

PERMISSION TO CARE:

HOW CERTIFICATE OF NEED LAWS HARM PATIENTS
AND STIFLE HEALTH CARE INNOVATION

ABOUT AMERICANS FOR PROSPERITY FOUNDATION

Americans for Prosperity Foundation is a 501(c)(3) nonprofit organization committed to educating and training Americans to be courageous advocates for the ideas, principles, and policies of a free and open society.

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EXECUTIVE SUMMARY

In 1974, Congress mandated states establish certificate of need ("CON") laws to receive federal health care funds. These laws require health care providers to gain government approval before opening or expanding a facility, adding imaging devices and other medical technology, or offering new services. They were meant to keep down costs and ensure access to care. Congress later repealed the federal mandate in 1986 after CON laws proved ineffective; nevertheless, via path dependency and protectionism, CON programs persist in dozens of states across the country.¹

State governments typically dole out certificates of need according to a state health plan composed by a central planning authority. The plans attempt to project the state's need, according to the government planning committee, for regulated facilities and services such as hospital beds, nursing home beds, neonatal intensive care, and others. In many states, like South Carolina and Michigan, the planning committee is staffed in part by incumbent providers who have an interest in protecting their businesses from new competition. By design, these plans restrict the supply of health care services.

Americans for Prosperity Foundation ("AFPF") analyzed publicly available data in four states that maintain CON programs: Iowa, Michigan, South Carolina, and Virginia. AFPF's analysis includes data on applications for CON in each state over several years and case studies of specific applicants. The survey reveals CON boards block millions of dollars in investment and artificially limit the supply of health care services, leading to diminished quantity and quality of patient care.

Beyond the millions of dollars in denied CON applications, the true value of health care services forfeited in each state is much greater. This is because although health care entrepreneurs may aspire to offer some services in a state, they are unlikely to submit a CON application that they know will likely be denied.

While this effect is usually unseen, the data from Michigan provide a glimpse at this suppressed, latent supply of health care. In late 2019, the Michigan Department of Health and Human Services projected a need for nearly 3,000 additional nursing home beds, signaling to providers that CON applications would be seriously considered for approval. By January 2020, health care entrepreneurs submitted dozens of CON applications to build new nursing homes or add beds to existing nursing homes, estimated at over \$630 million in investment. The providers were confident they could fill these new beds.

But at the urging of incumbent providers, the CON Commission suddenly reduced the projected need for beds tenfold. As a result, approximately three-fourths of the applications were denied or withdrawn—despite the clear indication of need from market signals. If Michigan's initial (and artificial) cap of 3,000 was so quickly met, how many more beds are *actually* needed in the state? It is evident Michigan's CON process restricts patient's access to health care by precluding the provision of facilities and services, beyond just the CON applications the Commission disapproves.

In nearly every state with CON laws, competing care providers can intervene in the CON process. Competitors can oppose other providers' applications to offer similar services and even challenge the state's decisions in court, drawing out the CON process for extraordinary lengths of time. In two recently resolved cases in South Carolina, legal challenges to CON decisions delayed the openings of muchneeded hospitals in two counties by over a *decade*.

Matthew D. Mitchell, Certificate-of-Need Laws: Are They Achieving Their Goals?, MERCATUS CENTER AT GEORGE MASON UNIVERSITY, April 2017, https://www.mercatus.org/system/files/mitchell-con-qa-mop-mercatus-v2.pdf.

A quote from a 2018 South Carolina Supreme Court opinion on CON applications originally submitted in 2005 and mired in years of litigation illustrates the problem: "The parties have stressed to us the obvious point that it has been almost twelve years since DHEC made the determination an acute-care hospital was necessary in York County." Construction on the hospital in that case began in the spring of 2021, 16 years after the government identified a need.

Similarly, in Iowa, an established cancer center told the Iowa State Facilities Council that it would be "forced to close" if the Council approved a CON application for a radiation therapy program at another hospital.³ The council denied the application with one member offering justification, saying, "There was just too much controversy."⁴

The hospital resubmitted the application the following year and again the competitor protested, claiming "it would threaten the continued viability of the [existing cancer center]." This time, though, the application was approved after receiving support from the community. When the new radiation therapy center opened a few years later, the competing cancer center did not close its doors. Instead, it announced it was combining services with another provider and undergoing a \$2.2 million renovation "focused on the patient experience." Access to care and quality of care improved for those in the area needing radiation therapy, but Iowa's CON laws delayed it by a year, nearly preventing this positive outcome altogether.

But these delays and denials can have tragic consequences. In Virginia, the State Health Commissioner twice denied one hospital's applications for a neonatal intensive care unit ("NICU"). Virginia's Department of Certificate of Public Need ("DCOPN") recommended the hospital's applications be denied because NICU services were available at another hospital nearby. Months later, a pregnant mother and her baby were admitted in urgent need of NICU care but specialized transport to the other hospital was unavailable. Despite

doctors' best efforts, the baby was lost because they were denied the proper equipment to potentially save the child's life.

This is another way CON laws harm providers and patients. In Iowa, South Carolina, Virginia, and many other states with similar programs, CON laws pit providers against each other to fight for the government's favor while the people lose out on health care options that would otherwise be available.

Even without competitor opposition, the CON process can be prohibitive for potential providers. It can take months to years and be very costly. In Michigan and South Carolina (excluding the applications tied-up in litigation), the average time to decision for CON applications in AFPF's samples was approximately five months. In all four states, AFPF estimates the average fee per application to be in the thousands of dollars, not including exorbitant costs for the consultants or lawyers often necessary to complete the process. And for providers, who spend tens of thousands of dollars and months navigating red tape just to apply to introduce or expand services, there is no guarantee of approval.

This analysis of CON programs and their effects on providers and patients in these four states is just the tip of the iceberg. CON laws are on the books in 35 states and the District of Columbia. The harm they cause patients and providers is far greater than that covered in this survey.

States commonly cling to the same justification the federal government abandoned more than 30 years ago: CON laws keep down health care costs and ensure access to care. But recent scholarship conducted by the Mercatus Center showed states with CON laws are associated with higher health care costs, 6 lower quality care, 7 and less access8 to health care.

CON proponents often argue limiting competition with CON laws enables providers to afford to operate in rural areas and care for patients that cannot pay,⁹ but empirical research contradicts these claims as well. In <u>a 2017 letter</u> to the Commissioner of Georgia's Department of Community

^{2.} Amisub of S.C., Inc. v. S.C. Dep't of Health & Envtl. Control, 813 S.E.2d 719, 721 (S.C. 2018).

^{3.} Jeff Montgomery, Back to drawing board? State board votes 'no' on Mercy cancer center request, TELEGRAPH HERALD, Oct. 27, 2017, https://www.telegraphherald.com/news/tristate/article-688320b4-50ee-53f5-ac63-53e5ea5ec157.html.

^{4.} Id.

