additionally, CMS should commission a comprehensive federal study comparing CON versus non-CON states. This study could build on prior critiques from the Federal Trade Commission and further guide federal health policy to better align with the principles of competition and care quality. For instance, the federal government has historically used Medicaid funding as leverage to encourage states to expand eligibility under the Affordable Care Act. These efforts have paired with the threat of a reduction in federal matching funds if states failed to comply. Similarly, past federal grants have been tied to the adoption of specific reform such as electronic health records (EHR) systems. Both instances exemplify that CMS had the authority—and precedent—to leverage federal funding to state-level policy changes. Reforming restrictive CON laws should be among these priorities.

To further incentivize states, the DOJ could leverage its legal authority, issuing updated antitrust guidelines and pursuing enforcement actions against anticompetitive practices enabled by CON regulations. Through collaboration with CMS funding incentives and reform, the DOJ could aid states in aligning their practices with federal goals of improving access and reducing the cost of healthcare.

These steps are critical. States alone struggle to challenge entrenched hospital systems that invest millions in lobbying to protect their facilities. Patients, meanwhile, continue to come in last place—waiting longer, traveling farther, and paying more for care. The federal government not only has the authority but also the responsibility to act. It must correct the unintended consequences of the CON laws it once promoted.

#### VIII. Conclusion

State CON laws, exemplified by West Virginia, raise costs, limit services, and worsen outcomes—creating a national healthcare challenge the federal government can no longer afford to ignore. Cardinal proposes decisive federal action: tie funding to reform, study the outcomes, and support a competitive, accessible healthcare system. Drawing from West Virginia's experience and strong empirical evidence, this comment presents a path to dismantle CON barriers and promote equitable, affordable care nationwide.