How Virginia's Hospital Licensing Laws Led to an Infant's Death

The deadly consequences of an obscure medical licensing law.

Eric Boehm | January 25, 2017

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Dr. John Harding was on call when the patient arrived. Twenty-four weeks pregnant, she was bleeding and in pain, suffering from a condition known as a placental abruption, where the placenta detaches from the inner walls of the uterus and triggers premature labor. It can be deadly for both mother and child.

As his colleague in the obstetrics unit at LewisGale Medical Center in Salem, Virginia, tended to the patent, Harding rushed to the phone. At Carilion Medical Center, six miles away near downtown Roanoke, there was a special treatment center for premature and ill infants. The other hospital had a special ambulance equipped with bassinets—incubators equipped with a suite of advanced medical tech for monitoring and treating newborns. Harding knew the mother and baby needed that ambulance as quickly as possible.

"We've got a chance," he later recalled thinking.

But the special ambulance was not available. It was on another call, miles away on the opposite side of the service area, he was told. There was no way to get the critically ill newborn to the neonatal intensive care unit at Carilion.

"I had to go back in there and tell her, you know, it's not coming," Harding said, describing the incident a month later during a public hearing with officials from the state Department of Health.

With no emergency transportation available, Harding and his colleague Kevin Walsh called for whatever assistance they could muster. A pediatrician and anesthesiologist joined the two doctors and their nurses in the delivery room.

They saved the mother's life.

The baby didn't make it.

That infant, who died in February 2012, died not only because of medical complications but because the hospital where it had the misfortune to be born did not have the equipment necessary to give it a better chance at survival. The institution was not equipped to handle the difficult birth because the government of Virginia had refused to let it have high-tech neonatal care facilities, declaring that they were not necessary.

This baby died, at least in part, because bureaucrats in Richmond—acting in accordance with the wishes of LewisGale's chief competitor and against the wishes of doctors, hospital administrators, public officials, and the people of Salem, Virginia—let it happen.

Like many states, Virginia has a Certificate of Public Need (COPN) law requiring hospitals and other medical providers to get special permission from the state government before they are allowed to offer new services, like the specialty nursery that may have saved that child's life in 2012. These COPN licensing processes are supposed to balance the interests of hospitals with the needs of the public, but in reality they are fraught with politics and allow special interests to effectively veto unwanted competition.

In July 2010, two years before the baby died, administrators from LewisGale Medical Center submitted an application to the state Department of Health seeking permission to build a small specialty care nursery service. It was denied. The state's refusal ensured that, sooner or later, some child would face an ugly fate.

A *Reason* investigation relying on public records requests, legal documents obtained from sources who worked on LewisGale's COPN applications, and interviews with experts in the COPN process reveals how Virginia's hospital licensing laws are driving up prices, lowering the quality of care, and putting lives at risk.

Winning Permission From the State

LewisGale's initial application for a COPN license called for a $3.4 million project that would have included an eight-bed neonatal specialty care unit, or NICU.

The hospital was growing, as was the surrounding community. Though it's the smaller half of the binary Roanoke-Salem metropolitan area, it's by no means insignificant. More than 24,000 people live in the city itself and more than 300,000 call the Salem area home, making it the fourth largest metro area in the state and the largest, by far, in the state's mostly rural, mountainous southwestern quadrant.

Photo by Eric Boehm

The number of babies born in the area had nearly doubled in just two years, LewisGale reported in its 2010 application to the state Department of Health. The hospital had expanded its obstetric staff accordingly, and now it was hoping to expand the services available to mothers and babies.

It had to win permission from the state first.

LewisGale Medical Center is the smaller of the two hospitals operating in the Roanoke-Salem area. Even though it's a 500-bed facility that's part of a larger regional hospital system, it competes with the 760-bed Carilion Roanoke Memorial Hospital—known locally as Carilion Clinic—that houses a 60-bed NICU, the third largest such facility in the state.