Bennet Goldstein, TH EXCLUSIVE: Health care providers join hands to launch new Integrated Cancer Center, TELEGRAPH HERALD, Sept. 27, 2020, https://www.telegraphherald.com/news/tri-state/article_142d309a-5f5c-5823-ab7e-aafb18887ba5.html.

^{6.} James Bailey, Can Health Spending Be Reined In through Supply Constraints? An Evaluation of Certificate-of-Need Laws, MERCATUS CENTER AT GEORGE MASON UNIVERSITY, July 2016, https://www.mercatus.org/publications/certificate-need/can-health-spending-be-reined-through-supply-constraints-evaluation.

Thomas Stratmann and David Wille, Certificate-of-Need Laws and Hospital Quality, MERCATUS CENTER AT GEORGE MASON UNIVERSITY, Sept. 2016, https://www.mercatus.org/system/files/mercatus-stratmann-wille-con-hospital-quality-v1.pdf.

^{8.} Thomas Stratmann and Christopher Koopman, Entry Regulation and Rural Health Care Certificate-of-Need Laws, Ambulatory Surgical Centers, and Community Hospitals, MERCATUS CENTER AT GEORGE MASON UNIVERSITY, Feb. 2016, https://www.mercatus.org/system/files/Stratmann-Rural-Health-Care-v1.pdf.

^{9.} Improving Health Care: A Dose of Competition AHPA Response, AMERICAN HEALTH PLANNING ASSOCIATION, http://www.ahpanet.org/AHPAargfavorCON.pdf.

Health regarding the state's CON program, the Federal Trade Commission wrote, "empirical evidence contradicts the assertion that dominant providers use their market power to cross-subsidize charity care." Mercatus also found that states with CON laws are associated with fewer facilities serving rural areas than states without. 11

The COVID-19 pandemic further exposed CON's shortcomings as public health policy. At the onset of the public health emergency, states with CON laws moved quickly to suspend them, recognizing that their CON programs would prevent health care providers from ramping up services to properly respond to the crisis. But CON laws always restrict the supply of health care, not just during pandemics, and they hinder preparedness for the next public health emergency. One working paper even found higher mortality rates from COVID in states with CON laws compared to those without them.

After nearly 50 years, the evidence shows CON laws have failed to reduce health care costs and increase access, as intended. By design, CON laws limit the supply of health care, and many states place industry incumbents, who have an interest in limiting their competition, as the gatekeepers—thus elevating crony profits over patient wellbeing. Further still, high costs, red tape, and competitor opposition curb CON applications and delay construction of facilities and provision of services.¹²

"Hospitals use the process to protect existing market share—either geographic or by service line—and block competitors, but they find the CON process onerous if they are attempting to enter a market... One state hospital association respondent said member hospitals initially had mixed views about the benefits of CON but banded together to support the process after realizing it was a valuable tool to block new physician-owned facilities."

MAY 2011

HEALTH CARE CERTIFICATE-OF-NEED (CON) LAWS: POLICY OR POLITICS? NIHCR RESEARCH BRIEF NO. 4

"CON laws have failed to produce cost savings, higher quality healthcare, or greater access to care, whether in underserved communities or in underserved areas...the evidence suggests CON laws are ineffective. There is no compelling evidence suggesting that CON laws improve quality or access, inefficiently or otherwise...Evidence also fails to support the claim that CON programs would increase access to care for the indigent, or in medically underserved areas."

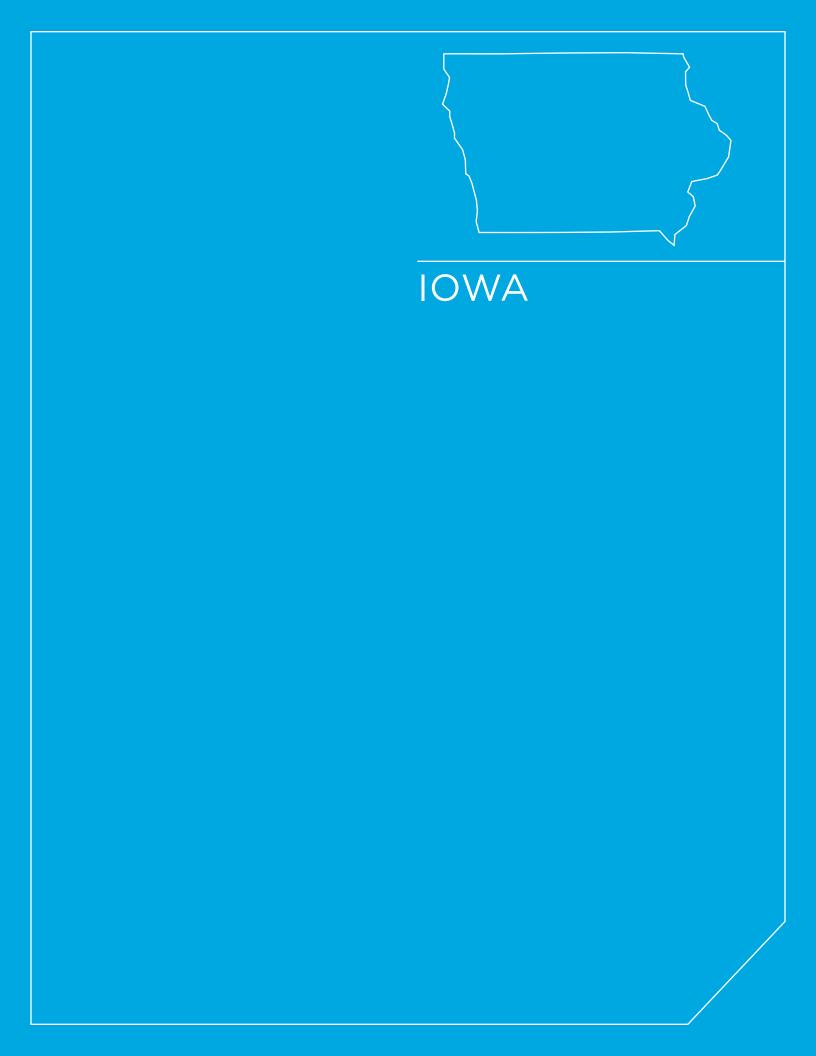
DECEMBER 3, 2018:

REFORMING AMERICA'S HEALTHCARE SYSTEM THROUGH CHOICE AND COMPETITION. A JOINT REPORT BY THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, U.S. DEPARTMENT OF THE TREASURY, AND U.S. DEPARTMENT OF LABOR

^{10.} Letter from Federal Trade Commission to Frank W. Berry, Commissioner, Georgia Dept. of Community Health (Oct. 16, 2017), https://goldwaterinstitute.org/wp-content/up-loads/2018/08/v180001gaconleecounty_and_attachments.pdf.

^{11.} Supra note 8

^{12.} Sriparna Ghosh, Agnitra Roy Choudhury, and Alicia Plemmons, Certificate-of-Need Laws and Healthcare Utilization During COVID-19 Pandemic, July 29, 2020, available at SSRN: https://ssrn.com/abstract=3663547 or https://dx.doi.org/10.2139/ssrn.3663547.



