MEMORANDUM

To: Dr. John E. Stapleford, Chair  
   Dr. Stacie Beck, Board Member  
Cc: Vil Vongphrachanh, Director of Communications  
From: Justin Chan, Research Intern  
Sent: June 19, 2019  
Subject: Delaware Certificate of Need (CON)

This memorandum is a discussion about the Certificate of Need (CON) process in the State of Delaware, its impacts on the health care market, and a meta-analysis about the effectiveness of the CON process. The memorandum also sets out recommendations and conclusions based on the evidence collected and analyzed.

Background Information on Certificate of Need Laws
Certificate of Need (CON) laws originated in the mid-1960s with New York State passing the first CON law in 1966 that limited additional beds to current hospitals or the creation of a new healthcare facilities without permission from state officials.¹ The main purpose of the law was to limit the excess capacity of health care facilities and equipment that was surging during the 1960s and 1970s. The notion was that by having excess capacity of health care services there would be a medical arms race for customers, but not necessarily improved quality of healthcare service. For example, there would be an emphasis on patient comfort, including the plushest waiting rooms. Due to the excess capacity, law makers during this time period wanted to limit the supply of these expansions in the health care industry in order to limit the potential drastic rise in costs.

The federal government passed the National Health Planning and Resource Development Act in 1974 which was a mandate for states to have CON laws for health care facilities and services in order to receive Medicare and Medicaid funding. Prior to 1974, over a dozen of other states had laws similar to the New York State CON law.² With this enactment, all the

states besides Louisiana (Louisiana had a CON law with similar processes, but under a different name), would enact their own CON laws.

In the 1980s, in the era of deregulation, the National Health Planning and Resource Development Act was repealed with regards to the CON requirement with evidence from many case studies in specific states called for the federal repeal. The main reason that Congress repealed the CON requirement in 1987 was that the states would artificially create monopolies and restrict, or have artificial barriers of entry, to the health care market. The natural outcome of the artificial restrictions and barriers to entry is a burden of cost, quality, and access to the consumer.³

Currently, there are 35 states that have some form of the CON process, whether that be for specific industries in health care or a moratorium on facilities. The most recent state to include a CON process was Indiana in 2018 and the latest repeal was in New Hampshire, effective in 2016. For the State of Delaware, the CON program was established in 1978 and is still in effect today.⁴

Certificate of Public Review Process in the State of Delaware
The State of Delaware enacted the CON process in 1978 through the passage of 61 Del. Law, c. 393, §1 which later became 16 Del. Code 9301 under Title 16 of Health and Safety, Chapter 93 of Health Planning and Resources Management in the Delaware Code. In this subsection, the memorandum will go over the statutory criteria and regulations, review process, and court challenges in the review application process of Delaware’s CON program.

The CON process was replaced with the Certificate of Public Review (CPR) process in 1999 as a part of the Delaware State Health Care Innovation Plan, which gave direction to the Delaware Department of Health and Social Services for oversight into health care service facilities and equipment under the new Certificate of Public Review Process.⁵

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³ Roger Stark, Why Washington’s restrictive Certificate of Need medical services law should be repealed
Bylaws and Regulations

Under 16 Del. C. 93., a Delaware Health Resources (DHR) Board in the Delaware Department of Health and Social Services is created and consists of fifteen members appointed by the governor, including members from the health care industry, government agencies, and the Secretary of the Department of Health and Social Services. They are tasked with the review, approval or rejection, and appeals process with regards to the CPR process. In addition to this, the Board is responsible for developing a Health Resources Management Plan (HRMP) that assesses the state of the supply of health care services, equipment, and facilities in the State of Delaware. 6

Specifically, there are seven statutory criteria and their appropriate guiding principles that the Board has to follow with regards to the CPR process. 7

1. The Relationship of the Proposal to the Health Resources Management Plan (HRMP)
2. The need of the population for the proposed project
3. The availability of less costly and/or more effective alternatives to the proposal
4. The relationship of the proposal to the existing health care delivery system
5. The immediate and long-term viability of the proposal in terms of management and financials
6. Anticipated effect of proposal on costs and charges
7. Anticipated effect of proposal on quality of health care

