

# Certificate of Need Process – Study

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Division of Compliance and Administration



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## Executive Summary

Iowa and 37 other states currently require some form of Certificate of Need (CON) process that regulates actions related to the development of or change to health care services. The CON process in this state requires the Iowa Department of Health and Human Services (Iowa HHS) to review applications through a lengthy process that includes a technical review, public notification of all affected parties, a public hearing on the application, and a formal evaluation against statutory criteria.

This report presents the results of Iowa HHS's study of the CON process which evaluated its current effectiveness and makes findings and recommendations. Iowa HHS reviewed the intent of the original law enacted in 1977, assessed the current statutory language and requirements and performed an empirical analysis of the historical decisions from 2000-2024. A discussion of the challenges to implement data-driven decision making and a summary of existing literature assessing the effects of CON on health and economic outcomes are also included.

This report concludes the following. First, the current statutory language is unclear and imprecise. Additional precision and clarity would improve the accuracy and consistency of the CON process. Second, the required data to conduct an accurate and unbiased evaluation required by law is not available to Iowa HHS. Statewide data on medical claims that include all payers, and a comprehensive database of all types of health care providers is necessary to properly evaluate CON applications. Third, the evidence presented in the academic literature suggests that repealing CON laws improves population outcomes, but many of the articles fail to consider the startup and ongoing costs to provide the care that led to these improved outcomes. The shortage of high-quality research on the overall welfare effects indicates that policymakers should carefully consider the limitations of the existing evidence. Fourth, the economic costs to administer the CON process are significant to both the healthcare system and state government. If the current law is to stand in any form, additional administrative spending is required to ensure that the CON process produces value to the taxpayer. The recommended policy changes are given below.

### **Recommendation Option A: Improve the Current CON Process**

Several changes could be made to improve the current CON process by clarifying the statutory language, standardizing the application review criteria within an economic framework, conducting formal tracking of approved projects, and ensuring access to the necessary data for rigorous evaluation. These recommendations are interdependent and would need to be implemented together.

#### **1. Statutory Definitions to be Clarified or Removed**

Many definitions in Iowa Code 2025, Chapter 10A require additional clarification. For example, precise economic definitions for costs, patient needs, access, and efficiency will improve the value of the CON process.

Section 10A.714(2)(b) calls for a determination as to whether existing facilities are operating appropriately and efficiently. The statute directs the regulator to deny a CON if it is determined that similar services *could be* delivered if existing facilities were operating appropriately and efficiently. However, if a CON is denied for such a reason, there is no guarantee that existing facilities *will improve* their efficiency to meet the demand for the services the CON applicant was proposing to provide. This requirement effectively incentivizes incumbents to operate inefficiently to block new entrants and should be removed from the evaluation criteria.

Additional examples are provided within the Analysis of the Current Policy Language section below.

## 2. Application Review Criteria to be Standardized

The review criteria required under law should be standardized using an economic framework. For example, markets should be defined using access patterns, service substitutability, and existing constraints on labor, facility capacity, and equipment.

## 3. Approved Projects to be Tracked

Approved CON applications should be tracked in a more robust manner, including project completion rates, duration, and total realized costs. Projects requesting CON extensions with significant cost increases over initial estimates should be considered carefully.

## 4. Data Representative Claims and Financial Databases

Iowa HHS currently lacks the necessary data to perform accurate, complete, and unbiased evaluations of CON applications. Historical and current claims data from all payers and a comprehensive healthcare provider database is necessary to characterize access, patient travel patterns, identify competitors, predict demand, and estimate any future cost increases. Statewide coverage of medical claims and existing facilities and providers is necessary to ensure complete and representative results.

Approved CON applications should be tracked in a more robust manner, including project completion rates, duration, and total realized costs. Projects requesting CON extensions with significant cost increases over initial estimates should be considered carefully.

## 5. Required Analysis to Improve CON Regulation

Implementing a rigorous, data-driven CON evaluation process requires significant resources. Even under the recommended statutory clarifications, standardized review

criteria, and full access to comprehensive data, each CON application requires case-specific analyses that define the geographic and service markets, cost structures, and health outcomes. This work includes constructing multiple datasets from numerous sources with different levels of aggregation, applying advanced econometric models for causal interpretation, and documenting methodologies and results for transparent review.

Under these conditions, a single application may require 8-12 weeks of concurrent work by a multidisciplinary team or 16-24 weeks if performed sequentially by a smaller team. Such rigorous evaluation may complete 2-3 applications a year without additional resources, reflecting the complexity of preparing reproducible, defensible evaluations that produce unbiased conclusions. Current application fee revenue averages \$105,000 per year, while labor costs for proper implementation would be several times higher. These high labor and financial costs highlight the substantial administrative and opportunity costs associated with maintaining CON regulation at a level consistent with the best practices of empirical economics.

### **Recommendation Option B: Implement a Less Restrictive CON Process**

Option B provides recommendations for reducing the regulatory burden of the CON process. For Option B to be successful, Option A must also be implemented.

#### **1. Updating Exclusions**

Iowa HHS's analysis (described more fully below) revealed very high approval rates (above 90% in most cases) for CON applications with projects involving behavioral health, cardiac services, imaging, intermediate care, nursing facilities, and radiation therapy. These account for only 25% of total estimated project costs but represent 80% of all applications. Such high approval rates imply that the CON process is not serving as a meaningful policy restriction in these areas. Explicit exclusions for such projects will result in a less restrictive process, reduce regulatory costs, and improve healthcare access for the population.

#### **2. Changing the Public Hearing under 10A.716**

The data within this report supports the observation that opposition from incumbent providers during public CON hearings has influenced regulatory decisions in their favor, generating real economic costs. Lawmakers should consider reforms to this process to minimize incumbent influence.

### **Recommendation Option C: Repeal Iowa's CON law**

The legislature should consider fully repealing Iowa's CON law. While the existing scientific literature has limitations and includes mixed results, the weight of evidence suggests that CON laws are ineffective at ensuring access and controlling costs and repealing them improve access and health outcomes. The arguments that CON laws

are needed to protect the community benefits that incumbent hospitals provide are neither supported by the evidence nor the original intent of the law. Policymakers must decide whether the absence of evidence justifies maintaining strict regulation.

## Purpose

In 2024 via Senate File 2385 of the 90th Iowa General Assembly, the Iowa Department of Health and Human Services (Iowa HHS) was tasked with completing a Certificate of Need Process Study. This bill required Iowa HHS to study the effectiveness of the existing certificate of need process and make findings and recommendations related to the continuation of the process or the implementation of a less restrictive alternative.

This report fulfills this requirement by providing an analysis of Iowa's Certificate of Need law and process. Through this report, Iowa HHS discusses the background and original intent of the law, provides an overview of data on CON reviews and outcomes, summarizes available literature on the impact of CON laws for both cost savings and health outcomes, and offers recommendations for potential policy and process changes.

## Effectiveness of Certificate of Need Regulation

### Analysis of the Current Policy Language

#### Language

The preamble of the 1977 Iowa Acts states the initial goal of the certificate-of-need (CON) regulation:

*WHEREAS, it is the public policy of this state that the offering or development of new institutional health services be accomplished in a manner which is orderly, economical and consistent with the goal of providing the necessary and adequate institutional health services to all of the people of this state while avoiding unnecessary duplication of institutional health services and preventing or controlling increases in the cost of delivering these services.*

In 2025, Iowa Code Chapter 10A, Sections 711-723 governs the implementation of CON regulation<sup>1</sup>. The statute defines key terms, outlines the powers and duties of the regulator (formerly the Health Facilities Council, now the Iowa Department of Health and Human Services), and specifies exemptions from CON requirements. Section 714 sets forth the criteria for evaluating applications, divided into two subsections.

Section 10A.714(1) states:

*In determining whether a certificate of need shall be issued, the department shall consider the following...*

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<sup>1</sup> Sections 724 – 729 govern uniform financial reporting, including details on required annual reports, analyses and studies by the department, data to be compiled, and civil penalties. These sections are intended to enable the department to “have available the statistical information necessary to properly monitor hospital and health care facility charges and costs”.