In its COPN application, LewisGale argued that "there is tremendous, on-going public need for NICU services." More than 2,300 residents of southwest Virginia signed petitions in support of the project. The Department of Health's review of the application noted that LewisGale's proposed NICU "enjoys an atypically broad array of informed, enthusiastic support from nearly 70 leading citizens, business leaders, and government leaders and officials who are not working in health care or otherwise stand to be professionally affected by approval of the project," including state lawmakers, a congressman, county officials, and the mayors of five towns in the area.

"We are talking about families, we are talking about babies who have great needs, we are talking about the need for bringing the mothers and babies together at a time when sometimes they are separated because of the need to go to a hospital with specialty-level care," said state Sen. John S. Edwards (D–Roanoke) during a public hearing on LewisGale's application.

Ninety-four people came to that hearing. The Department of Health noted, in an August 2011 report, that "no one who attended spoke in opposition, or otherwise indicated opposition to the project."

The only opposition came from Alice Ackerman, a professor of pediatrics at Virginia Tech's medical school—the Carilion School of Medicine, which has longstanding ties to Carilion hospital. In written testimony submitted to the Department of Health, Ackerman argued that the number of specialty bassinets at Carilion was sufficient to meet the needs of southwest Virginia. Approval of a small NICU at LewisGale, she wrote, "has the potential to erode the existing high level of neonatal care" because "small, low-volume NICUs are generally not in the best health interests of the community."

Google MapsLewisGale was willing to spend the money to build and staff a new NICU. It had nearly unanimous support from the Roanoke-Salem community. Still, after months of consideration, the state Department of Health's Division of Certificate of Public Need sided with Ackerman and Carilion. Building a NICU at LewisGale, the bureaucrats concluded, "would foster institutional competition."

"Patients and obstetricians who may have been reluctant to choose [LewisGale Medical Center] for obstetrical care, due to its lack of either specialty or intermediate level special care nursery services, will be more inclined to use LGMC if the project is approved," wrote Douglas Harris, the state-appointed analyst who handled the first COPN application from LewisGale, essentially arguing that giving people a choice would mean some people choose to take it.

He recommended to Karen Remley, then the state's health commissioner, that the application be rejected "despite the many expressions of community support" because the facility "is not needed."

Two weeks after Harris filed his report, Remley accepted his conclusions and denied LewisGale's license application. Under Virginia's Certificate of Public Need laws, she alone had the final say in the matter. (Remley resigned from the state Department of Health in 2013 to take a position at M. Foscue Brock Institute for Community and Global Health at Eastern Virginia Medical School. She left that job in 2014 and is now CEO of the American Academy of Pediatrics. She did not return requests for comment.)

Virginia's Department of Heath had never before rejected a COPN application to build a NICU. In approving a similar proposal from Chesapeake General Hospital in 2007, it had noted that on-site specialty care for infants "appears to be becoming the standard of care for hospitals providing substantial volumes of newborn care as safety has improved and technology and expectations have evolved."

Less than six months after Remley rejected LewisGale's application, doctors Harding and Walsh would fight a losing battle on behalf of a premature infant.

The Roots of Certificate of Public Need Laws

Certificate of Public Need laws—or Certificate of Necessity (CON) laws, as they are known in most of the country—have their roots in the 19th century. Politicians decided that, if they were going to subsidize railways, they should take steps to ensure they weren't building too many in a certain location. In other words, they wanted to make sure they were spending the public's money only in places where railroads were actually needed and not helping competing rail lines operate in a location where one line would be sufficient.

Today, these laws are used in a variety of ways to give government planners greater control over the economy. Often, the agencies responsible for determining the "public need" for certain services are controlled by the very industries they are regulating. Even when a direct conflict of interest is not present on the boards governing CON licensing processes, the process allows incumbent businesses to object to new competition, as Carilion did when LewisGale proposed building a NICU.

The result is to give incumbent businesses what critics call a "competitors' veto."

"It's not about increasing access to health care. It's a government permission slip to compete

that favors established businesses."

Darpana Sheth, an attorney with the Arlington, Virginia–based Institute for Justice, a libertarian law firm, says CON laws should be called "Certificates of Monopoly."

"It's not about increasing access to health care," she says. "It's a government permission slip to compete that favors established businesses."