In addition to the seven statutory criteria, the Health Resources Board must take into consideration issues of access, cost, and quality of the proposal in the service area. These considerations include the demographic need in the area, alternatives to the proposal—even including those out-of-state alternatives, viability in the short and long-run, impacts on the cost, and impacts on the quality of health care service. 8

A Certificate of Public Review is required for any person taking on the activities of: construction or development of a health-care facility, acquisition of a health care facility, change in bed capacity of a health-care facility of ten or more beds or 10%

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7 Delaware Health Care Commission, Delaware Health Resources Board Certificate of Public Review Health Resources Management Plan
8 State of Delaware, Title 16 Health and Safety Hospitals and Other Health Facilities Chapter 93. Health Planning and Resources Management
increase in the bed capacity, or acquisition of a major medical equipment of $5.8 million or more.\textsuperscript{9}

\textit{Review Process}
There are five main procedural steps before the decision on the proposal to accept or reject the application for the Certificate of Public Review process.

\textit{Notice of Intent}
The first step is the Notice of Intent, which is to precede the filing of the application itself within an advance of 30 days or less. The Notice of Intent itself is rudimentary and only asks for basic contact information, as well as estimated capital expenditure and a one page or less description of the proposed project.

\textit{Application Filing}
Second is the filling of the application. The application includes three section of background information, review considerations, and schedules of the intended proposal.

The background information includes basic contact information, and questions regarding the organization of the firm. Questions include: if the firm are associated with the Blue Cross and Blue Shield of Delaware, if the firm has overall management services, and if the firm has audited financial statements and long-range plans. It should be noted that based on the statutory criteria of the Health Resources Board, it is beneficial for the firm to have a contract with the Blue Cross and Blue Shield of Delaware and have a long-range plan with the proposal. If the firm does not, it would be detrimental to their applicant status.

The review considerations section has the applicant answering how the proposal meets the seven statutory criteria listed by the Health Resources Management Plan. Of these questions, there are two sub-sections that stand out—the \textit{Need} and of \textit{Energy Conservation Principles}. The \textit{Need} sub-section requires the collection of patient origin data and also how the proposal increases utilization and uses the demographic data of patients in the firm as consideration. The Department of Health and Social Services has created formulas, for the application and Board approval to use, based on demographic data to justify changes—such as bed capacity increases. The formulas are highly volatile and subject to change. In addition to this, the energy conservation

\textsuperscript{9} Ibid.
principles in the design of the proposal has nothing to do with the statutory criteria set out and only complicates the application process.

The firms must also comply with charity care such that the firms must develop a charity care plan to provide primary medical services to indigent persons that have an annual income of 350%, or less, of the Federal Poverty Level. The multitude of obtuse questions regarding architectural barriers, alternatives to the projects, and financial feasibility of the firm only add onto the regulatory hinderance that firms have to go through in the Certificate of Public Review process.

The last section, if necessary, is immediate approval for emergency situations, in which the questions stated are rudimentary such as the Notice for Public Review.

Presentation to the Board
Thirdly, there will be a presentation by the applicant to the board and an internal staff review. These presentations are publicly available and include information that is included in the application form, information regarding the firm, their organizational structure, what they provide and their services, and plans for the proposal.

Review Committee
Fourthly, the review committee will deliberate with the applicant about the proposal. This review committee is mainly composed of staff of the Health Resources Board and will provide a recommendation to the Board as a whole if the applicant has met the statutory criteria for approval.

Decision and Appeal
Finally, the committee will report to the Board and the Board will make the decision to accept or reject the proposal. If the Board approves the proposal, the applicant must comply with all state and federal licensing requirements for the operations of the proposal. The decision of the Board on the proposal is subject to a maximum review period of 90 days.

