

Should Minnesota Reinstate a Certificate of Need Program for Health Care Capital Expenditures?

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Executive Summary

The Minnesota Department of Health regulates capital investments made by hospitals, ambulatory surgery centers, diagnostic imaging centers, and physician clinics. The primary purpose of these regulations is to reduce health care spending by preventing the development of excess health care supply capacity. Most states regulate health care investments using a certificate-of-need (CON) law. CON programs require “prospective” review of expenditures, meaning that health care providers must obtain permission from the state before making major capital investments. Minnesota has not maintained a formal CON program since 1984. Instead, Minnesota mainly uses a “retrospective” review process in which the state reviews capital investments only after the provider has already made an investment. The building of additional hospital beds is the only type of investment that requires prospective approval in Minnesota.

Analyses by the state have determined that current capital expenditure regulations are not providing significant cost control for Minnesota’s health care system. This report examines whether reinstating a CON program would improve the law’s effectiveness in controlling health care costs. This report also assesses the impact that a CON program would have on other dimensions of the health care system, such as quality and access to care.

To project the impact of CON on Minnesota, this report relies on an extensive literature that examines the relationship between state CON programs and health care costs, quality and access. The main findings of this report are as follows:

- Reinstating CON would likely not hold down costs more effectively than Minnesota’s current capital expenditure regulations. Empirical studies consistently indicate that CON programs can affect the distribution of health care investment, but do not reduce overall health care spending. In the short run, CON may actually increase health care costs as providers accelerate their investment plans in anticipation of more stringent regulation.
- Reinstating CON would likely not improve health care quality. CON could theoretically improve quality by preventing small-volume providers from entering the market, increasing the number of procedures performed by high-quality regional providers. Empirical evidence indicates that CON laws do increase the number of procedures performed by incumbent providers, but there’s little evidence to demonstrate a direct association between CON and improved outcomes for patients.
- Reinstating CON would likely have little impact on access to care for the indigent. CON could theoretically improve access to care by limiting the competition faced by safety net hospitals that serve a disproportionate number of poor and disadvantaged patients. Safety net hospitals often

“cross-subsidize” care for the indigent by providing profitable specialty care, but safety net hospitals may be less able to cross-subsidize if competitors attract the most profitable patients. However, empirical studies to date have not documented any association between CON laws and the financial viability of safety net hospitals.

On the basis of these conclusions, this report recommends that Minnesota maintain its existing capital expenditure regulations instead of adopting a CON program. The remainder of this report is organized as follows: The first section describes Minnesota’s capital expenditure regulations in detail, and briefly explains why policymakers deem the laws ineffective. The second section provides background on CON programs, and reviews the empirical literature assessing the impact of CON on cost, quality, and access in health care. The third section discusses these findings and concludes.

Health Care Capital Expenditure Regulation in Minnesota

Minnesota maintains two laws that regulate health care capital expenditures. The capital expenditure reporting law applies to most categories of capital investment, whereas the hospital construction moratorium applies specifically to new hospital beds.

Capital Expenditure Reporting

The health care capital expenditure reporting law requires hospitals, outpatient surgical centers, diagnostic imaging centers, and physician clinics to submit an annual report of all health care-related capital expenditures in excess of \$1,000,000. Expenditures covered under the law include construction and renovation of facilities, purchasing of medical equipment, expenditures for new service lines, and investment in electronic medical records. The Minnesota Department of Health retrospectively reviews each spending commitment to determine the expenditure's "impact on cost, access, and quality of health care; the clinical effectiveness and cost-effectiveness of the major spending commitment; and the alternatives available to the provider." The Department is not authorized to prevent the commitment if it fails review, but failure automatically places the provider on prospective review for at least five years. Providers under prospective review cannot make a capital expenditure worth more than \$1,000,000 without the Department's prior approval.¹

Free-standing radiation therapy facilities are subjected to additional scrutiny under the law. Reviews of free-standing radiation therapy facilities must also consider "the alternatives available to patients in terms of avoiding an unwarranted duplication based on whether additional capacity is needed of services, facilities, or equipment in and around the location of the major spending commitment; and the best interests of the patients, including conflicts of interest that may be present in influencing the utilization of services, facility or equipment related to the major spending commitment." There are also more severe penalties for radiation therapy facilities placed on prospective review, including fines equal to triple the amount of the capital expenditure, permanent injunction against the violating provider, and invalidation of any contracts related to the capital expenditure in question.²

The law exempts certain categories of capital investment from review, including investments designed to support medical education or medical research, building maintenance, expenditures not related to patient care, and mergers or acquisitions that "do not involve a substantial expansion of service capacity or a substantial change in the nature of health care services provided."³

¹ Expenditure Reporting, Minnesota Statutes 62J.17 (1992).