Hospitals that want to build a NICU—or open a new surgical center, purchase new medical imaging equipment, or make any substantial capital investment in their facility—are already subject to licensing and inspections by the state. The CON process has nothing to do with protecting patients' health or safety and everything to do with preventing unwanted competition, Sheth says. The underlying idea is that central planners can better sort out patients' needs than the hospitals serving those patients.

The Institute for Justice has challenged CON laws in several states. The firm has also been involved in a legal challenge to a COPN ruling that prevented a doctor from opening a new, non-invasive colonoscopy clinic in Virginia because the state decided there were already enough medical imaging devices being used by other providers.

Thirty-six states now employ some form of CON regulations for health care, according to the National Conference of State Legislatures, thanks to a twisted history that involves hospital lobbyists, the influence of the federal government, and inertia in state capitals.

In the early part of the 20th century, CON laws were still used mostly used to regulate the transportation industry. That changed in 1964, when New York passed a law requiring a government permit before new hospitals or nursing homes could be built. A 2009 study by Pamela Smith and Dana Forgione, originally published in the *Journal of Health Care Finance*, recounts how four other states (California, Connecticut, Maryland, and Rhode Island) followed suit by the end of the '60s, as hospital executives began to recognize the value of getting governments to erect barriers to future competition.

Starting in 1969, the American Hospital Association began lobbying for a federal CON law. It never got the law it wanted, but three years later, within a series of amendments to the Social Security Act, Congress included a mandate that states review all capital expenditures for hospitals and medical facilities costing more than $100,000 or for any changes to existing services.

In 1974, Congress doubled down by tying federal Medicaid funding to the mandate, so states that did not comply risked losing their federal subsidies. The arm-twisting worked. By the end of the 1970s, every state except Louisiana had passed some form of CON requirement, giving state officials the final say on whether new hospitals could be built or offer new medical services.

In theory, this was supposed to reduce costs. Proponents argued that too much investment in health care in one place would mean higher prices for customers. Giving states control over hospitals' capital investments was supposed to prevent overinvestment and keep hospitals from having to charge higher prices to make up for unnecessary outlays.

But the mandate did not reduce costs. Instead, as a 1982 Congressional Budget Office (CBO) study found, it increased them.

That study found "no evidence that CON review has limited the growth in hospital unit costs" and noted that state-level CON laws were more focused on the distribution of health care services, even though the intention of the federal mandate was to control costs. In one study cited by the CBO, the availability of hospital beds had fallen by 6 percent, though the CBO said it could not prove the regulations had led to the decline in access.

In 1987, with support from the Reagan administration, Congress killed the CON mandate. Since then, 14 states have repealed their health care CON laws. But many others—including Virginia—still rely on them.

In 2016, the Federal Trade Commission and the U.S. Department of Justice issued a joint statement calling for state governments to roll back CON laws in order to free health care markets and lower prices. "CON laws raise considerable competitive concerns and generally do not appear to have achieved their intended benefits for health care consumers," the two agencies concluded, warning that these laws have been exploited by competitors seeking to protect exclusive markets by raising the cost of entry.

"It's been a big failed experiment," says Sheth.

Mothers Separated From Newborns

Just weeks after watching an infant die on their watch, doctors Harding and Walsh sat before a state Department of Health committee, pleading for help in making sure something like that would not happen again. Walsh had come down with the

flu, but he made the trip to the campus of Western Virginia Community College anyway, because "this is so important." (The full transcript of the hearing can be found here.)

The occasion was the first and only public hearing held by the Virginia Department of Health's Certificate of Public Need Committee regarding LewisGale's second application to build a NICU. The hospital had, in January 2012, applied to add eight specialty basinets. Again, the crowd at the public hearing was nearly unanimous in favor of letting the hospital do what it wanted.

Walsh told the story of how his patient had come to the E.R., bleeding and in pain. He told the committee about the placental abruption, the calls to the Carilion, and the ambulance that never came. The mother, he said, now was being treated for depression.

"The one question I can't answer for her is: Why was there not a way for her baby to be stabilized?"

"We've tried to help her understand what's happened, because she's had a loss, and there's no good spin on this," he said. "And the one question I can't answer for her is: Why was there not a way for her baby to be stabilized?"