The law then lists 18 criteria to be considered, such as the need of the population served, the availability of alternative, less costly, or more effective methods, and the probable impact of the proposed project on total health care costs.<sup>2</sup>

Section 10A.714(2) imposes additional, stricter requirements:

*In addition to the findings required with respect to any of the criteria listed in subsection 1 of this section, the department shall grant a certificate for a new institutional health service or changed institutional health service only if it finds in writing, on the basis of data submitted, that:*

- a. Less costly, more efficient, or more appropriate alternatives to the proposed institutional health service are not available and the development of such alternatives is not practicable;*
- b. Any existing facilities providing institutional health services similar to those proposed are being used in an appropriate and efficient manner;*
- c. In the case of new construction, alternatives including but not limited to modernization or sharing arrangements have been considered and have been implemented to the maximum extent practicable;*
- d. Patients will experience serious problems in obtaining care of the type which will be furnished by the proposed new institutional health service or changed institutional health service, in the absence of that proposed new service.*

## Discussion

A cursory review of the statutory language may conclude that a clear and straightforward implementation of the law has been laid out. However, a more comprehensive review reveals that many terms can be interpreted in several ways when attempting to implement the regulation in practice. There is ambiguity in the original intent and current statutory language that presents challenges for economic analyses. For example, in an economic analysis, the following questions should be asked when implementing the law

1. What determines “necessary” and “adequate” health services?
2. How is “unnecessary duplication” determined?
3. Which type of costs should be considered?
4. What constitutes a “controlled” increase in cost?
5. How rigorous should the 18 criteria in 10A.714(1) be evaluated?
6. For 10A.714(2):

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<sup>2</sup> These are too long to list here but include various requirements to be considered by the department, such as the relationship of the proposed health service to the long-range development plan of the applicant or the relationship of the proposed project to the existing health care system. See §10A.714 (1) for more detail.

- a) What qualifies as an “alternative” or “similar” service?
- b) How are “less costly”, “more efficient”, and “more appropriate” defined?
- c) What is the threshold for “maximum extent practicable”?
- d) What defines “serious problems in obtaining care”?

A robust, consistent, and accurate implementation of CON regulation requires precise definitions and decision rules to address these questions. For example, if “necessary and adequate” and “unnecessary duplication” are defined based on consumer (or patient) preferences, then a full set of service characteristics must be considered. These may include:

- Price (out-of-pocket costs, insurance coverage)
- Clinical effectiveness
- Quality and safety
- Convenience (e.g. travel times, wait times)
- Cultural appropriateness
- Transparency and continuity of care
- Choice of provider or setting

The regulator must decide if an existing lower-quality service is “adequate” if a proposed project offers higher quality but at higher initial cost. The regulator must weigh the full costs of entry and operating fixed costs against the long-term economic benefits to consumers, including improved health outcomes.

The definition of “costs” is also pivotal. For example, the regulator could consider:

- Charges per service
- Reimbursement rates
- Total costs (fixed + variable)<sup>3</sup>
- Per capita costs

Different definitions can lead to different CON application decisions. For example, a new service might raise per-unit costs due to advanced technology but reduce total spending if it lowers utilization (i.e. lower visits) or improves health outcomes. The regulator must also consider demand responsiveness, labor availability, service substitutability, and payer negotiations. The introduction of a new higher cost service will likely impact the demand for existing substitute and complementary services. Thus, denying a project based solely on higher per-unit costs may overlook the complex nature of the market and any broader welfare gains that may result.

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<sup>3</sup> In economics, fixed costs refer to costs that are independent of the quantity of output, such as rent, maintenance, and salaries. These represent the use of resources that could be used for other economic activities. Variable costs are costs that change as the quantity of output changes, such as medical supplies. These costs can be adjusted in the short-term in response to changes in demand.

Even with a clear cost definition, the regulator must also specify what level of cost increase is acceptable. A 10% cost increase may be justified if the expected consumer benefits exceed that cost. Without proper definitions and precise decision rules, the regulator is faced with denying an application that has a higher per unit cost that generates a total reduction in spending and increases consumer welfare.

Section 10A.714(1) includes additional language with ambiguous economic interpretation within the 18 specified criteria. Some are straightforward, such as:

*b. The relationship of the proposed institutional health services to the long-range development plan, if any, of the person providing or proposing the services.*

*g. The relationship of the proposed institutional health services to the existing health care system of the area in which those services are proposed to be provided.*

These may be satisfied by simple documentation or acknowledgement. Others may require a more sophisticated analysis, such as the general equilibrium effects<sup>4</sup> of a new ambulatory surgery center (ASC) on access, health outcomes, labor markets, and insurer negotiations. The law should specify how rigorously each criterion is to be evaluated and document thresholds for approval and consistency in decision-making.

Other criteria involve counterfactual outcomes or measurements, such as:

*f. The immediate and long-term financial feasibility of the proposal presented in the application, as well as the probable impact of the proposal on the costs of and charges for providing health services by the person proposing the new institutional health service.*

*p. In the case of a construction project, the costs and methods of the proposed construction and the probable impact of the proposed construction project on total health care costs.*

These require forecasting based on proposed services, market conditions, startup costs, and long-term price adjustments.

Ultimately, Section 10A.714(1) calls for a comprehensive evaluation. While the statute only requires the department to “consider” the 18 criteria, the original intent likely calls for a more substantive analysis. This requires clear definitions and decision rules to guide consistent, accurate, and transparent decision-making.

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<sup>4</sup> In economics, general equilibrium effects refer to the broader, system-wide impacts of a policy change, beyond the immediate or direct effects. In the context of CON regulation, this means considering how approving or denying a new healthcare facility might affect not just the applicant, but also other providers, patients, labor markets, and insurers. For example, a new surgical center might improve access for patients, but also draw staff away from nearby hospitals, shift bargaining power with insurers, or reduce the financial viability of providers offering public-like services. These effects are important for understanding the full consequences of regulatory decisions.

Section 10A.714(2) is more demanding. For example, defining “alternatives” and what makes them “more efficient” or “appropriate” is complex. Medical services are highly specialized and even with access to high-quality data, defining substitutes is empirically challenging. This is the primary challenge of 10A.714(2)(a). Iowa HHS’s review of decisions from 2000-2024 revealed that these criteria determine the CON application outcome, which is consistent with the statute.

Consider an ambulatory surgery center specializing in ear, nose, and throat (ENT) services. The regulator needs to determine if medical management (e.g. nasal steroids) should be considered a substitute for surgical interventions like tympanostomy tube placement or eustachian tube balloon dilation (ETBD). The regulator also needs to consider how complementary procedures, such as adenoidectomies, should be included in the analysis. These determinations depend on current and expected demand, labor supply, and the scope of services offered by incumbents.

Once the set of substitutes or alternatives is defined, the next challenge is interpreting what it means for existing facilities to be “used in an appropriate and efficient manner” under Section 10A.714(2)(b). In several denied proposals, this criterion has been central to the final decision. For instance, a 2002 denial of a proposed orthopedic ambulatory surgery center cited the fact that incumbent hospital operating rooms were “operating at much less than capacity” as evidence of inefficiency. However, this interpretation conflates underutilization with inefficiency. In economic terms, efficiency can refer to different concepts, most commonly allocative efficiency and productive efficiency<sup>5</sup>. In perfectly competitive markets, allocative efficiency occurs when resources are distributed in a way that maximizes total social welfare<sup>6</sup>. But healthcare markets, which are generally local in nature, are rarely perfectly competitive. They are more accurately described as monopolistic or oligopolistic<sup>7</sup>. In such settings, allocative efficiency is unlikely to be achieved due to pricing power and other market frictions.

That said, productive efficiency is achieved by minimizing the cost of producing a given level of output and is relevant in this context. Fixed costs such as building space and capital equipment are sunk and do not vary with output. What matters is whether the hospital is minimizing its variable and operational fixed costs given current demand, staffing constraints, and regulatory requirements. Thus, operating rooms that are not fully booked do not necessarily indicate productive inefficiency.

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<sup>5</sup> Productive efficiency implies that a producer cannot increase the production of one output without sacrificing the production of another.

<sup>6</sup> In other words, resources are not wasted by producing goods or services that are not as valued by society.

<sup>7</sup> In economics, markets are often categorized by how many sellers exist and how much control they have over prices. Monopoly is characterized by a single firm that has market power and the ability to change the price of a good/service and earn excess profits. Oligopoly is characterized by a few firms and significant barriers to entry.

Moreover, the current statute does not provide a mechanism to address or correct alleged inefficiencies in incumbent facilities. If the regulator denies a CON application on the grounds that current facilities are being used in an inefficient manner, but no policy intervention follows to improve that efficiency, Section 10A.714(2)(b) may inadvertently incentivize underperformance. Furthermore, it may incentivize strategic behavior by incumbents: by suppressing capacity or delaying investment to appear inefficient they can effectively block new entrants. This undermines the regulator's ability to assess true market need and may reduce the efficiency of the overall market.

Finally, defining "serious problems in obtaining care" under 10A.714(2)(d) is essential. The regulator should decide if and how much travel times, waiting times (or time-to-treatment), and out-of-pocket costs should contribute to determining if serious access problems exist. Consumer preferences vary, with some patients willing to travel farther for better care while others may not. Revealed preferences (e.g. observed willingness to travel or pay more) can offer insight but are difficult to measure. Section 10A.714(2)(d) is inherently difficult to measure using *observed* patterns of care, as this only represents consumers with the ability and willingness to obtain care. In other words, those with the most serious problems in obtaining care include patients who are not seeking care, which is *unobservable* in the extreme. A consistent, data-driven approach is needed to implement this criterion.