A public hearing request can be made to the Health Resources Board if deemed that there is newly presented information, changes to the operations, or failure in procedure adoption by the applicant. In addition to this, there may be an appeal to the decision of the Health Resources Board, in which the Superior Court of Delaware will now have jurisdiction to determine if the Health Resources Board acted accordingly.
Since 2000, there have been three cases on appeal to the Superior Court of Delaware: *Genesis Healthcare v. Delaware Health Resources Board* (2015), *Broadmeadow Investment LLC v. Delaware Health Resources Board, et al.* (2012), and *Nanticoke Memorial Hospital, Inc. v. Delaware Health Resources Board, et al.* (2008). These cases took over two years to handle each dispute and illustrates the inefficiencies of having the Certificate of Public Review Process.

Inherently through the rigorous application process and the necessity to conform perfectly to all the statutory guidelines and principles of what the Health Resources Management Plan states, as well as the appeals and public hearing process, the Certificate of Public Review Process creates a larger barrier to entry into other markets for current health-care providers and those trying to enter the market in the first place. Not only does this create inefficiencies in Delaware’s healthcare system, but the Review Process also is biased in the formation of its board with representatives with health care coverage for employers with more than 200 employees, members with business ties to the industry, as well as practitioner themselves.  

Some trends to be noted of include those proposals that got approved by the Health Resources Board. Christiana Care, Beebe Healthcare, and BayHealth have the most approvals in the last decade and amounting to approximately $892 million. Moreover, those health care service providers such as the Delaware Veteran Home and a vast majority of other providers only have one proposal approved with each averaging around $2 million dollars for each improvement.

**Court Challenges**

The appeals process for decisions made by the Health Resources Board are subject to review for 90 days and anyone can make an appeal on the decision to the Superior Court of Delaware. It is evident through the court cases, such as the three cases discussed below from 2000-2019, that the appeals process creates monopolistic practices for those firms already in the system and only hinders the development of health care in terms of quality and accessibility. Often times these appeals process drags on the review process for 2-3 years and there are symptoms of political bias in a system that is not supposed to be.

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The Center at Eden Hill, LLC submitted a Certificate of Public Review to the Health Resources Board for approval of a 80-100 bed skilled nursing facility in Kent County, Delaware. Genesis Healthcare which is also an operator of skilled nursing facilities appealed the decision of the Delaware Health Resources Board of approval of the CPR for Eden Hill. During the public review, it was noted that Eden Hill had failed two statutory criteria for approval, not complying with the Health Resources Development Plan and not being in line for the proposed population. The Superior Court of Delaware ruled in favor of Eden Hill stating that the Board had the regulatory power to view the statutory criteria holistically and approve the application.

The case was appealed to the Supreme Court of Delaware on the issue of timeliness of the application and further proceedings. The Board had extended the deadline for materials to be submitted for public review from both Genesis and Eden Hill, and Genesis argued that the lack of timeliness was a technical error for which the Board erred. The Supreme Court of Delaware dismissed the appeal and stated the Board’s decision was final.

This case is clear evidence of the inefficiencies of the Delaware Resources Board in determining the degree and standards for approval and how the public review process inherently keeps competition out. The appeals process is a barrier to entry as there are firms already in the process that will continue to appeal and lobby for other firms to enter the market through the judicial and administrative processes.12

Broadmeadow Investment LLC., v. Delaware Health Resources Board and HealthSouth Middletown Rehabilitation Hospital, LLC. (2012)

Broadmeadow Investment operates a nursing home in Middletown, Delaware and was granted a certificate of public review in 1996 to construct and operate a nursing home, which was finished in 2005. In 2010, Health South filed an application to the Health Resources Board to create a 34-bed rehabilitation center in Middletown, Delaware, in which the application was approved. Broadmeadow would appeal the approval to the Superior Court of Delaware, such that Broadmeadow did have standing to appeal the decision of the Health Resources Board providing approval to Health South.

Broadmeadow appealed on the grounds that the new competition from Health South would

12 Genesis Healthcare v. Delaware Health Resources Board, No. 214 (Del.2015).
reduce revenue and that they feared outside competition. The Superior Court granted the motion to dismiss on the case such that Broadmeadow did not have standing.