IOWA

Iowa's CON program requires health care providers to receive permission from the State Health Facilities Council ("SHFC"), made up of five political appointees, prior to introducing new or changing health services. The Department of Public Health says CON applications are reviewed "against the criteria specified in the law," but AFPF's review of the program finds that fights over applications are more like political campaigns, rife with opposition research and mudslinging from incumbent providers to generate controversy and shut down new competition.²

AFPF's examination of all CON applications submitted from July 2016 to February 2020 finds the SHFC denied over \$250 million in investment, including one application that failed because the vote tied. Applicants had to pay an estimated average of \$15,774 per CON application in fees, not including the cost of legal representation or outside consultants to prepare applications.

Health care entrepreneurs in Iowa face serious barriers to entry: thousands of dollars in application fees, public opposition from their competitors, and the burden of waiting for the arduous process to play out.

For example, in 2017, Mercy Medical Center applied for a radiation therapy program CON. The story of that application shows how incumbent providers leverage the CON process to protect themselves from new competition. At the October 2017 meeting of the SHFC, Mercy proposed a \$5.7 million

acquisition of a linear accelerator and CT simulator to start a radiation therapy program to treat cancer patients. The SHFC denied the application, with one council member <u>explaining</u> the proposal generated "too much controversy."³

This "controversy" was manufactured by a competing health care provider, the Wendt Cancer Center, which told the Council: "Mercy's proposed radiation therapy program threatens the continued existence of the Wendt Center ... If you approve the proposal, we could be forced to close."

Mercy re-applied in July 2018 backed by "230 letters of support received in 2017 and 2018 from patients and families, health care providers, government and community leaders, and community members; and eight individuals who testified at hearing regarding patient experiences." The Wendt Cancer Center again warned the Council: "The bottom line is this: If you approve Mercy's application ... it would threaten the continued viability of the Wendt Cancer Center." This time, the Council approved the application with a 3-1 vote.

Despite the apocalyptic warnings, the Wendt Cancer Center did not close; instead, competition led the Center to combine services with Grand River Medical Group and undergo a \$2.2 million renovation "focused on the patient experience." The Telegraph Herald noted the "opening follows that of the MercyOne Dubuque Cancer Center, which began accepting patients in June." This outcome shows how health care

^{1.} Certificate of Need, IOWA DEPARTMENT OF PUBLIC HEALTH, https://idph.iowa.gov/policy-and-workforce-services/cert-of-need (last visited Aug. 4, 2021).

^{2.} Ed Tibbetts, Iowa panel again deadlocks on psychiatric hospital in Bettendorf, QUAD CITY TIMES, Oct. 27, 2016, https://qctimes.com/news/local/govt-and-politics/iowa-panel-again-deadlocks-on-psychiatric-hospital-in-bettendorf/article_fd2bc8cd-0b04-54ae-9517-f25d33d7cdfc.html.

^{3.} Jeff Montgomery, Back to drawing board? State board votes 'no' on Mercy cancer center request, Telegraph Herald, Oct. 27, 2017, https://www.telegraphherald.com/news/tri-state/article_688320b4-50ee-53f5-ac63-53e5ea5ec157.html.

^{4.} Id.

^{5.} Jeff Montgomery, In reversal, state board approves Mercy's cancer center bid, TELEGRAPH HERALD, July 25, 2018, https://www.telegraphherald.com/news/breaking/article_bc84a467-7204-5a03-9f54-cc80921a4e11.html.

^{6.} *Id*

^{7.} Bennet Goldstein, *TH EXCLUSIVE: Health care providers join hands to launch new Integrated Cancer Center*, Telegraph Herald, Sept. 27, 2020, https://www.telegraphherald.com/news/tri-state/article_142d309a-5f5c-5823-ab7e-aafb18887ba5.html.

^{8.} *Id*

markets could work in the absence of CON laws: new market entrants pressure existing providers to invest in quality of service to compete for patients. Instead, Iowa's CON laws delayed that market-driven improvement by more than a year.

Another provider's similar experience—after applying to open a psychiatric hospital—also highlights how Iowa's CON laws harm patients and needlessly delays new facilities. Strategic Behavioral Health applied for a CON for a new hospital in 2015. Two competing providers opposed the new 72-bed mental health facility, arguing the additional beds were not needed. Ultimately, competitor opposition and two 2-2 ties before the State Health facilities Council delayed the mental hospital five years before seeing its first patient.9

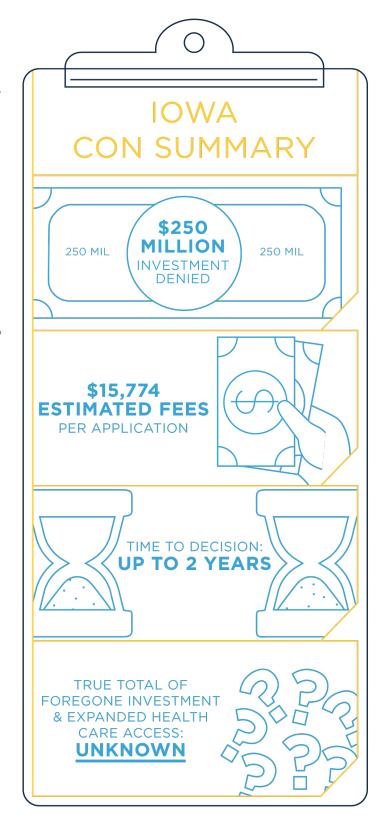
Incredibly, these *same two competitors* funded a <u>report</u> just two years earlier decrying the condition of Iowa's mental health care system, arguing "the need for inpatient care has gone largely unmet."10

A subsequent investigation by the Goldwater Institute found the same thing. The report recounts a terrifying story of a mental health patient who, despite days of searching, could not find a bed in a mental health hospital in Iowa. The patient was an adult who suffered from autism and found himself in the criminal justice system for an assault for which he was not criminally responsible due to his condition. "He needed treatment, not punishment," the judge said.11

However, despite the best efforts of Iowa's court system, law enforcement, and medical providers, they could not find the patient the care he needed. For over a week, he was forced to remain shackled and untreated due to the limited number of mental health care beds mandated by Iowa's CON program.

The Goldwater investigation concluded "it was clear that existing providers were using the CON process to thwart their competition for financial reasons unconnected to treating those in need."12

The statement holds true for mental health care, cancer treatment, and all seventeen health care services regulated under Iowa's CON program. Iowa's CON program pits



^{9.} Kevin Schmidt, PHOTOS: Ribbon-cutting Eagle View Behavioral Health, QUAD-CITY TIMES, June 16, 2020, https://qctimes.com/news/local/photos-ribbon-cutting-eagle-view-be-

^{10.} Jackie Anhalt, et. al., A Safety Net In Peril: The State of Public Mental Health in the Quad-Cities, 2013, https://www.unitypoint.org/quadcities/filesimages/SafetyNetinPeril Web.pdf.