### **Analysis of the Data from Iowa's CON History**

To evaluate the history of Iowa's CON regulation, Iowa HHS compiled two distinct datasets based on materials submitted by applicants, supporting and opposing parties, and official decision documents. The first dataset includes information that was scraped from the history of Certificate of Need Decision documents from 2000-2024. These documents, almost exclusively portable document formats (PDFs), include information on the applicant organizations, the application of decision type (e.g. application, extension request, rehearing request, cost overrun/modification), the project description, the expected cost, if affected parties in support and/or opposition were present, the hearing date, and the decision.

The second dataset covers a subset of projects from 2011-2025 and was compiled manually due to the structure of historical recordkeeping. This dataset complements the first by including the date of application submission which was used to calculate the length of review and the number of supporting or opposing letters received for each project.

Appendix Table 1 summarizes the 2000-2024 data. Of the 638 total decisions, 333 were applications and 276 were extensions. The remaining consist of cost overruns or rehearing requests. Approval rates were high: 87% for applications and 99% for extensions. Notably, no cost overrun or modification requests were denied. In contrast, rehearing requests had a much lower approval rate of 36%, suggesting that once a decision is made, it is rarely revisited.

Appendix Table 2 shows the application approval rates and counts by year, demonstrating some variation over time. The average number of applications with hearings in the years after 2019 is statistically lower than the average number of applications with hearing in the prior years, likely reflecting the impact of COVID-19 on providers' ability to expand or change health services<sup>8</sup>. This trend aligns with the peer-reviewed findings that CON regulations made it more difficult to expand services in response to increased demand during the pandemic (Mitchell & Stratmann, 2022) (Choudhury, Ghosh, & Plemmons, 2022).

Further investigation highlights important variation in the application counts and approval rates by the type of service or stated project purpose. Using the project descriptions, Iowa HHS categorized the applications into 12 unique service types for analysis. These include ambulatory surgery services, behavioral health, birth centers, cardiac services, general hospitals, imaging and other equipment, intermediate care facilities, long-term care, nursing facilities, radiation therapy<sup>9</sup>, rehabilitation, and other services.

Table 3 in the Appendix reports these statistics. Long-term care applications, broadly defined, have the lowest approval rate at 46%, followed by hospitals and ambulatory surgery centers at 60% and 67%, respectively. Those with the highest approval rates include cardiac services and imaging/equipment applications at 96% and intermediate care facilities at 95%. Table 1.3 reports these statistics by grouping the purpose of an application into four distinct categories, including bed capacity changes, new health services, replacement/relocation, and other/uncategorized. Replacement or relocation applications have approval rates at 100% and bed capacity changes at 95%. New health services are less likely to be approved at 80%.

Overall, these high approval rates suggest that the CON regulation may not be functioning as a binding constraint on investment decisions for certain project types. From an economic perspective, if approval is nearly guaranteed, providers may have made the same investment decisions even in the absence of regulation. This raises questions about whether the administrative costs of CON review are justified by marginal benefits in cost control, access, or quality assurance. For regulation to be effective, there must be a credible threat of denial.<sup>10</sup> Given that CON hearings are

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<sup>8</sup> See Table 12: T-test for Difference in Means in the Appendix for the formal statistical test. Note that a simple comparison of means before and after the pandemic doesn't necessarily isolate the causal effect of the pandemic on the number of CON applications. It is likely that the nursing facility long-term bed moratorium that temporarily paused the new construction of a nursing facility of permanent increase in bed capacity that began July 1, 2023, explains some of the decrease in applications in 2023 and 2024.

<sup>9</sup> Note Iowa HHS specifically separated radiation equipment from imaging and other equipment to be included in radiation therapies.

<sup>10</sup> A binding constraint is some requirement that limits behavior and acts as a barrier that prevents certain actions unless specific conditions are met. CON regulation is intended to be a binding constraint on healthcare investment by preventing unnecessary or duplicative services that increase costs without commensurate benefits.

public, providers likely factor in approval probabilities and weigh them against startup costs and expected returns when making investment decisions.

Understanding the economic costs associated with Iowa’s CON regulation is essential for informed policymaking. These costs can be separated into direct and indirect components. Direct costs may include the application fees paid by the applicants, the labor and administrative costs associated with application review, potential legal/consulting fees or labor costs incurred as a result of developing and supporting the application. Iowa HHS currently lacks data on the time or costs associated with preparing and supporting applications in Iowa<sup>11</sup> but do have estimates of the application fees collected.

Table 6 reports the total project costs and fees by decision for CON applications. From 2000-2024, a total of \$1.3 billion in project value has been approved and over \$450 million denied. This represents 291 approvals and 42 denials. In the absence of regulation, this \$450 million is a lower bound on forgone investment. The true figure is likely higher, as it excludes any projects deterred from applying. Approximately \$2.6 million has been collected by the state in application fees over these 25 years, equivalent to \$104,552 per year. Table 2.2 highlights the variation in fees collected by proposed service type,<sup>12</sup> with some denied projects having lower average project costs and fees than approved projects for the same category of service. We return to discuss to this observation in more detail below.

Indirect costs include opportunity costs from review delays. These vary by project. For example, a bed capacity change with no capital costs could generate revenue immediately, so delays represent lost income. A new outpatient facility with a five-year timeline might have begun serving patients months earlier without regulatory delay. The present discounted value of these foregone services is a meaningful cost. Additionally, the time and effort spent by parties in opposition (and support) that participate in the review process are additional costs associated with this regulation.<sup>13</sup> We return to the discussion of incumbent opposition below.

Using the second dataset, the average review period from submission to decision was 150 days for projects between 2011-2025. The interquartile range shows that 75% of applications took more than 56 days, and 25% took over 133 days. Applying these figures to all 333 applications from 2000–2024 yields an estimated cumulative review

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<sup>11</sup> Data on preparation costs and time would be very useful for a more complete evaluation of these administrative costs. (Conley & Valone, 2011) estimate that for North Carolina in 2011, per application preparation consulting fees were between \$25,000-\$50,000, public hearing consulting fees between \$2,000-\$15,000, and appeal costs up to \$300,000, for a total between \$27,000-\$365,000.

<sup>12</sup> This is an approximation based on the fee formula and stated project costs in each application received from 2000-2024.

<sup>13</sup> For example, in many public hearings, opposing parties have organized members to speak or present prepared materials to support the case against a proposed new service. These organizational, preparation, and time costs may be substantial, and rational incumbents would be willing to spend resources to secure a favorable outcome below the expected loss in revenue from entry.

time of at least 14,000 days. While some reviews occurred concurrently, each application represents a distinct economic opportunity cost tied to its timeline, financing, and service delivery.

We can estimate these costs using reported project values and assumed capital returns. Table 2.1 reports the reported total project costs. Assuming a 5% yearly return on capital and 56 days of review, the opportunity costs for capital would be over \$13.6 million. Assuming the mean review period of 150 days, these opportunity costs rise to over \$36.5 million.<sup>14</sup> These are conservative estimates, as they exclude the 30-day letter-of-intent period and ignore costs borne by opposing parties.

In sum, the application process alone imposes substantial costs, including application fees, regulatory labor, preparation and opposition efforts, and opportunity costs from delays. While these quantify the costs of delayed capital investment, they do not capture the full social costs of restricted entry of health care services.

### **Analysis of the Welfare Implications of CON Regulation**

From a welfare economics perspective, evaluating CON regulation requires considering its impact on both consumers (patients) and providers. Although the 1977 Iowa Acts preamble does not precisely define “costs”, the stated goal of CON regulation in Iowa is to ensure the provision of necessary and adequate health services while avoiding unnecessary duplication and controlling costs. A rigorous analysis must account for the complexity of healthcare markets, including commercial insurance dynamics, administratively set reimbursement rates for public insurance, labor constraints, and the geographic and service-specific nature of healthcare markets.

Consider the regulator’s role as a social planner: maximizing consumer welfare subject to budgetary limits, regulatory capacity, and system-wide goals such as access, quality, and cost containment. The regulator must weigh the costs of new entry, including regulatory and opportunity costs, against the consumer benefits from increased access, quality, and competition. In a formal economic model, it is common to assume that health care prices are fixed in the short run, as many are administratively set (e.g., Medicare, Medicaid) or negotiated in advance by commercial insurers. As a result, providers often compete among non-price dimensions, such as quality, convenience, and safety (Gaynor, Ho, & Town, 2015).<sup>15</sup>

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<sup>14</sup> Another approach could assume a daily opportunity cost that depends on forgone revenue, which would vary significantly by service type. For example, assuming daily revenue of \$1200 per patient and several patients served, the opportunity costs would sum to the same order of magnitude of the capital approach.

<sup>15</sup> It is possible that some new entrants or providers entering new geographic areas may face uncertainty in payer negotiations, delays in credentialing or network inclusion, with some initial price disadvantages if providers are out-of-network for the local set of consumers. In the long run, prices are not fixed and can change as health outcomes, input costs, and risk profiles change.