"I implore whoever can help us with this decision," Walsh said. "Give us the tools we need to take care of our patients, the people that have come to us and entrusted their care in us." Anything short of that, he said, was unacceptable.

After Walsh spoke, Harding took to the microphone to tell his version of the tragic events that had unfolded a few weeks earlier. "I had to go back to the mother and tell her, 'We did what we could, but your baby died,'" he recalled.

"We need that NICU," he said, his voice cracking. "We just—we need it."

Over the next hour, the committee heard from LewisGale doctors and nurses, hospital administrators, local residents, elected officials, and business leaders. If there was any difference between the March 2012 hearing and the one that took place in 2010, it was the frustration that comes across even in the written transcripts of the event.

"I'm not happy to be here again," said Alice Gordon. She had given birth at LewisGale, but her son had to be transported to Carilion's NICU when he had trouble breathing the next day. The boy turned out to be fine, but mother and child were separated for days and the ordeal created weeks of stress, as well as a hefty ambulance bill, for the new mother.

When LewisGale applied for a COPN to build a NICU in 2010, Gordon had traveled to Richmond, more than three hours away, to share her story at the public hearing. The experience left her embittered at the state's health care bureaucracy. "After hearing—having the opportunity to go as a layperson and hear even more-qualified individuals testify in favor of this petition, I sat there and listened, and I got angry," she told the committee.

Gordon wasn't the only one who couldn't understand why the first application had been rejected.

"The state's denial of LewisGale's previous application has robbed us of our ability to provide the best quality care to the people of southwest Virginia," said Kim Beck, a labor and delivery nurse at the hospital, during the March 2012 hearing. "If LewisGale is willing to spend the money and the time to add these facilities, the staff, and the equipment for better patient care, I don't see a reason why they should be denied it," testified Natasha Lee, another woman whose son was delivered at LewisGale. "If it can save one baby's life, if it can prevent one baby from having permanent complications—because, you know, it is about life and death, but it's also about preventing long-term lifelong complications that babies can have from not getting the early care they need."

Lee spoke from experience. Her son was born in May 2011 without complications. The next night, however, his oxygen levels dropped and his skin color changed. He had to be transferred to Carilion. Lee then discharged herself from LewisGale—against her doctor's wishes—so she could be with her newborn child. He survived and recovered. But it left a

mark. It was, she told the COPN board, "the worst experience of my life."

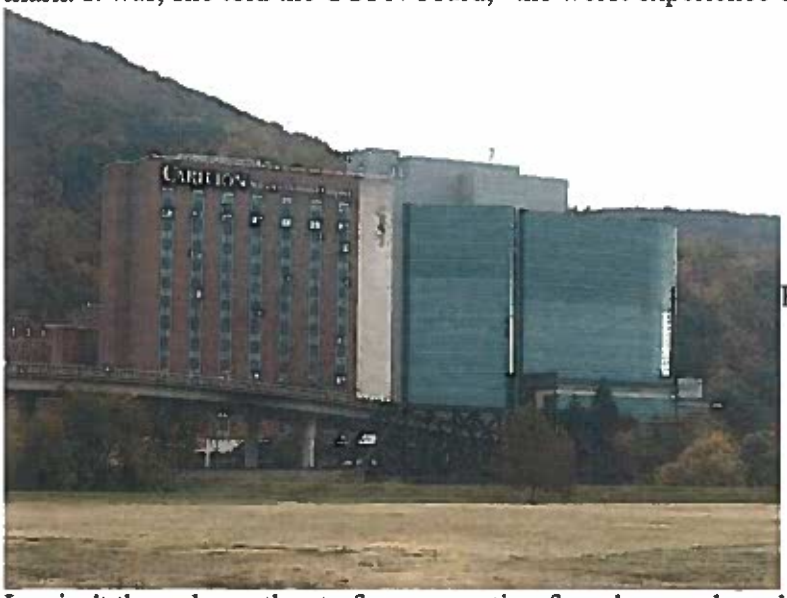


Photo by Eric Boehm

Lee isn't the only mother to face separation from her newborn because of LewisGale's lack of facilities. Misty McGuire's son was born at LewisGale in April 2008 and began suffering from seizures a day later. He needed to be transported to Carilion, McGuire told the board, but her insurance wouldn't cover it. She ended up with a $4,200 medical bill for the 10-minute drive between hospitals. But the worst part for the new mother was that she had to be away from her child so soon after he was born.