11. Mark Flatten, CON JOB: State Certificate of Need Laws are Limiting Mental Health Options, GOLDWATER INSTITUTE, Sept. 25, 2018, https://goldwaterinstitute.org/conjob-2/.

providers against each other to fight for government favor while patients lose out on health care. A study by the Mercatus Center estimated that without its CON program Iowa would have 51 more hospitals, 33 of which would serve rural areas.¹³

Iowa's CON laws restrict Iowans' access to health care and divert providers' attention from protecting patients' health to protecting themselves from competition. In short, CON hurts people.

BLOCKING COMPETITION

"The certificate of need idea was created to prevent duplication and control the costs of health care. Unfortunately, it has become a way for certain (organizations) to keep out competition."

MARCH 2, 2016: FORMER IOWA GOVERNOR TERRY BRANSTAD

"It is easy to see how established businesses turn Iowa's certificate-of need requirement into a certificate of monopoly."

JUNE 2017: INSTITUTE FOR JUSTICE CASE PROFILE OF AN OPHTHALMOLOGIST WHOSE CON APPLICATION WAS DENIED FOUR TIMES OVER A DECADE

^{13.} Matthew D. Mitchell et al., Certificate-of-Need Laws: Iowa State Profile, MERCATUS CENTER AT GEORGE MASON UNIVERSITY, November 11, 2020, https://www.mercatus.org/system/files/iowa_constateprofile_2020.pdf



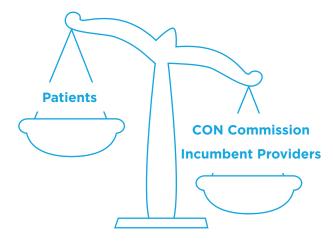
MICHIGAN

Michigan claims its **CON** program is "intended to balance the cost, quality, and access of Michigan's health care system." But good intentions have led to less patient access, inferior health care quality, and higher consumer costs. The "balance" favors incumbent health care providers who exploit the systems to protect themselves from competition at patients' expense.

Michigan's CON laws require health care providers to gain permission from the state before offering or expanding new services. The CON program is administered by the Michigan Department of Health and Human Services ("MDHHS") and the Certificate of Need Commission. The Commission is an eleven-member board appointed by the governor and approved by the Senate that is responsible for developing, approving, or revising the state's CON Review Standards. The standards are used by MDHHS to issue CON decisions.

AFPF's analysis of Michigan's CON applications submitted from January 2018 to February 2021 reveals a forgone supply of health care provisions that would be available to Michiganders if not for CON laws. For example, in 2019, the CON Commission projected a need for approximately 3,000 additional nursing home beds in the state. The projection, which was based on research conducted by MDHHS, signaled to health care providers that applications for nursing home beds would be seriously considered.

Inside of three months, the state received dozens of CON applications to build new nursing homes and add beds to existing homes—estimated at over \$630 million in new health care investment. But suddenly, the Commission arbitrarily reduced the projected need by nearly ten-fold at the urging of existing nursing home providers.² Approximately four-fifths of the applications were subsequently disapproved or withdrawn,



denying health care access to thousands of people that, clearly, the market predicted would need it.

A CON Commission meeting transcript tells the story. The projected bed need for nursing homes was higher than the Commission expected. Why? Because the data submitted by incumbent providers in previous years, on which prior bed need projections were based, was inaccurate. An executive with the Health Care Association of Michigan admitted, "[D]ata was missed. It is much better data today."3

Despite the projected need for nursing home beds being based on better data, the chairman of the board of directors for the Health Care Association of Michigan, who operates 16 nursing facilities in Michigan, appeared at the meeting and requested the Commission reject the bed need projection. When asked at the meeting about its members submitting inaccurate data, his response was blunt and unapologetic in its aim to overturn the original bed need numbers: "Point taken. Please give us the chance to put this [Standard Advisory Committee] together. I mean, this can be taken care of extremely fast."4

Certificate of Need, MICHIGAN.GOV, https://www.michigan.gov/statelicensesearch/0.4671,7-180-24786-243251--.00.html (last visited Aug. 4, 2021).
 Michigan Dept. of Health and Human Services Certificate of Need Comm'n, Commission Meeting Transcript, Sept. 19, 2019, https://www.michigan.gov/documents/mdhhs/9.19.19 CON Commission Transcript 667476 7.pdf.

This all runs into the obvious question: if there's no need, then why did so many providers so quickly fill the gap? Were they planning on throwing money away? The answer is plain: they know the patients are out there seeking quality care, but existing businesses intervened to preserve their monopoly.

The decision to lower the projected nursing home bed need is especially concerning given that the cost of a nursing home room is rising in Michigan. The average cost for a semi-private or private room in a nursing home in Michigan rose 13% from 2016 to 2020, according to Genworth's Cost of Care Survey. Economics 101 teaches us that limiting supply increases prices.

Michigan also suffers from a dire shortage of psychiatric care beds, especially for children, adolescents, and the elderly. The psychiatric bed standards came up for discussion at another recent CON Commission meeting. One commissioner asked if a change in the standards could result in the overabundance of psychiatric care beds. The Chair of the Commission responded no, explaining, "And so especially with psych, [providers] don't want to overbuild because then [they] have a built in [sic] expense and if [they] don't have the patients to fill it, that's not a good situation economically or patient carewise." In other words, the Chairperson acknowledged both that CON restrictions are not necessary to balance the supply of psychiatric care beds and that providers respond rationally to market-signals and patient needs when unrestricted.

Meanwhile, children across the state, some with severe and dangerous mental health disorders, wait "stacked up" for days to weeks in emergency rooms for psychiatric care beds to become available.⁷ One psychiatric care provider, who the state granted 40 additional beds as an emergency measure during the pandemic, recently applied to add 60 more beds; however, the state denied the application in March 2021 despite obvious need.⁸

Amanda Skrzypchak, Northern Michigan needs access to more mental health care, UPNORTHLIVE.COM, May 17, 2021, https://upnorthlive.com/news/local/north-ern-michigan-needs-access-to-more-mental-health-care.



Scott Witt and Jeff Hoyt, Nursing Home Costs, SENIORLIVING.ORG, June 22, 2021, https://www.seniorliving.org/nursing-homes/costs/.

Michigan Dept. of Health and Human Services Certificate of Need Commin, Commission Meeting Transcript, Dec. 10, 2020, https://www.michigan.gov/documents/mdhhs/12.10.20 Commission Transcript 712174 7.pdf.

Ross Jones, Kids 'stack up' in Michigan ERs as hospitals resist adding 100+ needed psychiatric beds, WXYZ DETROIT, June 14, 2021, https://www.wxyz.com/news/ local-news/investigations/kids-stack-up-in-michigan-ers-as-hospitals-resist-adding-100-needed-psychiatric-beds.