On the supply side, entry costs include application preparation, legal and administrative costs (including costs of opposing applications by incumbents), time delays (opportunity costs of capital and service delays), and facility construction/renovation. Post-entry fixed costs, such as building costs, maintenance, salaries, and equipment, must also be considered. In the absence of CON regulation, the relevant costs include startup costs and post-entry fixed costs (Cutler, Huckman, & Kolstad, 2010).

On the demand side, consumer welfare is generally measured by consumer surplus<sup>16</sup>. Consumers may see welfare gains along several dimensions, including geographic and temporal access, higher quality (better outcomes, lower infection rates, better amenities), and lower costs. While prices are often fixed in the short run, shifting services to lower-cost settings can yield significant savings for consumers.<sup>17</sup> General equilibrium effects also matter. For example, new entrants may pressure incumbents to improve efficiency or may reduce the capacity of incumbents to provide public-like services such as emergency care.<sup>18</sup>

Although the regulator’s problem is conceptually clear, it is empirically challenging to solve. Consider a relatively simple application to replace a PET scanner with a PET/CT scanner at a cost of \$6.06 million<sup>19</sup>. The entry and regulatory costs include the application preparation and certificate of need hearing participation. Opportunity costs include delayed service. Entry and regulatory costs include application preparation and participation in the CON hearing. Opportunity costs stem from delayed service availability. Fixed costs include the scanner itself, facility upgrades, maintenance, and staffing. Reimbursement rates for PET/CT may differ from PET alone but bundled payments and fixed short-term prices complicate cost comparisons. Differences in reimbursement rates by payer adds additional complexity.

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<sup>16</sup> In its simplest definition, consumer surplus is given by the difference between a consumer’s maximum willingness to pay for a given health service and the price, or out-of-pocket costs, aggregated across the entire population receiving the service. This maximum willingness to pay for a given service may depend on several non-price attributes, such as quality. Quality is a service attribute in health care that is likely highly valued.

<sup>17</sup> The amount of consumer savings will depend on the insurance coverage of the individual, including deductible amounts. Lower prices may result in lower deductible payments, or rather the value of a consumer’s deductible effectively increases. Long-term savings may be reflected in adjusted premium rates if new entrants lead to better health outcomes and these lead to lower spending by payers.

<sup>18</sup> Recall that general equilibrium effects refer to the broader, system-wide impacts of a policy change. In this context, general equilibrium effects may include increased competition that leads to reduced costs for incumbent providers. General equilibrium effects may also result in incumbent providers cutting services as a direct result from this increased competition, which may include “public-like” services. We refer to public-like services in the sense that no services are truly public services/goods in the standard economic sense, meaning services that are non-excludable and non-rival. For example, ER services or charity/indigent care are rival: ER and facility space to provide charity/indigent care have capacity limits for which one person’s use of the service necessarily diminishes another’s. Hospital and other medical services that cannot exclude individuals from receiving the services might be considered common-pool resources.

<sup>19</sup> In 2002, a certificate of need was approved for a replacement PET/CT scanner at an estimated project cost of \$6.06 million.

On the demand side, benefits include improved diagnostic accuracy and earlier treatment, which may lead to better outcomes. These benefits can be monetized using the value of a statistical life (VSL) or quality-adjusted life years (QALYs). The key unknown is the magnitude of consumer welfare gains from replacing a PET scanner with a PET/CT scanner. Facility type also matters. If the scanner is located in a for-profit outpatient setting, the regulator must consider how this affects demand for PET services at existing providers and whether it undermines the provision of public-like services. Defining the relevant geographic market is also critical. For example, the regulator must determine if the service area is limited to a few counties or if it spans one of the state’s seven insurance rating areas.

The welfare test compares regulatory and fixed costs to clinical benefits and spillover effects within the relevant service and geographic markets. Without reliable estimates of these costs and benefits, the regulator cannot make an informed and accurate decision.

In the absence of the regulation the applicant would have likely procured the replacement equipment. Thus, CON regulation imposes additional costs that require proportionally greater consumer benefits to justify the investment. To approve the \$6.06 million project, the regulator must believe that patient benefits exceed the sum of project costs, ongoing capital and maintenance expenses, and regulatory costs. Without regulation, the threshold for welfare improvement would be lower.

Now consider a more complex application: constructing a new ambulatory surgery center (ASC) for specialized ENT services at a project cost of \$12 million. Some proposed services could be performed in existing outpatient hospital settings, while others require the specialized staff of the new ASC<sup>20</sup>. If the regulator has access to detailed information on equipment, facility costs, and post-entry fixed costs, the total costs can be approximated.

The primary challenge lies in estimating demand-side and general equilibrium effects. First, the regulator must define the relevant service market. This involves identifying which procedures are substitutes, using economic concepts such as cross-price elasticity<sup>21</sup>. For example, radiofrequency thyroid tumor ablation and hypoglossal nerve stimulation are unlikely substitutes, while tympanostomy tube placement and eustachian tube balloon dilation may be. Once the service market is defined, the geographic market must be determined. Most healthcare services are locally supplied, though telehealth is an exception. Geographic markets can be defined using hospital service areas (HSAs), hospital referral regions (HRRs), Primary Care Service Areas (PCSAs), marketplace

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<sup>20</sup> For example, suppose one of the sponsoring surgeons is the only pediatric otolaryngologist and facial traumatologist in the state.

<sup>21</sup> The cross-price elasticity demonstrates how the quantity of a particular surgery changes as the prices of other surgeries change. A positive cross-price elasticity implies that as the price of tympanostomy tube placement increases, the demand for eustachian tube balloon dilation increases. A negative cross-price elasticity would imply that these two services are complements, as a positive increase in price would lead to a decrease in the demand for the other.

rating areas, commuting zones, or community detection methods<sup>22</sup>. Given that willingness to travel changes over time, flexible approaches like community detection may be more appropriate<sup>23</sup>.

Once service and geographic markets are defined, the regulator must estimate consumer benefits from ASC entry. A new facility may improve access by reducing travel and wait times. For services with existing substitutes, entry affects incumbents based on attributes such as staffing, quality, pricing, and proximity. If the ASC offers lower prices and higher quality, consumer welfare is likely to increase. For novel treatments, welfare gains arise from previously unmet demand.

However, if ENT services shift from hospitals that provide public-like services to the ASC, the regulator must consider the broader implications. Suppose ASC prices are lower than hospital prices for overlapping services. Some demand will be new, driven by lower prices and increased availability. The amount of this new demand depends on characteristics of these services, such as the travel times, number of operating rooms, and the price and quality elasticities<sup>24</sup>. Other demand may shift from incumbents, the magnitude of which will depend on how patients substitute between the ASC's and incumbent's services (i.e. the substitution elasticities).

To assess the welfare impact of this shift, the regulator needs additional information. The regulator needs to determine if incumbent hospitals are nonprofit and exempt from taxes, the value of their forgone tax revenue, and the value of their community benefits. The regulator also needs to know the markups on ENT services, and how much of these profits subsidize community benefits. It is also imperative to know if incumbents are operating efficiently or if ASC entry could prompt cost-saving reforms. For example, lobbying expenses or legal fees used to oppose CON applications might be redirected toward efficiency improvements.

Opposition to CON applications also sends a signal to the regulator. Incumbents incur costs to oppose applications, including organizing letters, attending hearings, acquiring legal representation, and lobbying. If an incumbent chooses to oppose, they incur a cost

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<sup>22</sup> Iowa CON review doesn't use any of these standard approaches for defining the geographic market. Instead, the relevant geographic area is defined under Iowa Administrative Code (IAC) 481—2202.1. “For applications regarding hospitals, hospitals located in the same county and in Iowa counties contiguous to the county wherein the applicant hospital's proposed project will be located. 2. For applications regarding health care facilities, other health care facilities located in the same county and in Iowa counties contiguous to the county wherein the applicant's proposed health care facility will be located. 3. For applications sponsored by other than the hospitals or health care facilities specified in paragraphs “1” and “2,” those providers within the same county who offer similar service or might logically be viewed as potential providers of such service.” This approach is not sufficient as the relevant market for one type of service inherently depends on the current availability of those services and the willingness of the consumers to seek such services, not a fixed county-level definition that is otherwise arbitrary.

<sup>23</sup> See <https://graveja0.github.io/health-care-markets/> for a discussion on community detection.

<sup>24</sup> A quality elasticity is similar to the notion of a price elasticity. The quality elasticity tells how changes in quality leads to changes in the quantity of the services demanded. Given that prices are fixed in the short run in healthcare markets, quality elasticities are important relationships to identify.

C and reduce the probability of approval to  $p_o$ . If the application is approved, the incumbent loses an additional amount,  $A$ , through competition. If they abstain from opposing, the probability of approval is higher,  $p_a$ , and face a competitive loss of  $A$  if approved. Thus, the incumbent is willing to spend up to  $[p_a - p_o] \times A$  to oppose a project. This implies that opposition spending reflects the expected revenue loss from new entry.