"We couldn't understand why LewisGale did not have the ability to care for our new baby," she said at the hearing. "I want doctors that know me, that know my family, nurses that care and will be honest with me, and that does not come with changing hospitals."

Midway through the hearing, the lone voice of opposition spoke up.

Wanda Ostrander, vice president of the Carilion Clinic Children's Hospital, spent a few brief moments at the microphone to explain the Roanoke hospital's opposition to letting a competitor build a NICU.

"We have the capacity to take care of all the babies in the region," she said.

All the babies in southwest Virginia would be perfectly fine, Ostrander maintained—as long as they were born at her hospital instead of a competitor's.

Ostrander did not return requests for comment, and a spokesman for Carilion hospital declined to answer a direct question from *Reason* about the hospital's ability to care for all the newborn infants in the Roanoke area. Instead, the spokesman directed us to a 2014 letter from Carilion School of Medicine's Ackerman to Virginia's Department of Health. The letter repeats the same arguments made by Ackerman in 2010 and Ostrander in 2012, points out that Carilion's NICU typically is filled to 75 percent capacity, and concludes by telling the state that "another neonatal specialty care nursery is not needed in southwest Virginia."

The letter also acknowledges one of the strongest arguments in LewisGale's favor: that separating mothers and infants creates unnecessary emotional stress, which could be prevented if LewisGale had a NICU on location. "We agree that this type of transfer is not ideal for mother and baby," Ackermann conceded. Citing state-issued health guidelines, she argued that potentially sick or premature babies should be transferred to Carilion "in utero for optimal outcomes."

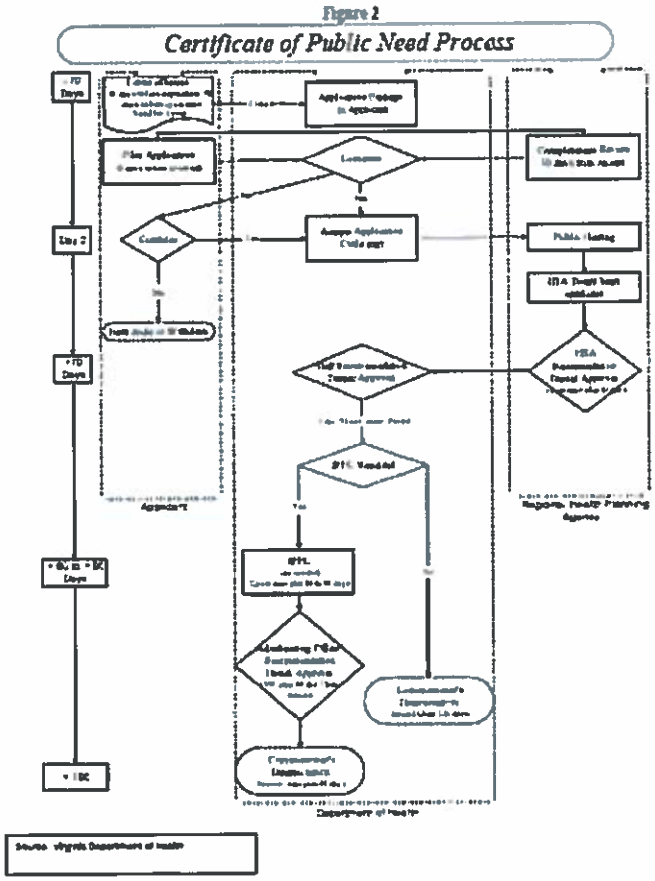
Ackerman suggests that the best way to avoid transferring babies to Carilion after birth is for mothers to give birth at Carilion. That's also a prominent feature of Carilion's advertising efforts, which stress the fact that it has the region's only NICU.