In addition to nursing home and hospital beds, Michigan's CON program regulates 18 different health care services.9 In AFPF's sample of CON applications, MDHHS disapproved more than \$500 million in proposed investment in the state's health care system. But the examples above bring to light an often-obscured consequence of Michigan's CON laws: providers are prevented from supplying new health care facilities and services beyond just those MDHHS denies. Half a billion in denied investment is a substantial figure on its own, but the value of this latent supply of services Michiganders are missing out on is undoubtedly far greater. That is because providers are typically unwilling to submit an application they expect MDHHS will deny. In fact, the state now requires providers applying to add new beds to submit a form certifying the Commission has projected a need for those beds in the provider's area of operation, or else the application will not be accepted. This is a direct and needless quota on the provision of health care in Michigan that results in real harm to real people.

In 2019, the Michigan Legislature blocked a move by the Commission to regulate a class of innovative cancer treatments, known as immune effector cell therapy ("IECT"), through the CON program. It is <u>reportedly</u> the first time the state legislature has overruled the Commission.¹⁰ The legislature's <u>resolution</u> disapproving the Commission's regulatory power grab notes the CON program would limit access to the new cancer treatment and discourage providers from offering it.¹¹ It should be clear these statements hold true for Michigan's entire health care system beyond just this new cancer treatment. That is, CON laws limit patients' access to care, stifle innovation, and discourage providers from offering vital services.

The COVID-19 public health crisis also highlighted how Michigan's CON program unnecessarily restricted Michiganders' access to health care. In March 2020, Governor Whitmer issued an executive order that authorized MDHHS to issue emergency CON and skip time-consuming procedural requirements of the application process. The order also allowed the Department of Licensing and Regulatory Affairs to grant waivers for hospitals to open new facilities. ¹² Governor Whitmer issued the order because it was apparent CON would prevent or delay necessary care provisions. But CON laws always restrict the supply of health care, not just during times of pandemic—and they hinder preparedness for the next public health emergency.

Recent research conducted by the Mercatus Center sought to measure some of the restrictive effects of Michigan's CON program. The study calculated that Michigan would have as many as 71 more hospitals without CON.¹³ This additional access to health care would not be limited to urban or affluent areas as the study found the state's rural regions could expect 25 more hospitals.¹⁴

Michigan's CON program harms the elderly who require assistance, children in need of psychiatric care, and patients seeking all types of treatment, along with their families and even the providers who are barred from offering them the care they need.

^{9.} Matthew D. Mitchell et al., Certificate-of-Need Laws: Michigan State Profile, MERCATUS CENTER AT GEORGE MASON UNIVERSITY, November 11, 2020, https://www.mercatus.org/system/files/michigan_constateprofile_2020.pdf.

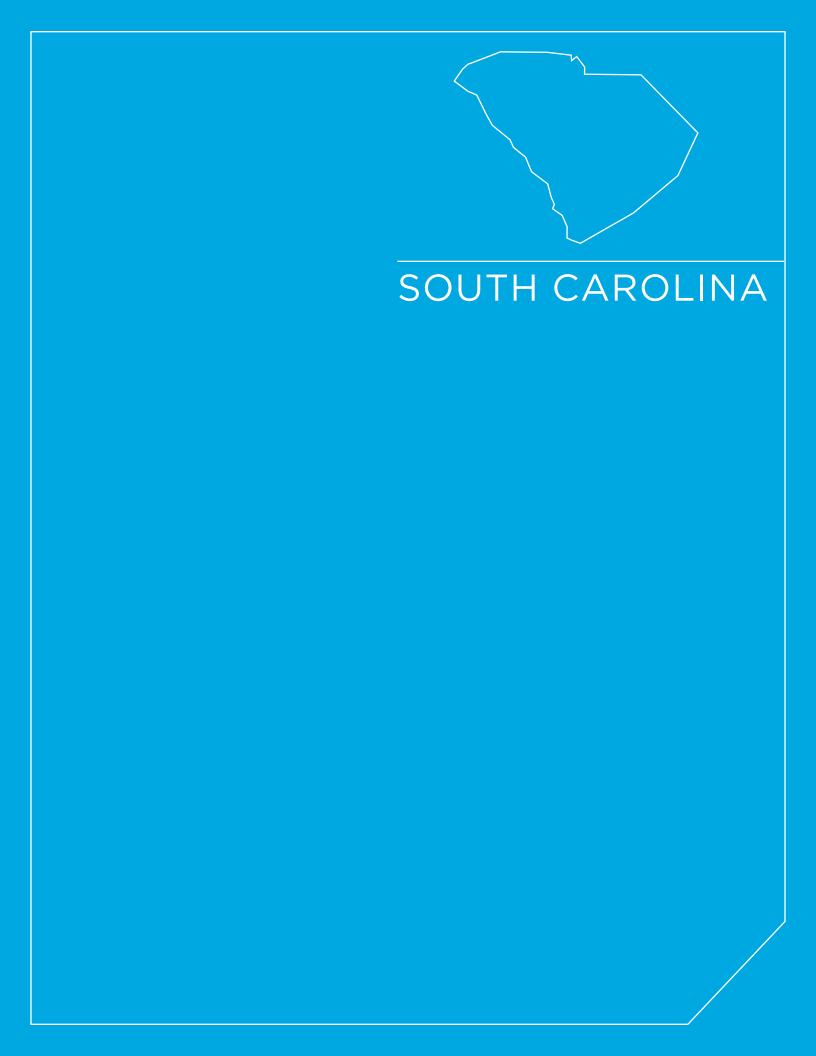
^{10.} Michigan Senate rejects regulation over CAR-T cancer treatment, MODERN HEALTHCARE, Oct. 31, 2019, https://www.modernhealthcare.com/law-regulation/michigan-senate-rejects-regulation-over-car-t-cancer-treatment.

^{11.} Mich. S. Concurrent Resolution 0014 (2019).

^{12.} Mich. Exec. Order 2020-13 (Mar. 17, 2020), https://ij.org/wp-content/uploads/2020/06/Mich-Exec.-Order.pdf.

^{13.} Supra note 9.

^{14.} *Id*.



SOUTH CAROLINA

South Carolina's CON program requires medical providers to seek approval from the state—and fend off seemingly endless legal challenges from competitors—before opening new facilities, expanding services, upgrading equipment, or undergoing a renovation. South Carolina's Department of Health and Environmental Safety (DHEC) says the purpose of the program is to "guide the establishment of health facilities and services which will best serve public need and ensure high quality services are provided in health facilities in this State." But AFPF's review of South Carolina's CON program, including an examination of all applications submitted from January 2018 to February 2021, finds that politics and legal challenges from competitors—not public need of quality health facilities and services—are the key drivers of the CON process in South Carolina.

Over the 3-year period, over \$455 million in health care investment, 25% of the total value of all CON applications during that time-period, was denied, withdrawn, or stuck in an appeals process.

The CON process in South Carolina is widely considered to be broken, even by its supporters and incumbent providers. The President and CEO of the South Carolina Hospital Association, which supports maintaining the CON program, recently admitted to the Senate Medical Affairs Subcommittee that the CON process can take extraordinary lengths of time, "which does not serve the community." As a result, health care entrepreneurs face incredible barriers to start or expand services in the state. These barriers allow

competing care providers to wield significant influence to shut down competition and reduce consumer choice in health care.