Table 5 shows that approval rates are substantially lower when opposition is present. For example, applications for ASCs, behavioral health, birth centers, and rehabilitation services were over 50 percentage points less likely to be approved when opposed. Long-term care and nursing facility applications were nearly 20 percentage points less likely to be approved when opposed. While these are summary statistics and other factors may help explain these differences (e.g., project cost, new construction, council composition), the overall pattern is striking.

To further investigate, Iowa HHS ran regression models to control for project costs, service types, project purposes, new construction, and time (month-by-year) effects to isolate the effect of opposition on the likelihood of approval. Table 11 shows that opposition is associated with a 32-percentage point reduction in the approval probability. This represents a 36% reduction relative to the mean and is significant at the 1% level<sup>25</sup>. This suggests that incumbents may be willing to spend up to 32% of their expected revenue loss to oppose new projects. These findings are consistent with the political economy literature on the effect of lobbying and incumbent opposition on certificate of need regulatory decisions (Stratmann & Monaghan, 2017)(Ohlhausen & Luib, 2015).

This discussion illustrates the complexity regulators face when evaluating CON applications. Some proposals involve straightforward cost-benefit tradeoffs, such as equipment replacement. Others, like new specialty ASCs, require nuanced analysis of market definitions, substitution effects, and spillovers. In all cases, the regulator must determine whether consumer benefits exceed the full costs of entry, including those imposed by the regulatory process.

### **Analysis of the Literature on CON Regulation**

The existing literature on certificate-of-need regulation spans several disciplines, including law, policy, and economics. The reports and literature reviews discussed below include scores of studies and reports on the history or effects of certificate-of-need regulation. Rather than repeat those detailed discussions here, Iowa HHS directs

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<sup>25</sup> It is important to note that these results are suggestive, rather than causal, as there may be additional unobserved factors correlated with opposition being present that may affect the size and significance of this result. For example, the proximity to existing healthcare facilities may be positively correlated with opposing parties being present at a public hearing, indicating that the reported effect is overstated. This level of analysis is beyond the scope of the current report.

readers to refer to these reviews and the citations therein for more detailed information and focuses on broad conclusions and articles relevant to the current report.

Several national and statewide reports have been published.<sup>26</sup> One national report ranks all 50 states by the restrictiveness of their CON laws and presents evidence that these laws may increase healthcare prices (Jones & Jones, 2024). Another national report critiques CON regulation for requiring approval for small capital investments, new technologies with minimal risk of duplication, and for lacking data-driven decision-making (Cavanaugh, et al., 2020). Two state-level reviews recommend full repeal of CON laws after evaluating their policy landscapes and summarizing the literature (Denson & Mitchell, 2023) (Smith & Scheck, 2021).

Peer-reviewed articles also contribute to the understanding of CON regulation. (Simpson, 1985) reviewed the state of CON laws during a period of expansion and repeal, emphasizing the need for continuous evaluation and adaptation to market conditions. (Conover & Bailey, 2020) reviewed 90 studies and estimated that CON regulation reduces social welfare by several hundred million dollars annually, although their confidence intervals include the possibility of no effect.

Mitchell (2024) summarizes the recent literature, finding that most articles produce evidence that CON laws are associated with higher spending per service, higher total expenditures, poorer access, and poorer health outcomes. The author proposes various options to address the limitations of the current regulation, including full repeal, a phased repeal to provide incumbents time to adapt, the elimination of certificate of need requirements for certain projects<sup>27</sup>. The author also suggests raising review thresholds, updating the standards for assessing need, ending the ability of incumbents to oppose applications, and increasing the transparency of the system. In a follow-up review Mitchell (2025) reviews 128 academic evaluations and over 450 statistical tests, concluding that CON regulation increases spending, reduces access to care, and restricts quality.

Although not peer reviewed, (Courtemanche & Garuccio, 2025) provide a working paper focused on hospitals. They assess whether studies use causal identification strategies and find many lack the empirical rigor expected in modern economics. They argue that while causal studies yield more mixed results, the overall evidence supports the conclusion that CON laws reduce competition for incumbent hospitals. They also find that quality improvements following CON repeal are more likely in services that can be delivered in both hospital and non-hospital settings, while hospital-only services show no change in quality.

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<sup>26</sup> These reports have not been published in peer reviewed journals.

<sup>27</sup> Such as projects serving harm-vulnerable populations, low-cost alternatives, and services unlikely to be overprescribed (such as dialysis, cancer treatment, or neonatal intensive care).

(Courtemanche & Garuccio, 2025) also note mixed findings on the effects of CON on the number of hospital beds, efficiency, and aggregate expenditures. They observe that Mitchell's (2025) summary, which reports that 51 percent of studies find positive effects and 36 percent find null effects, can be interpreted that finding a null effect is almost as likely as finding a positive effect from CON repeal. However, this observation is misleading to policymakers. While a substantial share of studies presents null effects from the repeal of CON, many of these results may be due to low statistical power (the ability to detect a true effect), not a true absence of effect. Therefore, policymakers should interpret null findings with caution.

The literature on the economic effects of regulation is well established, with foundational work by (Stigler, 1971), (Joskow & Rose, 1989), and (Djankov, La Porta, Lopez-de-Silanes, & Shleifer, 2002), with welfare-focused contributions by (Peacock & Rowley, 1972) and (Barr, 1992), and healthcare-specific studies by (Arrow, 1963) (Anderson, 1991) and (Gaynor, Ho, & Town, 2015). In contrast, the literature that specifically estimates the welfare effects of CON regulation is small.

Modeling the welfare effects of restricted entry, such as CON regulation, is challenging. It requires assumptions about observable and unobservable variables, including the size and recoverability of setup costs, the sensitivity of profits to entry and exit, service substitutability, expectations about post-entry competition, and the efficiency of potential entrants (Berry & Reiss, 2007). Regulatory uncertainty and the complex nature of the markets for healthcare and insurance further complicates modeling (Gaynor, Ho, & Town, 2015). (Chetty, 2009) offers an alternative approach requiring fewer economic variables, offering a general framework that can be used to answer policy questions regarding welfare with fewer assumptions.

(Kessler & McClellan, 2000) provides strong evidence that increased hospital competition through the growth in Health Management Organizations (HMOs) post 1990 resulted in substantially lower costs and significantly lower rates of adverse outcomes. In other words, under HMO payment structures, hospital competition unambiguously improves social welfare. When combined with evidence that CON laws reduce competition, the results of (Kessler & McClellan, 2000) imply that repealing CON laws is likely to increase social welfare.

Another well-designed article, (Cutler, Huckman, & Kolstad, 2010), study the welfare effects of hospital entry in coronary artery bypass graft (CABG) surgery following Pennsylvania's CON repeal. They find that repeal increased the number of hospitals providing CABG surgery and improved outcomes (reduced mortality) through greater use of high-quality surgeons. The authors find that incumbent hospital's operating margins were larger several years after the repeal of certificate of need, indicating no negative medium-term effect on hospital sustainability. Overall, the benefits of entry offset the fixed costs, suggesting welfare neutrality in this market.

(Rosenkranz, 2025) finds that CON repeal in the dialysis market increases patient welfare through better access, improved patient-treatment match, and lower congestion. The author estimates that the repeal was equivalent to reducing patient travel by over 9000 miles.

(Melo, Sigaud, Neilson, & Bjoerkheim, 2025) evaluates the effect of certificate of need repeal across North Dakota, Pennsylvania, Nebraska, Ohio, and New Hampshire. The authors find causal evidence that repealing certificate of need regulations increased hospitals per capita in both rural and urban areas, effectively increasing access for rural populations. Interestingly, the average number of beds per hospital declined more in urban areas, suggesting that urban incumbents were more affected by repeal than rural ones.

The findings of (Conover & Bailey, 2020), (Cutler, Huckman, & Kolstad, 2010), and (Rosenkranz, 2025) demonstrate that welfare effects depend on the specific market being studied. Policymakers should be aware of these limitations and the assumptions required to generalize these findings across settings. (Courtemanche & Garuccio, 2025) emphasize the need for additional research based on national data and frontier empirical methods to better understand the heterogeneity of CON effects.

Despite these limitations, the comprehensive reviews by (Conover & Bailey, 2020), (Mitchell, 2024), (Mitchell, 2025), and (Courtemanche & Garuccio, 2025) suggest that repealing CON these laws would likely improve patient outcomes and access, raise physician salaries (Bhai, 2025), enhance responsiveness to demand shocks (Mitchell & Stratmann, 2022) (Choudhury, Ghosh, & Plemmons, 2022), and would not lead to hospital closures (Cutler, Huckman, & Kolstad, 2010) (Stratmann, Bjoerkheim, & Koopman, 2025).