Broadmeadow would then appeal to the Supreme Court of Delaware, in which the decision of the Superior Court was reversed such that “any person” qualifies Broadmeadow to have standing and appeal the decision of the Health Resources Board. In addition to this, Broadmeadow claimed that there was political bias in the decision as the prior two applications from Health South failed, but after changes in the Board membership the application was approved.13

*Nanticoke Memorial Hospital, Inc. v. Delaware Health Resources Board, et al. (2008)*

In this case, Nanticoke Memorial Hospital was appealing the decision of the Delaware Health Resources Board of providing approval to the application of Certificate of Public Review to the Seaford Specialty Surgery Center. The main reason is that Nanticoke claimed that “since all of [Seaford’s] operating rooms are not being used, the community does not require an [ambulatory surgery center].” For multiple times in the committee meetings, there were memorandums and extensions given to review and rebuke arguments from both sides during the Public Review process. When the decision to approval was given by the Board, Nanticoke appealed the process to the Superior Court of Delaware where their appeal was unsuccessful as they did not have standing in the “Appeal-Applicant” section of the statute. The Certificate of Public Review process by the Seaford Specialty Surgery Center was started in 2006 and ended with the opinion by the Superior Court of Delaware two years after.14

**Generalized Arguments Against and For the Repeal of Certificate of Need Laws**

*Arguments for the Need of Certificate of Need Laws*

With the growing costs of Medicaid and Medicare in the 1970s and into the 1980s, there was the notion that an increase on the supply-side of the health care market would create excess capacity and thus increase the prices overall for health care service providers to their patients. Excess capacity refers a mismatch between the demand for a product of its

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13 Broadmeadow Investment, LLC, v. Delaware Health Resources Board and HealthSouth Middletown Rehabilitation Hospital, LLC, No. 175 (Del.2002).
14 Nanticoke Memorial Hospital, Inc. v. Delaware Health Resources Board, a Delaware Independent Public Instrumentality; and Seaford Specialty Surgery Center, LLC, a Delaware Limited Liability Company, No. 07A-12-005 (Del.2008).
potential output compared to the actual output. Excess capacity can be beneficial to the consumers in some sense if the companies provide lower prices so the firm can pay for their fixed costs. In this case of health care, the excess capacity was created due to overinvestment in health care services and the government wanted to limit excess capacity in order to reduce the amount of lost resources.

Moreover, the American Health Planning Association states that, “The rationale for imposing market entry controls is that regulation, grounded in community-based planning, will result in more appropriate allocation and distribution of health care resources and, thereby, help assure access to care, maintain or improve quality, and help control health care capital spending.”

Present-day CON arguments state that through these regulations, they create safety nets and increase access and affordability to the indigent and in rural communities to hospitals and other health care facilities. This is either through the charity policy care provision, as previously mentioned, or having statutory guidelines for proposals to include impacts on those indigent. Delaware has both of these criteria, both in how the firm addresses those participants that are on Medicaid and are uninsured or underinsured, as well as having the firm comply to have a charity plan as a conditional for acceptance of the proposal.

One last argument comes from the Economic Alliance for Michigan, in which they state that by government regulation and restriction on the supply of health care services through restricting geographic expansion, keeping excess bed capacity to a minimum, and making it more difficult for for-profit hospitals to enter the market, there is a limitation on the excess capacity of the health care market and thus a reduction on the average prices.

Arguments for the Repeal of Certificate of Need Laws
As the federal mandate was repealed in 1987, the federal government and private insurance was not held responsible to reimburse health care expenses on a cost-plus basis, which is reimbursing the company for expenses and a fixed amount of profit. The argument during this time was that by having the repeal, hospitals can negotiate with healthcare providers over prices and this would benefit the consumer. In contrast to the federal repeal, many states still had their CON process in place, even without the backing of federally mandated grants. As a result, state CON laws, just like in Delaware, deceivingly tax consumers in order to provide for those less fortunate.

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15 Tracy Yee, et al., Health Care Certificate-of-Need (CON) Laws: Policy or Politics?
16 Ibid.
The arguments of excess capacity are completely contradictory to what we know of the health care market in the 1970s and 1980s, retrospectively. A study by Tracy Yee and co-authors that examined the impact of CON laws in six states before and after their repeal found that the Medicaid payment reforms had a larger impact on maintaining health care costs than CON programs. In addition to this, the argument of excess capacity was dismantled when capacity issues peaked in the 1990s and then the market self-corrected itself by naturally lowering average prices overall among competitors.