Barriers arise before a potential provider even files an application for CON. Incumbent providers hold four of the 14 seats on the South Carolina Health Planning Committee, which provides advice to the South Carolina Board of Health and Environmental Control on the state's health plan. The South Carolina Health Plan is the central planning document for all sectors covered by the CON program. The bulk of the document consists of "projections of need for additional health care facilities, beds, specified health services, and equipment."³

These need calculations can be fatal to CON applications and preclude their submission. According to the health plan, applications *cannot be approved* in areas where DHEC has arbitrarily calculated a "surplus" of beds. The same is true for existing services DHEC determines are meeting certain capricious benchmarks for annual procedures. For nursing home beds, for example, the health plan specifies: "When a county shows surplus beds, additional beds will not be approved, except to allow an individual nursing facility to add some additional beds in order to make more economical nursing units. The health plan calculates its arbitrary need for nursing home beds not by looking at the unique needs of South Carolinians, but "[b]ased on observations of methodologies from other states operating a Certificate of Need regime."

^{1.} Certificate of Need (CON), SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL, https://scdhec.gov/health-regulation/health-facility-regulations-licensing-con/certificate-need (last visited Aug. 4, 2021).

^{2.} South Carolina Senate Medical Affairs Subcommittee Meeting on S.290 and S.370, May 12, 2021, https://www.facebook.com/AFPSC/videos/913478242714485/.

^{3.} S.C. Dep't of Health and Env't Control, 2020 South Carolina Health Plan (2020), https://scdhec.gov/sites/default/files/media/document/2020 South Carolina Health Plan-June 12 2020 0.pdf.

^{4.} *Id*.

^{5.} *Id*.

^{6.} *Id*.

The reliance on the stringent caps in the health plan artificially reduces the number of CON applications the state would likely receive and, further still, the health care services that would be provided in the program's absence.

The next barrier is submitting a CON application along with the required application fee. CON applications submitted between January 2018 and February 2021 required an estimated average of \$5,787 per application in fees, and there is no refund for denied applications.

The biggest barrier for health care entrepreneurs navigating South Carolina's CON process is the ability of competitors to intervene. Competing health care providers can submit opposing comments on CON applications, request the DHEC board review the staff's decision to issue CON, contest the board's decision in the Administrative Law Court, and appeal the Court's ruling to the Court of Appeals and then the state's Supreme Court.

In addition to potentially swaying a CON decision against an applicant, competitors can add years and thousands of dollars in legal fees to the application process. In at least two recently resolved cases in South Carolina, legal challenges to CON decisions delayed the openings of much needed hospitals in two counties by over a *decade*.

In one legal challenge, presented in the timeline below, the state identified a need for hospital beds in 2004. After more than 15 years of litigation, the prevailing provider that received the CON was finally able to start construction of the hospital in spring of 2021.⁷

While proponents of the CON program argue repeal would endanger rural hospitals, a Mercatus Center study found that, without CON laws, Palmetto State residents would have access to 34 more hospitals—including nine rural installations—12 more ambulatory surgery centers, and more medical imaging services outside of hospitals.⁸

Providers and industry leaders in South Carolina, and even administration officials from the last two presidencies, have called out the shortcomings of the state's CON program, which fails to increase access to, improve the quality of, and reduce the costs of health care.

Matthew D. Mitchell et al., Certificate-of-Need Laws: South Carolina State Profile, MER-CATUS CENTER AT GEORGE MASON UNIVERSITY, November 11, 2020, https://www.mercatus.org/system/files/south-carolina-state-profile.pdf.



Carolina Hudson, Construction begins on long-planned Fort Mill Medical Center, CHARLOTTE BUSINESS JOURNAL, May 27, 2021, https://www.bizjournals.com/charlotte/news/2021/05/27/fort-mill-medical-center-construction-begins.html.
 Matthew D. Mitchell et al., Certificate-of-Need Laws: South Carolina State Profile, MER-

CON SUPPORTERS AND INCUMBENTS AGREE THE SYSTEM IS BROKEN

OVER A DECADE OF DELAYS FOR TWO HOSPITALS

"We shouldn't have to wait two years to put in a mental health facility... We are being handicapped by a process that was meant to help."

IULY 21, 2016:

DR. JON PANGIA, THE EMERGENCY MEDICAL DIRECTOR AT GRAND STRAND REGIONAL MEDICAL CENTER IN MYRTLE BEACH, SC

"In the past, and in the recent past, a lot of healthcare entities have used [CON] to stifle competition."

JULY 21, 2016

DICK TINSLEY, THEN ADMINISTRATOR OF MCLEOD LORIS SEACOAST, A HOSPITAL IN LORIS, SC

"[A]ppeals can go on for a decade, which does not serve the community."

MAY 12, 2021:

THORNTON KIRBY, PRESIDENT AND CEO, SOUTH CAROLINA HOSPITAL ASSOCIATION TESTIFYING BEFORE THE SENATE MEDICAL AFFAIRS SUBCOMMITTEE

"It's being appealed. Everyone is appealing it, which means all the attorneys are going to sue everybody for it, right? It's going to take probably two years for that to make it through the legal system, and then the build time is somewhere in the 2024 range. You're probably talking, before the first patient would ever be seen in that facility, probably four years from now give or take."

ULY 22, 2021:

CONWAY MEDICAL CENTER CHIEF FINANCIAL OFFICER BRIAN ARGO ON A 50-BED HOSPITAL RECENTLY APPROVED FOR A CON

"[I]t has been almost twelve years since DHEC made the determination an acute-care hospital was necessary in York County."

APRIL 25, 2018:

SOUTH CAROLINA SUPREME COURT DECISION REGARDING A CHALLENGED CON APPROVAL FROM 2005. THE HOSPITAL STILL HAS NOT COMPLETED CONSTRUCTION.

"After a decade-long legal battle that pitted one hospital system against another in bids to build facilities in the county, Berkeley County could now have three hospitals in the future."

AUGUST 9, 2018: STORY IN THE POST AND COURIER

FEDERAL TRADE COMMISSION ON SOUTH CAROLINA'S CON LAW

"First, CON laws create barriers to entry and expansion, limit consumer choice, and stifle innovation. Second, incumbent firms seeking to thwart or delay entry or expansion by new or existing competitors may use CON laws to achieve that end. Third, as illustrated by the FTC's recent experience in the Phoebe Putney case, CON laws can deny consumers the benefit of an effective remedy following the consummation of an anticompetitive merger. Finally, the evidence to date does not suggest that CON laws have generally succeeded in controlling costs or improving quality. For these reasons, explained more fully below, the Agencies historically have suggested that states consider repeal or retrenchment of their CON laws, and, in this case, respectfully suggest that South Carolina repeal its CON laws." (emphasis added)

JANUARY 11, 2016:

JOINT STATEMENT OF THE FEDERAL TRADE COMMISSION AND THE ANTITRUST DIVISION OF THE U.S. DEPARTMENT OF JUSTICE ON CERTIFICATE-OF-NEED LAWS AND SOUTH CAROLINA HOUSE BILL 3250

HOW CON STIFLES COMPETITION & HURTS SOUTH CAROLINIANS

SOUTH CAROLINA CON BARRIERS TO ENTRY

SOUTH CAROLINA HEALTH PLAN

- Decrees when applications cannot be approved.
- Incumbent providers part of committee that drafts the plan.