## Recommended Policy Options

This report has presented an in-depth analysis of Iowa's CON regulation. We found that the current statutory language lacks the clarity and structure necessary for consistent, systematic, and accurate evaluation of applications. We also summarized application and decision data from 2000 to 2024, including approval rates by service type, average project costs, fees collected, and the presence of opposing parties at public hearings. Additionally, we provided the first estimates of application review durations from 2011 to 2025.

Our statistical analysis suggests that incumbent providers have historically exerted significant influence over CON decisions, substantially reducing the likelihood of approval when opposition is present. We also discussed the direct and indirect economic costs of the regulation, emphasizing the importance of accurate cost accounting to weigh regulatory costs against potential benefits. Finally, we reviewed the literature on the health and economic effects of CON regulation, highlighting the balance of evidence that supports repeal.

Based on these findings, we offer the following policy recommendations related to the continuation of the process or the implementation of a less restrictive alternative:

### **Recommendation Option A: Improve the Current CON Process**

If any form of CON regulation is to remain in place, several changes are necessary to improve its consistency, accuracy, and objectivity. These recommendations are intended to be implemented together, as they are interdependent. Policymakers should note that enhancing data requirements and evaluation rigor will increase the administrative costs of the program.

#### 1. Statutory Definitions to be Clarified or Removed

Certain definitions in Iowa Code 2025, Chapter 10A require clarification. This includes precise economic definitions of relevant costs, patient needs, access, efficiency, appropriate, and decision rules that determine “serious problems in obtaining care”. Definitions of consumer benefits need to be clearly specified and flexible enough to apply to the wide range of project types.

Iowa HHS also recommends removing Section 10A.714(2)(b) from the evaluation criteria. This provision creates incentives for incumbents to operate inefficiently in order to block new entrants. The law does not require the regulator to investigate or correct inefficiencies, even when they are strategically manipulated.

#### 2. Application Review Criteria to be Standardized

Review criteria should be standardized using economic principles. Geographic and service market definitions should reflect travel patterns, service substitutability, and production constraints such as labor availability, facility capacity, and equipment limitations.

#### 3. Approved Projects Need to Be Tracked

Approved CONs represent the starting point for new or modified health services. The regulator should track project completion rates, time to completion, and actual costs incurred. Iowa HHS’s analysis shows that CON extensions are approved 99 percent of the time, suggesting that cost overruns rarely lead to denial. However, significant increases in startup costs may reduce the marginal benefits of entry and should be monitored.

#### 4. Data Recommendations – Representative Claims and Financial Databases

Iowa HHS’s review of historical decisions shows that the Health Facilities Council has relied almost entirely on data submitted by applicants or opposing parties<sup>28</sup>. While

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<sup>28</sup> For bed capacity changes and radiation therapy proposals, the Health Facilities Council frequently relied on additional data, such as county-level bed counts and utilization or the locations of existing linear accelerators.

applicants are appropriate sources for equipment, labor, and construction costs, the regulator should independently verify projected service volumes using market-level data. Data submitted by opposing parties, especially prepared presentations, should be treated with caution.

Currently, Iowa HHS lacks access to the necessary data to perform an accurate, complete, and unbiased evaluation of CON applications. The regulator should have access to historical data on the market for health services, including details on the consumers receiving the services (e.g. residential locations, insurance coverage, demographics), the list of services rendered (e.g. procedure codes, places of service, etc.), the reasons for the services (e.g. diagnosis codes), and the facilities and providers performing services. Statewide coverage across all insurers is required.

In addition, financial data reporting under Sections 10A.724 to 10A.729 must be enforced. Iowa HHS's internal analysis shows that only 26 hospitals reported financial data annually from 2017 to 2025. All hospitals and healthcare facilities should be required to comply. Providers should also report related-party transactions to prevent underreporting of profits (Gandhi & Olenski, 2025). These data will allow the regulator to define services precisely, assess community benefits, and evaluate provider profitability.

#### 5. Required Analysis to Improve CON Regulation

Suppose the regulator has access to the necessary improvements outlined in Option A parts (1), (2), and (4) – those relevant to the initial evaluation of an application. In other words, the relevant terms have been precisely defined, review criteria standardized, and the full universe of necessary data is available to Iowa HHS (i.e. all-payer claims, provider database, patient locations, etc.). Iowa HHS would then need to conduct intensive and in-depth analyses for each application submitted via this process. As noted above, completing these robust statistical and econometric analyses will increase the amount of state-funded administrative costs needed to properly implement the CON program.

To properly evaluate each incoming application, Iowa HHS will need a team of staff to review the unique circumstances that surround each project. While some evaluations may initially appear similar, implying that certain components of this work to be reusable, the execution of such analyses is not so straightforward. While the framework may be consistent, each CON application will require the regulator to define different services, locations, competitors, and costs unique to the characteristics of the proposed project. For example, an application proposing the expansion of cardiac catheterization will have different service definitions, relevant health outcomes to estimate consumer benefits, and types of costs than a skilled nursing facility applying to increase its bed capacity. Even similar types of projects, such as two proposals for ambulatory surgery centers, will require distinct analyses based on the set of services (e.g. ENT vs podiatry) proposed, associated market definitions, and expected patient outcomes.

To anchor the discussion, one approach to a rigorous evaluation could include the following steps. For each application, an economist might consult a clinician to determine the initial set of relevant services to the proposed application.<sup>29</sup> Next, a data analyst or data scientist would need to work with the economist to prepare and combine the multiple data sources to produce the necessary statistical files for preliminary analysis.<sup>30</sup> Additionally, the team must estimate the startup costs and fixed costs of maintaining the proposed services once operational.<sup>31</sup> The initial set of work includes testing and finalizing the service and geographic market definitions, developing statistical files appropriate for estimating health outcomes, price and cost effects, and a statistical file that can be used to estimate the effects of entry on incumbent provider sustainability. Each of these datasets will include different variables and levels of aggregation – each unique to the submitted proposal. This preliminary work would likely take one full-time equivalent (FTE) economist and one FTE data analyst/scientist at least 8-12 weeks to complete. These two FTEs could complete the preparation for evaluation for 4.3-6.5 applications, or 30-50% of the 13.3 applications received each year.

While two employees are spending all their full FTE performing preliminary analyses and preparing the data for evaluation, additional resources are needed to conduct concurrent econometric evaluations.<sup>32</sup> The estimation of the impact of the proposed project on the set of relevant measures is no small task. For example, consider the effect of a new coronary artery bypass graft service at a hospital on various patient outcomes: readmission rates, length of stay, patient travel times, cardiovascular-attributed mortality, and quality of life. Each relevant outcome may require a different econometric (or statistical) model, and the economist would need to utilize various approaches to ensure the results are robust to a range of different assumptions. For

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<sup>29</sup> For example, the economist and clinician would need to map out the likely set of procedure codes, billing provider types, place of service, reimbursement structure, and patient outcomes, among others. Consider an application for additional beds licensed and certified for skilled nursing care. The demand for SNF beds will depend on the substitution for similar services provided at home or the community (e.g. HCBS) which are not reported in institutional claim forms but billed through professional services. Thus, to identify the market for institutional SNF beds, the team must identify institutional utilization based on revenue codes and home-based care utilization based on procedure codes (i.e. HCPCS/CPT codes) as professional claims don't report revenue codes.

<sup>30</sup> For example, line-level claims will need to be run through an algorithm identifying the likely set of relevant services to be aggregated at the unit of observation (e.g. patient-level, facility-level, or market-level). Patient travel patterns need to be analyzed and combined with claim-level data to identify the relevant geographic markets, which change over time as preferences and the supply of services change. Patient outcomes need to be coded, and cost data prepared.

<sup>31</sup> For example, the start-up costs for a new facility can be estimated using fair market rates for construction costs per square foot, labor costs, and equipment costs. As discussed above, it is important for the regulator to rely on their own analyses as applicants have incentives to underreport estimates.

<sup>32</sup> To see this, suppose the previous month was spent by the first economist and data analyst/scientist in preliminary work and data preparation. In the current month, another application is submitted and thus the first economist and data analyst/scientist must start the preliminary and data preparation for the next application while a different team begins and conducts the evaluation.

example, historical data may include a previous coronary artery bypass graft service that entered the market that the regulator wants to leverage to estimate the outcomes of interest. However, that effects of such an entry will depend on market conditions in the past, some of which are unobservable. A facility may enter the coronary artery bypass graft market if they *expect* to make a profit based on the current health of the target population. Thus, using historical entry in the coronary artery bypass graft market to estimate the benefits of a new proposed CON application for coronary artery bypass graft service may bias the conclusions without the proper empirical strategy.