From this same study, they found that among all six states, the repeal of the CON process increased provider competition in rapidly growing geographically urban areas and in health care services that are considered lucrative. This is in contrast to rural areas, where they found that the repeal of the CON process had negligible impact.

Studies from Georgia State University and Duke University both confirm the findings from Tracy Yee and co-authors. In the Georgia State University Study, they found through a multi-state analysis that CON regulation creates higher prices for private inpatient care and creates less competitive markets. From the Duke University study by Dr. Christopher Conover and Dr. Frank Sloan they, “examined data through 1982 and found that CON was associated with a 20.6 percent increase in hospital spending and a 9 percent increase in spending on other health care. Overall, the study found that CON was responsible for a 13.6 percent increase in per capita spending on personal health care services.” They also found that CON laws resulted in a 2 percent reduction in bed supply and increased costs per day and per admission at hospitals.

The process of many CON programs themselves are inherently inefficient and create monopolistic practices—government sponsored cartels, in a fashion. The lengthy review process, including that of appeals, can negatively impact the quality of health care services, especially as it pertains to the acquisition of technology and medical advancements. Moreover, hospitals and board members that are facilitators on CON approval boards can protect their own market shares as a barrier of entry if they find the CON process with one of their competitors to be onerous.

19 Tracy Yee, et al., Health Care Certificate-of-Need (CON) Laws: Policy or Politics?
The Case for Repeal of the CON Law in Delaware

A seminal study by the Mercatus Center, a research center at George Mason University, looked at the impact of repealing the CON law in over 35 states. Fellows, Matthew D. Mitchell and Christopher Koopman, cited that in the State of Delaware, there would be a $270 saving on total health care per capita and $99 savings in physician spending per capita without the CON law. With approximately one million residents in Delaware, this would equate to a $270 million saving on total health care and a $99 million savings in spending on physicians.

In addition to this, the research found that there would be greater access to healthcare services, especially in rural areas. The study estimates that total hospital numbers will increase 42% and the number of ambulatory surgical centers would increase by 17%.

Finally, on the issue of quality, there would be a decrease in the mortality rate and readmission rate across the board. In addition to this, there would be an estimated 5.8% less post-surgery complications and 4.8% increase in patient ratings all if the CON laws had not been in place.²⁰ It is evident on the key issues of price, accessibility, and quality that the repeal of the CON law in Delaware is not only needed, but also essential to the wellbeing of the consumer.

It is clear that the old arguments regarding excess capacity in order to reduce the increasing prices are inherently wrong. The issue with the charity and protecting the underinsured and uninsured is that the current CON process uses market share and power to divert spending from health care providers to those less fortunate. Instead of mandating a monopolistic practice between health care providers and creating a larger barrier to entry, incentives such as tax-breaks can be more efficient in lowering the average price and protecting those uninsured.

Case Studies of Industries in the Healthcare Market with Certificate of Need Laws

Nursing Home and Long-Term Care
In a study by the National Institutes of Health by David Grawbowski and co-authors, they found that the elimination of CON programs did not have a significant impact on nursing

homes or long-term care costs. Nursing homes admit higher paying private residents first and then Medicaid recipients. From studies using the National Nursing Home Survey of 1973-1974 and a survey of nursing homes from 1980 through 1993, they found that with the CON program there was higher occupancy rates and higher operating costs per resident. **Inherently, the system combined with the CON program discriminates against those less fortunate because they are last in line to get into long-term care and by having higher rates, they become more and more unable to pay.**

The study found that if CON laws were repealed, Medicaid individuals would gain higher access to nursing home services and there would be an expansion in the supply of nursing homes, which would reduce the operating cost per resident.

**Currently, since 2014 Delaware has a 5-year restriction on the expansion of bed capacity in nursing homes. This, as previously mentioned, will increase the occupancy rates and thus higher operating costs.**

A similar study by Momotazur Rahman and co-authors found that the repeal of CON laws in 10 states did not increase the Medicaid spending on nursing home care. Moreover, they found that CON laws led to a decline in the number of home health agencies and that the market power that nursing homes have due to CON laws does not allow for the market to operate efficiently—implying a government regulated monopoly.