Carilion Clinic Maternity Care - 60-second commercial

Asked why the hospital has repeatedly, single-handedly opposed the building of a NICU at LewisGale, Carilion Clinic spokesman Chris Turnbull pointed to the state's authority. "The Commonwealth of Virginia has established through its repeated reviews of the request for an 8-bed NICU that there is already adequate or excess capacity for NICU patients in our region," he told *Reason* via email.

Denise King, who joined the LewisGale board of directors in 2005, was at the COPN hearing in 2012 Even now, she remains angry about it. A resident of Salem for more than 30 years and a former president of the region's Chamber of Commerce, King was shocked to find out that LewisGale's first application for a NICU was denied. She says the lack of such a unit hurts the hospital's ability to provide top-notch care for patients, and she believes the rejection was the result of the state putting Carilion's interests ahead of the community's.

"In a region as big as ours, to only have one option [for infants needing intensive care], it's just difficult for me to understand," she says. "It's never a problem to have competition in business."



Source: Virginia Department of Health

According to the state Department of Health, the COPN application process takes at least 90 days (see flow chart at right). It took more than two years for the state Department of Health to make a decision about LewisGale's second application to build a NICU. When the decision came, the state again said no.

"While there is substantial support for the proposed project, there is compelling opposition from the regional perinatal center [Carilion] which is located reasonably close to the proposed project," the department concluded in April 2014.

A Hospital Turf War

Numerous sources describe the fight between Carilion and LewisGale as a "turf war." Carilion, with the backing of the Department of Health's Division of Certificate of Public Need, appears to be winning.

"You have two competing hospitals and you would expect a certain amount of we-don't-want-them-to-have-what-we-have between them," says King.

But what did Carilion really stand to lose? In a lawsuit appealing the Department of Health's second rejection of LewisGale's request, attorneys for the Salem hospital argued that even if its proposed NICU was filled to maximum capacity at all times, it would reduce Carilion's occupancy by no more than five percent. Carilion—with 60 bassinets in its NICU compared to eight at LewisGale—would remain the third largest provider of neonatal intensive care in the state.

This local conflict raises bigger questions about the role the state government, or any government, should play in the decisions made by hospitals, by doctors, and by patients. Who gets to decide whether LewisGale should build a NICU? Who gets to decide whether any hospital should build any new facility or offer new services? There's no compelling reason for anyone besides the hospital administrators to make that decision. They know what their doctors and their patients need, surely, better than a bureaucratic analyst or a commissioner in a state capital.

That would be true even if CON laws were serving their purpose and lowering the cost of health care. It's even truer when CON laws have failed so spectacularly, surviving only because of legislative inertia and the influence of those few special interests who benefit from limiting competition and keeping prices higher.

Competition between hospitals can lower prices for patients. In a 2015 paper, economists from Yale, Carnegie Mellon, and the London School of Economics evaluated claims data from Aetna, Humana, and UnitedHealth. They found that costs were 15.3 percent higher, on average, in areas with just one hospital compared with those served by four or more hospitals.

Competition also increases quality. In a paper published last year by the Mercatus Center at George Mason University,Thomas Stratmann and Davild Wille argue that hospitals in states with CON laws have higher mortality rates than hospitals in non-CON states. The average 30-day mortality rate for patients with pneumonia, heart failure, and heart attacks in states with CON laws is between 2.5 percent and 5 percent higher even after demographic factors are taken out of the equation.

"This is alarming news, but it shouldn't be too surprising," the researchers note. "Providers compete on a variety of margins beyond price, and quality is one of them. As a result, when CON laws artificially restrict the number of providers in a local market—protecting those few favored providers from increased competition—there is less pressure for them to worry about the quality of care. Patients are then left with fewer options."

There are other consequences that can't be easily measured. Because of the time and expense necessary to get a CON license—and without any guarantee that a competitor won't block your application—some would-be providers don't even try to enter the market in states, like Virginia, with onerous CON processes.

"It can easily cost six figures to go through the CON process," says Sheth, the attorney from the Institute for Justice. "You have to hire attorneys and other professionals, and you have to go through what's basically a legal process. It hurts independent doctors and small facilities the most."