There are similar challenges for estimating the effects of new entry on the availability of services provided by incumbents. To estimate the effect of entry on incumbents, historical data must include similar instances in which the quantity of services, costs, reimbursements, and financials are observable. However, there are two additional challenges. First, entry is again conditional on the historical market characteristics. Second, previous entry was likely determined by CON regulation. Suppose that previous CON regulation only approved the least costly and highest quality services in the past. Estimating current expected outcomes from a new CON application based on the estimates of historical entry may bias the results. If the current application is more costly with less quality, then using historical results will overestimate the benefits of the new entrant. On the other hand, if the current applicant is less costly and of higher quality than those in the past, using the historical results will underestimate the benefits of the new entrant. Unless the quality of the proposed services is observable across time, extrapolating historical effects to current CON evaluations will be insufficient to accurately estimate the effects to inform CON decisions.<sup>33</sup> The evaluation component would likely take one FTE economist and one FTE data analyst/scientist an additional 8-12 weeks to complete.

Overall, implementing Option A would require approximately 2-4 total FTEs. Two FTEs could conduct preliminary analyses and data preparation and two would conduct the necessary evaluations to inform consistent, robust, and transparent regulatory decisions. If four FTEs worked concurrently, it would take approximately 8-12 weeks to evaluate a single CON application. Alternatively, two FTEs could conduct all the necessary work sequentially, increasing the review time to 16-24 weeks. This effectively shifts the costs from Iowa HHS to the applicants and population in the form of delayed service delivery (opportunity costs).<sup>34</sup> At this rate, the regulator could process 2.2-3.3 applications per year.

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<sup>33</sup> The challenge lies in the fact that quality of the new entrant is unobservable. Alternatively, the regulator could rely on random or exogenous variation in the source of new entry to remove this sort of selection bias. This would require additional time to identify such events that are appropriate to the application in question.

<sup>34</sup> It may be more economically efficient for the regulator to hire additional labor to reduce the length of the review process if those additional costs are lower than the opportunity costs of forgone profit and health benefits from delayed service delivery.

Finally, recall that over the past 25 years, application fees generated an average of \$104,552 per year in revenue for the regulator to administer the CON program, indicating that the administration of the CON program is likely operating at a deficit. The labor costs to implement Option A, ignoring standard administrative costs currently incurred, would likely be 3-6 times higher than the current average revenue from application fees<sup>35</sup>. This excludes any additional costs to providers and health systems in terms of data reporting requirements. It follows that the high costs of properly implementing CON evaluation reduce the likelihood that this regulation will provide net benefits to the population.

### **Recommendation Option B: Implement a Less Restrictive CON Process**

In addition to the improvements outlined above in Option A, policymakers could reduce the regulatory burden by updating exclusions and modifying the public hearing process.

#### 1. Updating Exclusions

High approval rates for projects involving behavioral health, cardiac services, imaging, intermediate care, nursing facilities, and radiation therapy suggest that the regulation is not serving as a meaningful constraint in these areas. These projects account for 25 percent of total estimated project costs but represent 80 percent of all applications from 2000 to 2024. Excluding these categories from CON requirements would reduce regulatory costs and improve access.

#### 2. Changing the Public Hearing under 10A.716

As discussed earlier, opposition from incumbent providers during public hearings has likely influenced decisions and imposed economic costs. Lawmakers should consider reforms to reduce incumbent influence and improve the efficiency of the review process.

### **Recommendation Option C: Full Repeal of Iowa's Certificate of Need Law**

Lawmakers should consider fully repealing Iowa's CON law. While the literature has limitations, the weight of evidence suggests that CON laws are ineffective at controlling prices or total spending and are more likely to reduce access and worsen health outcomes.

Arguments that CON laws protect incumbent hospitals are not supported by the original intent of the law or by the available evidence. This is not to say that these concerns lack merit, but rather that policymakers must decide whether the absence of strong evidence justifies maintaining strict regulation.

Free entry does carry real economic costs, particularly the fixed costs of service provision. Policymakers should weigh these costs against the aggregate benefits to the population. If the goal is to preserve access to public-like services such as emergency care or charity care, then facilities providing these services should be transparent about

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<sup>35</sup> Assuming an average of \$153,000 per FTE with two to four total FTEs for evaluation.

the minimum subsidies required to sustain them and targeted policy aimed at supporting these services would likely be more cost-effective.<sup>36</sup>

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<sup>36</sup> Under such transparency, policymakers may be able to construct law or policy that supports these benefits, likely at lower cost than relying on incumbent providers proclaiming the costs under the current market conditions with imperfect information. The markups over marginal cost likely vary significantly across service lines and cost-to-charge ratios derived from the Medicare Cost Reports cannot identify this variation. Understanding service-line-specific markups over marginal cost which would be necessary to identify the extent to which current services subsidize any community benefits provided.

# Appendix

## Certificate of Need Summary Report

Table 1: Counts and Approval Rates

| Application Type              | Approval Rate | Opposing Parties Present | Supporting Parties Present | N   |
|-------------------------------|---------------|--------------------------|----------------------------|-----|
| Application                   | 0.87          | 0.23                     | 0.18                       | 333 |
| Cost Overrun/Modify/Re-review | 1.00          | 0.00                     | 0.00                       | 15  |
| Extension                     | 0.99          | 0.05                     | 0.00                       | 276 |
| Rehearing                     | 0.36          | 0.50                     | 0.79                       | 14  |

Table 2: Counts and Approval Rates by Year

| Year | Application Type | Approval Rate | N  |
|------|------------------|---------------|----|
| 2000 | Application      | 0.83          | 12 |
| 2001 | Application      | 1.00          | 12 |
| 2002 | Application      | 0.91          | 11 |
| 2003 | Application      | 0.82          | 22 |
| 2004 | Application      | 0.79          | 24 |
| 2005 | Application      | 0.94          | 16 |
| 2006 | Application      | 0.71          | 17 |
| 2007 | Application      | 0.80          | 10 |
| 2008 | Application      | 0.77          | 13 |
| 2009 | Application      | 0.69          | 13 |
| 2010 | Application      | 0.82          | 11 |
| 2011 | Application      | 0.82          | 11 |
| 2012 | Application      | 0.91          | 11 |
| 2013 | Application      | 1.00          | 14 |

| Year | Application Type | Approval Rate | N  |
|------|------------------|---------------|----|
| 2014 | Application      | 0.79          | 14 |
| 2015 | Application      | 0.92          | 13 |
| 2016 | Application      | 1.00          | 14 |
| 2017 | Application      | 0.86          | 22 |
| 2018 | Application      | 1.00          | 16 |
| 2019 | Application      | 1.00          | 8  |
| 2020 | Application      | 1.00          | 8  |
| 2021 | Application      | 0.89          | 9  |
| 2022 | Application      | 0.88          | 17 |
| 2023 | Application      | 1.00          | 9  |
| 2024 | Application      | 1.00          | 6  |

Table 3: Counts and Approval Rates by Service Type

| Service Type        | Approval Rate | N   |
|---------------------|---------------|-----|
| ASC                 | 0.67          | 27  |
| Behavioral Health   | 0.83          | 12  |
| Birth Center        | 0.60          | 5   |
| Cardiac Services    | 0.96          | 27  |
| General Hospital    | 0.60          | 5   |
| ICF                 | 0.95          | 44  |
| Imaging/Equip       | 0.96          | 24  |
| Long-term Care      | 0.46          | 13  |
| Nursing Facility    | 0.92          | 144 |
| Other/Uncategorized | 1.00          | 10  |
| Radiation Therapy   | 0.86          | 14  |

| Service Type   | Approval Rate | N |
|----------------|---------------|---|
| Rehabilitation | 0.75          | 8 |

Table 4: Counts and Approval Rates by Project Purpose

| Project Purpose        | Approval Rate | N   |
|------------------------|---------------|-----|
| Bed Capacity Change    | 0.95          | 148 |
| New Health Service     | 0.80          | 171 |
| Other/Uncategorized    | 1.00          | 4   |
| Replacement/Relocation | 1.00          | 10  |

Table 5: Approval Rates by Opposition Present

| Service Type      | Opposition Present | Approval Rate | N  |
|-------------------|--------------------|---------------|----|
| ASC               | No                 | 0.92          | 13 |
| ASC               | Yes                | 0.43          | 14 |
| Behavioral Health | No                 | 1.00          | 8  |
| Behavioral Health | Yes                | 0.50          | 4  |
| Birth Center      | No                 | 1.00          | 2  |
| Birth Center      | Yes                | 0.33          | 3  |
| Cardiac Services  | No                 | 1.00          | 20 |
| Cardiac Services  | Yes                | 0.86          | 7  |
| General Hospital  | No                 | 1.00          | 3  |
| General Hospital  | Yes                | 0.00          | 2  |
| ICF               | No                 | 0.95          | 44 |
| Imaging/Equip     | No                 | 0.96          | 23 |
| Imaging/Equip     | Yes                | 1.00          | 1  |
| Long-term Care    | No                 | 0.50          | 10 |

| Service Type        | Opposition Present | Approval Rate | N   |
|---------------------|--------------------|---------------|-----|
| Long-term Care      | Yes                | 0.33          | 3   |
| Nursing Facility    | No                 | 0.95          | 111 |
| Nursing Facility    | Yes                | 0.79          | 33  |
| Other/Uncategorized | No                 | 1.00          | 8   |
| Other/Uncategorized | Yes                | 1.00          | 2   |
| Radiation Therapy   | No                 | 1.00          | 9   |
| Radiation Therapy   | Yes                | 0.60          | 5   |
| Rehabilitation      | No                 | 1.00          | 5   |
| Rehabilitation      | Yes                | 0.33          | 3   |