HEALTH PLAN MANDATES

 Applications cannot be approved if area has an arbitrarily calculated surplus of beds or services.

CON APPLICATIONS

- Requires thousands of dollars in fees.
- Reviewed by DHEC staff.
- Competitors can file opposition comments.



FINAL DECISION

- Issued by DHEC Board.
- Affected Parties can request a contested case hearing with the Admin Law Court.

FINAL REVIEW CONFERENCE

- Conducted by DHEC Board of political appointees.
- Affected parties can argue their case.

CON DECISIONS

- Issued by the DHEC Staff.
- Decision is final unless affected parties request Final Review Conference.



CONTESTED CASE HEARING

- Conducted by Admin Law Court.
- May include expensive and time-consuming discovery.

ADMIN LAW COURT RULING

• Can be appealed to the South Carolina Court of Appeals.

COURT OF APPEALS

 Affected parties can present their case.



STATE SUPREME COURT DECISION

 May entail sending the case back to the Court of Appeals.

SUPREME COURT OF SOUTH CAROLINA

 Affected parties can present their case.

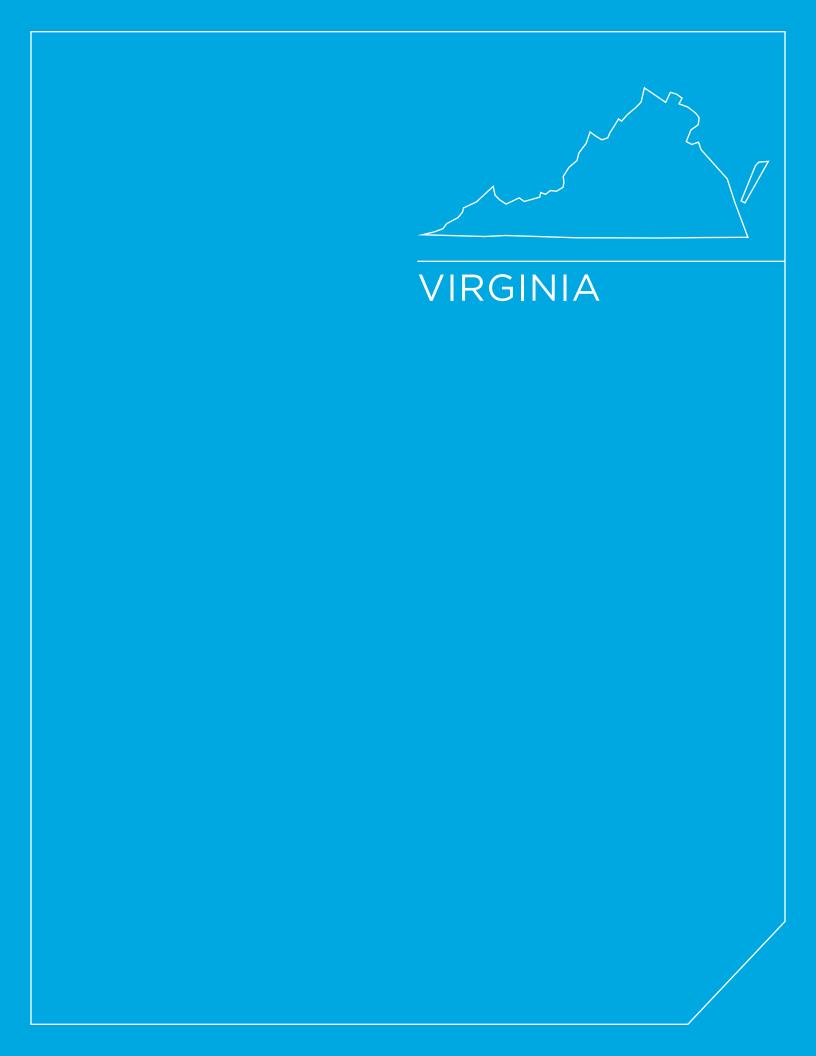
COURT OF APPEALS DECISION

 Can be appealed to the Supreme Court of South Carolina.

HOW SOUTH CAROLINA'S CON LAW SUBJECTS APPLICANTS TO YEARS OF DELAYS AND COSTLY LITIGATION

South Carolina identified a need for hospital beds in York County in its 2004-2005 state health plan, but due to legal challenges, the hospital has yet to be built.

2004-2005 State Medical Facilities Plan	DHEC identifies need for 64 hospital beds in York County.
November 22, 2004	Piedmont Medical Center submits CON application.
January 25, 2005	Piedmont Medical Center withdraws CON application and refiles a new application.
March 11, 2005	Three applicants file competing applications.
May 30, 2006	CON granted to Piedmont Medical Center and denied to three other applicants.
December 9, 2009	Administrative Law Court remands the case back to DHEC after finding it improperly awarded CON to Piedmont Medical Center.
September 9, 2011	DHEC grants CON to Carolinas Medical Center.
December 15, 2014	Administrative Law Court overturns DHEC decision and grants CON back to Piedmont Medical Center.
January 12, 2017	South Carolina Court of Appeals rules in favor of Piedmont Medical Center.
April 25, 2018	Supreme Court of South Carolina remands case back the Court of Appeals with instructions
August 22, 2018	South Carolina Court of Appeals affirms Administrative Law Court Decision.
February 21, 2019	Supreme Court of South Carolina denies appeal.
Jan 28, 2021	Piedmont Medical sets spring construction start for Fort Mill hospital.
May 27, 2021	Construction begins with anticipated opening in fall of 2022.



VIRGINIA

In Virginia, health care providers who wish to offer new services or expand their existing operations must apply for Certificate of Public Need ("COPN"). The regional health planning agency ("RHPA") for the applicant's region and the Department of COPN ("DCOPN") review the application and make a recommendation to approve or deny to the State Health Commissioner. Ultimately, the Commissioner makes the decision to approve, or not, for all COPN applications. A single unelected bureaucrat, appointed by the governor, decides for all of Virginia what health care facilities and services they can have.

Virginia claims its COPN program "seeks to contain health care costs while ensuring financial viability and access to health care for all Virginia at a reasonable cost." 1

But the true *cost* of Virginia's COPN program is that Virginians have access to fewer health care facilities and services, receive diminished quality of care, and pay more for care than patients in states without CON laws.

A recent <u>study</u> conducted by the Mercatus Center found that without the COPN program, Virginians would spend less annually on health care services per capita.² The study also estimated that Virginians would have access to as many as 49 additional hospitals as well as more facilities offering medical imaging services, even in rural areas. Virginians would also enjoy higher quality of care and experience better patient outcomes.