**Dialysis Industry**

For the dialysis industry, there are two issues that CON regulations have had—one of the issues of expansion and the other on the quality of healthcare. In a study by Jon Ford and David Kaserman in the Southern Economic Journal, they found that **CON laws have restricted supply and increased firms’ concentration in the dialysis industry** that were already existing. The CON regulations in the dialysis industry creates a negative impact and limits the expansion of capacity.

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Authors state that there are three main reasons for the decreased quality of health care and the limit of expansion due to CON regulations. First it is because private investors have access to more knowledge and capacity to the market. Secondly, firms already in the industry will reduce competition from coming in. Finally, CON regulation reduces net investment in the industry—an industry where medical advancement is a necessity and rapidly improving.23

Cardiac Care
There is one metric that cardiac care mainly focuses on and that is mortality rates. In a study in Health Services Research by Vivian Ho and co-authors, they found that states that had dropped their CON laws also had lower mortality rates for cardiac care.

Moreover, they found that states that had dropped the CON requirement for cardiac care have unadjusted mortality rates relative to CON states, and this trend was persistent from 1995 to 2002. The authors also found that the removal of CON law was correlated with a 29 percent drop in mean hospital volume, but also a 12.1 percent increase in the number of hospitals performing PCI. It is from this, that with cardiac care CON laws may be successful in restraining cost growth but at the cost of occupancy rates and accessibility.24

Case Studies of States with Certificate of Need Laws

Washington
In a meta-analysis by the University of Washington’s School of Public Health and Community Medicine, they concluded that the State of Washington’s (who repealed their CON law) CON law did not control the overall health care spending or hospital costs. On the other aspects of quality or accessibility, their study was inconclusive. The study stated that CON programs have been correlated with almost no overall reduction in hospital costs. In addition to this, they found in other states such as Arizona, Utah, Tennessee, and Ohio

24 Vivian Ho, Meei-Hsiang Ku-Goto, & James G. Jollis, Certificate of Need (CON) for Cardiac Care: Controversy over the Contributions of CON, Health Services Research, April 2009, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2677050/
that with the repeal of their CON laws there was a supply surge in multiple health care industries. With the surge in supply, there is a natural reduction in overall hospital costs.25

The Kaiser Family Foundation also found that health care costs are 11 percent higher in states with CON laws and that there is a 14 percent increase in per patient health care costs in states with CON laws.26

Illinois
An evaluation by the Lewin Group on Illinois’ Certificate of Need Program found that the CON law restricted providers and had a negative impact on the quality and accessibility of health care provided. CON laws prompted providers in Illinois to provide fewer services at higher costs and fostered anticompetitive policies. In addition to this, the Lewin Group found that CON laws slow down the shift of profitable health services from the inner-city to the suburbs and found that there was no evidence that safety-net hospitals are financially stronger in CON states when compared to states without CON laws.

Conclusion and Recommendations
It is inherently clear that the Certificate of Need in a multitude of states, including the State of Delaware, is inefficient and hinder the market forces of the health care industry. The U.S. Department of Health and Human Services, U.S. Department of Treasury, and the U.S. Department of Labor all concede that that CON program and their arguments of excess capacity is wrong and inefficient in controlling the rising health care costs—especially of Medicaid costs.27

The process of Certificate of Need is anti-competitive and does not let the market work efficiently. If there is a market for a profitable health care service, then providers that offer the lowest cost with the highest quality will gain the demographics that are needed in that area. The current process is riddled with

26 Roger Stark, Why Washington’s restrictive Certificate of Need medical services law should be repealed
political gain, excessive costs—both monetary and in time—and finally wrong economic foundations on the supply curve.

It should be then the natural conclusion in the State of Delaware that there should be a repeal of the Certificate of Public Review law. Moreover, the remedy for the charity process should not be a mandated requirement by the state government, but it is more favorable to create an incentive to assist the underinsured and uninsured such as a tax-break or a voucher system to the health care providers participating, which would improve efficiency of the charity care system.
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