Interest Groups Keep CON Laws On the Books

Sheth believes the best chance for change lies with state lawmakers, because courts view CON laws as a matter of regulatory policy and are often unwilling to wade into that thicket. Some legislators are trying to reform or end these laws.

Wisconsin and New Hampshire, for example, suspended the enforcement of their CON requirements in 2016.

Photo by Eric Boehm

In many state capitals, however, it's been difficult to muster support for repealing the laws, which remain popular with influential interest groups.

Delaware's failed effort to wipe its Certificate of Need laws from the books shows how hard it can be. In 1993, the state legislature passed a law freeing Delaware hospitals from CON regulations. It was supposed to take effect the following year. But before that could happen, lawmakers took up the issue again and extended the sunset date to 1996. They would later kick the expiration date back to 2002, then 2005, and eventually 2009. Finally, in 2009, legislators voted to remove the sunset provision and keep the law on the books.

Virginia's reform efforts have struggled as well. In 2015, lawmakers convened a "study group" to review the state's COPN laws for hospitals, ultimately recommending a series of reforms that would have trimmed the state Department of Health's ability to determine which hospitals would be allowed to offer what services.

But when bills implementing some of those reforms passed the state House and moved to the state Senate, hospital executives stepped up their efforts to kill the legislation, meeting directly with high ranking senators, according to the *Richmond Times-Dispatch*.

Meanwhile, the Virginia Hospital and Healthcare Association ran television ads across the state asking residents to call lawmakers and urge a negative vote on the bills. In the campaign-style ads, a voice-over warns that COPN reform will "financially ruin your local hospitals, putting lives at risk."

The bills never made it across the finish line. Fortunately, Speaker of the House William Howell (R–Stafford) has said he'll make them a priority during the 2017 legislative session. He's not alone.

"Reforming Virginia's outdated COPN laws is the most important thing legislators can do this year to help constituents get affordable care close to home," Virginia state Del. John O'Bannon (R–Henrico) told *Reason* in January, just as lawmakers were gearing up for the next legislative session. "These laws provide hospital systems with a protected monopoly that works against useful health care reform and patients' choice."

Real World Consequences

To protect favored hospitals from competition—under the guise of looking out for the public—state governments are driving up health care costs and decreasing the availability of quality care. The end result is that people die.

After its request was denied for the second time, LewisGale appealed the decision in circuit court, arguing that the Department of Health was wrong to have rejected its application. The case was ultimately dismissed, but during the legal battle the Department of Health filed a brief arguing that "there is no factual evidence to support the allegation that the baby would not have expired if LewisGale had a specialty level NICU in operation."

To protect favored hospitals from competition—under the guise of looking out for the public—state governments are driving up health care costs and decreasing the availability of quality care.

To ignore the government's role in the death that occurred at LewisGale Medical Center in February 2012 by declaring that maybe the infant would have died anyway is to ignore the facts of that specific incident and the general consequences of CON laws in health care.

Public records don't reveal the name of that baby or its mother, and Harding and Walsh declined to comment for this story. But public testimony and multiple interviews confirm that the death occurred, and they validate other details of the incident—like Harding's desperate phone calls to Carilion seeking emergency transportation. According to legal documents filed as part of a 2014 lawsuit, Carilion's NICU ambulance still had not arrived 45 minutes after it was requested, at which point the doctors canceled the call because the baby had died.

"Obviously we never know whether the outcome would have been the saving of the life," Denise King says. "But we knew that without the NICU there was no chance."

"Concerns about duplicative services pale when compared to the life and death real-world consequences of whether LewisGale's NICU application should have been approved," Charlotte Tyson, the hospital's chief operations officer, told members of the Virginia legislature during a public hearing in October 2015. "Pregnant women should be able to deliver their babies knowing that, God forbid, should something go wrong, the hospital they are in is able to offer the best treatment. The story of LewisGale's failed efforts to secure COPN approval for its NICU is a valuable lesson in how a law with good intentions can have terrible real-world consequences."

Correction: The original version of this article incorrectly identified Karen Remely's current job and title. The article has been corrected.

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