AFPF's analysis of COPN applications from January 2018 to March 2021 finds the State Health Commissioner denied applications for projects with an estimated total value of \$74 million. But the true value of health care services that would be provided if not for the COPN program is much higher, as providers are unlikely to submit a COPN application they expect will be denied.

For example, Dr. Mark Baumel's COPN application to offer "virtual colonoscopy" was denied despite the innovative service not being offered anywhere in the state. In an interview he states that other providers told him,

"Don't even bother with Virginia. Don't even try."3

The sentiment is revealing: Virginia's COPN program turns away health care providers and innovative treatments beyond the COPN applications denied.

Much like other states with CON programs, Virginia's COPN program turns the process of opening a facility or expanding operations from a business activity into a political campaign—a process that can last "six to seven months to complete." Providers launch full scale advocacy campaigns to support their applications, asking community members and health care professionals to write letters of support and sign online petitions. Currently, fights centered on the COPN program have led two competing health systems in the state into an ongoing all-out war, including litigation and an

^{1.} Certificate of Public Need Program, VIRGINIA DEPARTMENT OF HEALTH, https://www.vdh.virginia.gov/licensure-and-certification/the-certificate-of-public-need-program/ (last visited Aug. 4, 2021).

Matthew D. Mitchell et al., Certificate-of-Need Laws: Virginia State Profile, MERCATUS CENTER AT GEORGE MASON UNIVERSITY, November 11, 2020, https://www.mercatus.org/publications/certificate-need-laws-virginia-0.

Kate Masters, Inside (another) failed attempt to reform health care facility approvals in Virginia, Virginia Mercury, March 10, 2020, https://www.virginiamercury.com/2020/03/10/be-hind-the-failed-efforts-to-make-2020-the-year-of-copn-reform-in-virginia/.

^{4.} Supra note 1

^{5.} Jason Marks, With more beds clearly needed, hospital expansion coming to Suffolk's Harbour View, WAVY.COM, July 9, 2020, https://www.wavy.com/news/local-news/suffolk/with-more-beds-clearly-needed-hospital-expansion-coming-to-suffolks-harbour-view/.

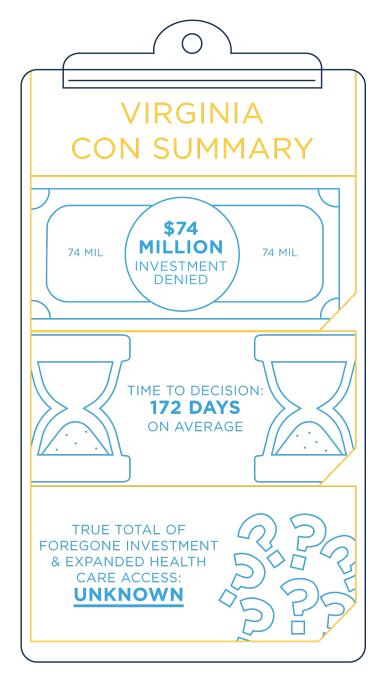
extensive melee in the press.⁶ Whenever providers have to fight for government favoritism to be able to provide services to patients, patients often miss out on those critical services.

Virginia's COPN restrictions can be tragic. In 2010, LewisGale Medical Center in Salem applied for a COPN to construct a neonatal intensive care unit ("NICU") at the facility to treat mothers and infants requiring special life-saving care. Per the DCOPN's recommendation, the State Health Commissioner denied the application. The state subsequently denied a second application for a NICU unit at LewisGale, stating both times that NICU services at LewisGale were unnecessary as they are offered at nearby Carilion Clinic in Roanoke.

Then, in 2012, <u>tragedy stuck</u>.⁷ A pregnant mother and baby were admitted to LewisGale in urgent need of NICU care but specialized transport to the Carilion Clinic was unavailable. Despite doctors' best efforts, the baby was lost because they were denied the proper equipment to potentially save the child's life.

LewisGale has since established a Level II NICU unit at the medical center. AFPF's data on COPN applications includes two additional applications submitted by LewisGale to upgrade and expand NICU services. An application to "introduce neonatal special care services at the Specialty Level" submitted in July 2018 was denied in December 2019. LewisGale submitted another application in January 2021 to "introduce neonatal special care services at the Intermediate Level with 6 bassinets." The Commissioner has not yet rendered a decision, but the DCOPN has recommended the application be denied. It appears the Commonwealth has not learned its lesson and is once again setting up the people of Salem for disaster.

The true cost of Virginia's COPN program is more than Virginians should be forced to bear. Virginia's COPN laws make health care more expensive and limit access to care, which can be the difference between life and death.



^{6.} Alia Paavola, Sentara sued, accused of trying to wipe out Virginia hospital's cardiology business, BECKER'S HOSPITAL REVIEW, May 18, 2021, https://www.beckershospitalreview.com/legal-regulatory-issues/sentara-sued-accused-of-trying-to-wipe-out-virginia-hospital-s-cardiology-business.html.

^{7.} Eric Boehm, How Virginia's Hospital Licensing Laws Led to an Infant's Death, REASON, Jan. 25, 2017, https://reason.com/2017/01/25/virginia-certificate-of-need-hospital/

THE COST OF GOING THROUGH THE COPN PROCESS

"After fighting with the state for two years, Medarva Healthcare has received approval from the Virginia Department of Health to build its West Creek Surgery Center in Goochland County...According to a press release, Medarva spent more than 1,000 hours of staff time and in excess of \$300,000 in legal and other fees during the Certificate of Public Need—or COPN—process. It submitted its first application in January 2015."

NOVEMBER 9, 2016: RICHMOND TIMES-DISPATCH STORY ON THE COSTS OF RECEIVING A COPN

FEDERAL TRADE COMMISSION ON VA COPN LAW

"[CON laws] [c] reate or increase barriers to entry and expansion to the detriment of health care competition and consumers; Undercut consumer choice, stifle innovation, and weaken the market's ability to contain health care costs; and appear to have generally failed in their intended purposes of controlling growing health care costs, increasing quality of health care, and ensuring access to care for uninsured and underinsured in urban and rural areas."

DECEMBER 4, 2015: FTC OFFICIAL TO VIRGINIA'S CERTIFICATE OF PUBLIC NEED (COPN) WORKGROUP

"We believe that CON regulation is unlikely to benefit health care consumers in Virginia, and we support the complete elimination of CON regulation... Consequently, CON regulation is likely to harm consumers on balance by increasing the price, and decreasing the quality, of health services in Virginia. CON regulation only offers protection for those that do not effectively meet consumer demands (because of excessive prices or inferior quality, or because they are inefficient), by deterring or blocking entry by firms that could do better."

AUGUST 6, 1997: FEDERAL TRADE COMMISSION LETTER TO VIRGINIA COMMISSION ON MEDICAL FACILITIES - CERTIFICATE OF PUBLIC NEED



- FOUNDATION -