### Certificate of Need Cost Report

Table 6: Costs by Decision

| Final Decision | Total Project Cost (\$1000s) | Average Project Cost (\$1000s) | Total CON Fees | Average CON Fee | N   |
|----------------|------------------------------|--------------------------------|----------------|-----------------|-----|
| Approved       | 1,320,297                    | 4,537                          | 2,257,716      | 7,758           | 291 |
| Denied         | 454,555                      | 10,823                         | 356,088        | 8,478           | 42  |

Table 7: Costs by Decision and Service Type

| Service Type      | Final Decision | Total Project Cost (\$1000s) | Average Project Cost (\$1000s) | Total CON Fees | Average CON Fee | N  |
|-------------------|----------------|------------------------------|--------------------------------|----------------|-----------------|----|
| ASC               | Approved       | 65,999                       | 3,667                          | 139,003        | 7,722           | 18 |
| ASC               | Denied         | 3,932                        | 437                            | 15,266         | 1,696           | 9  |
| Behavioral Health | Approved       | 150,808                      | 15,081                         | 85,889         | 8,589           | 10 |
| Behavioral Health | Denied         | 0                            | 0                              | 1,200          | 600             | 2  |
| Birth Center      | Approved       | 125                          | 42                             | 1,800          | 600             | 3  |
| Birth Center      | Denied         | 249                          | 125                            | 1,348          | 674             | 2  |

| Service Type        | Final Decision | Total Project Cost (\$1000s) | Average Project Cost (\$1000s) | Total CON Fees | Average CON Fee | N   |
|---------------------|----------------|------------------------------|--------------------------------|----------------|-----------------|-----|
| Cardiac Services    | Approved       | 81,108                       | 3,120                          | 219,400        | 8,438           | 26  |
| Cardiac Services    | Denied         | 1,972                        | 1,972                          | 5,916          | 5,916           | 1   |
| General Hospital    | Approved       | 152,971                      | 50,990                         | 63,000         | 21,000          | 3   |
| General Hospital    | Denied         | 312,102                      | 156,051                        | 42,000         | 21,000          | 2   |
| ICF                 | Approved       | 14,031                       | 334                            | 56,229         | 1,339           | 42  |
| ICF                 | Denied         | 142                          | 71                             | 1,200          | 600             | 2   |
| Imaging/Equip       | Approved       | 142,099                      | 6,178                          | 245,696        | 10,682          | 23  |
| Imaging/Equip       | Denied         | 5,500                        | 5,500                          | 16,500         | 16,500          | 1   |
| Long-term Care      | Approved       | 34,207                       | 5,701                          | 73,714         | 12,286          | 6   |
| Long-term Care      | Denied         | 56,774                       | 8,111                          | 105,881        | 15,126          | 7   |
| Nursing Facility    | Approved       | 430,311                      | 3,260                          | 1,061,940      | 8,045           | 132 |
| Nursing Facility    | Denied         | 46,772                       | 3,898                          | 107,197        | 8,933           | 12  |
| Other/Uncategorized | Approved       | 89,333                       | 8,933                          | 112,868        | 11,287          | 10  |
| Radiation Therapy   | Approved       | 114,436                      | 9,536                          | 124,179        | 10,348          | 12  |
| Radiation Therapy   | Denied         | 9,400                        | 4,700                          | 28,200         | 14,100          | 2   |
| Rehabilitation      | Approved       | 44,869                       | 7,478                          | 73,998         | 12,333          | 6   |
| Rehabilitation      | Denied         | 17,711                       | 8,855                          | 31,380         | 15,690          | 2   |

Table 8: Costs by Decision and Project Purpose

| Project Purpose     | Final Decision | Total Project Cost (\$1000s) | Average Project Cost (\$1000s) | Total CON Fees | Average CON Fee | N   |
|---------------------|----------------|------------------------------|--------------------------------|----------------|-----------------|-----|
| Bed Capacity Change | Approved       | 194,645                      | 1,390                          | 559,310        | 3,995           | 140 |
| Bed Capacity Change | Denied         | 2,454                        | 307                            | 9,094          | 1,137           | 8   |
| New Health Service  | Approved       | 1,057,214                    | 7,717                          | 1,573,525      | 11,486          | 137 |
| New Health Service  | Denied         | 452,101                      | 13,297                         | 346,994        | 10,206          | 34  |

| Project Purpose        | Final Decision | Total Project Cost (\$1000s) | Average Project Cost (\$1000s) | Total CON Fees | Average CON Fee | N  |
|------------------------|----------------|------------------------------|--------------------------------|----------------|-----------------|----|
| Other/Uncategorized    | Approved       | 2,830                        | 708                            | 9,840          | 2,460           | 4  |
| Replacement/Relocation | Approved       | 65,608                       | 6,561                          | 115,041        | 11,504          | 10 |

Table 9: Proposed Project Costs by Service Type (\$1000s)

| Service Type        | Total Cost | Mean Cost | Median Cost | SD     | N   |
|---------------------|------------|-----------|-------------|--------|-----|
| ASC                 | 69,932     | 2,590     | 913         | 4,487  | 27  |
| Behavioral Health   | 150,808    | 12,567    | 100         | 24,640 | 12  |
| Birth Center        | 374        | 75        | 50          | 103    | 5   |
| Cardiac Services    | 83,080     | 3,077     | 1,972       | 2,920  | 27  |
| General Hospital    | 465,074    | 93,015    | 82,102      | 88,115 | 5   |
| ICF                 | 14,173     | 322       | 0           | 1,336  | 44  |
| Imaging/Equip       | 147,599    | 6,150     | 2,709       | 9,619  | 24  |
| Long-term Care      | 90,980     | 6,998     | 6,500       | 5,552  | 13  |
| Nursing Facility    | 477,083    | 3,313     | 1,875       | 4,136  | 144 |
| Other/Uncategorized | 89,333     | 8,933     | 3,558       | 11,185 | 10  |
| Radiation Therapy   | 123,836    | 8,845     | 3,297       | 14,879 | 14  |
| Rehabilitation      | 62,580     | 7,822     | 5,008       | 8,893  | 8   |

Table 10: Proposed Project Costs by Project Purpose (\$1000s)

| Project Purpose        | Total Cost | Mean Cost | Median Cost | SD     | N   |
|------------------------|------------|-----------|-------------|--------|-----|
| Bed Capacity Change    | 197,099    | 1,332     | 140         | 2,408  | 148 |
| New Health Service     | 1,509,315  | 8,826     | 3,415       | 22,205 | 171 |
| Other/Uncategorized    | 2,830      | 708       | 75          | 1,317  | 4   |
| Replacement/Relocation | 65,608     | 6,561     | 2,592       | 7,180  | 10  |

## Certificate of Need Statistical Results

Table 11: Regression Results

| Term                | Estimate | Standard Error | Test Statistic | P-Value |
|---------------------|----------|----------------|----------------|---------|
| Intercept           | -0.109   | 0.326          | -0.335         | 7.4e-01 |
| log(Total Cost)     | 0.003    | 0.004          | 0.871          | 3.8e-01 |
| ASC                 | 0.272    | 0.175          | 1.555          | 1.2e-01 |
| Behavioral Health   | 0.323    | 0.187          | 1.725          | 8.6e-02 |
| Birth Center        | 0.269    | 0.227          | 1.185          | 2.4e-01 |
| Cardiac Services    | 0.624    | 0.177          | 3.533          | 5.0e-04 |
| ICF                 | 0.497    | 0.188          | 2.643          | 8.8e-03 |
| Imaging/Equip       | 0.468    | 0.183          | 2.559          | 1.1e-02 |
| Long-term Care      | 0.079    | 0.181          | 0.438          | 6.6e-01 |
| Nursing Facility    | 0.461    | 0.174          | 2.657          | 8.4e-03 |
| Other/Uncategorized | 0.354    | 0.207          | 1.710          | 8.9e-02 |
| Radiation Therapy   | 0.428    | 0.188          | 2.277          | 2.4e-02 |
| Rehabilitation      | 0.206    | 0.209          | 0.987          | 3.2e-01 |
| Supporting Present  | 0.041    | 0.059          | 0.700          | 4.8e-01 |
| Opposing Present    | -0.305   | 0.047          | -6.439         | 7.0e-10 |

Table 12: T-test for Difference in Means

| Difference | Mean Before 2019 | Mean After 2019 | Statistic | P-value |
|------------|------------------|-----------------|-----------|---------|
| 4.73       | 14.53            | 9.8             | 2.25      | 0.03    |

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