² *Ibid.*

³ *Ibid.*

Minnesota's State Legislature adopted the capital expenditure reporting law in April 1992 as part of an historic health care reform bill called the HealthRight Act. This legislation enacted a broad array of health care reforms intended to achieve greater cost control. The main cost control mechanisms created by the law were integrated service networks (ISNs) and a regulated all-payer option (RAPO). The health care capital expenditure reporting law was included in the bill as a supplementary cost control measure.⁴

Policymakers hoped the capital expenditure law would restrain costs while the state government implemented the ISN and RAPO. The Legislature hoped to prevent major capital expenditures that would "make future cost containment efforts more difficult," and voiced concern with the "possibility that the legislature's expression of its attempt to control health care costs may lead a provider to make major spending commitments before targets or other cost containment constraints are fully implemented."⁵

The Minnesota Legislature repealed the ISN and RAPO soon after the HealthRight Act was adopted, but the capital expenditure reporting law nevertheless remained in place. The Joint Health Care Task Force has since concluded that the capital expenditure reporting law is an ineffective cost control mechanism. The Task Force pointed out that the law's "review criteria are vague enough that it is difficult to discern how strictly the legislature intended MDH to judge applications." When the Task Force interviewed Minnesota health care providers to assess the impact of the law, the providers indicated that the retrospective review is an "administrative hurdle" that does not impact their investment or technology acquisition decisions. Only two providers have ever been placed on prospective review in the law's history.⁶

Hospital Construction Moratorium

The hospital construction moratorium prohibits the building of new hospitals as well as "any erection, building, alteration, reconstruction, modernization, improvement, extension, lease or other acquisition by or on behalf of a hospital that increases bed capacity of a hospital."^{7, 8}

The Minnesota Legislature requires the Department of Health to conduct a "public interest review" whenever hospitals or provider groups propose an exception to the

⁴ Chun, R., & Pender, T. R. (1994). *The Basics of MinnesotaCare: A Guide for Legislators*. Minnesota House of Representatives Research Department.

⁵ Joint Task Force on Health Care Costs and Quality. (2003). *The Health Care Capital Expenditure Reporting Law: Report to the Minnesota Legislature*.

⁶ *Ibid.*

⁷ Hospital Construction Moratorium, Minnesota Statutes 144.51 (1984).

⁸ Minnesota Department of Health. (2007). *Factors and Incentives Driving Investment in Medical Facilities*.

moratorium. In its review, the Department must consider whether the proposed facility would improve timely access to care or provide new specialized services, the financial impact of the proposed exception on existing hospitals, the impact on the ability of existing hospitals to maintain current staffing levels, the degree to which the facility would provide services to low-income patients, as well as the expressed views of all affected parties.⁹

These reviews must be completed within 90 days of the proposed project. However, the public interest review is not binding. The Minnesota Legislature ultimately decides which exceptions are allowed to go forward.¹⁰ Except for the fact that the Legislature makes the final determination about each project, the public interest review process for new hospitals and hospital beds closely resembles CON statutes in other states.

Policymakers hoped that the moratorium would be more effective than CON in reducing the growth of hospital beds. However, the Minnesota Department of Health has concluded that the moratorium is largely ineffective in restraining bed capacity. Many hospitals have strategically “banked” beds, allowing them to circumvent the review process. In 2005, while there were only 11,650 available beds, there were 16,392 licensed beds in the state, allowing many hospitals to rely on unused bed capacity when they expand services.¹¹

The following section will examine whether stronger capital expenditure regulations imposed through CON would reduce cost, improve access, or increase quality relative to Minnesota’s current capital expenditure regulations.

⁹ Minnesota Department of Health. (2007). *Factors and Incentives Driving Investment in Medical Facilities*.

¹⁰ *Ibid.*

¹¹ *Ibid.*

Figure 2 (Adapted from NSCL)

Number of States with CON by service category

Acute Hospital Beds	28	Home Health	18	Magnetic Resonance Imaging (MRI) Scanners	18+ DC	Rehabilitation	25
Air Ambulance	5+ DC	Hospice	18	Neo-Natal Intensive Care	23	Renal Failure/ Dialysis	12
Ambulance Services, Ground	1	Intermediate Care Facilities/Mental Retardation	22	Obstetrics Services	15	Assisted Living & Residential Care Facilities	5
Ambulatory Surgical Centers	27	Long Term Acute Care	26+ DC	Open Heart Surgery	25	Subacute Services	13
Burn Care	11	Lithotripsy	14+ DC	Organ Transplants	21	Substance/ Drug Abuse	19
Cardiac Catheterization	26	Nursing Home Beds/Long Term Care Beds	36+ DC	Positron Emission Tomography (PET) Scanners	20	Swing Beds	12
Computed Tomography (CT) Scanners	13	Medical Office Buildings	1+D C	Psychiatric Services	26	Ultra-Sound	4
Gamma Knives	15	Mobile Hi Technology (CT/MRI/PT, etc)	15+ DC	Radiation Therapy	23		

Many studies have evaluated the impacts of CON on cost, access, and quality, but not all of them employ sound methodologies. Below, I discuss important methodological features of CON studies.

CON Study Methodologies

Studies that examine CON typically compare states with CON to states without CON on an outcome of interest. Concerns about endogeneity arise from the fact that states with CON may be different from states without CON. For example, states with higher health care costs may have been more likely to maintain their CON programs. A simplistic comparison of health care costs between CON states and non-CON states would then misleadingly show that CON is associated with higher costs. Studies often moderate these underlying differences between states by employing multivariate regression that controls for observed differences between states like

the age distribution, per capita income, and health care market characteristics that would impact the outcome of interest. The best studies employ state-level or hospital-specific fixed effects to reduce the risk of omitted variable bias.

Studies must also consider how CON programs vary across states. A simple comparison between CON and non-CON states masks the heterogeneity between programs. A standard methodology for addressing heterogeneity is to measure the stringency of CON programs. Stringency metrics typically combine the minimum threshold for review for each state with the total number of services regulated. A state with a relatively low threshold and a relatively high number of regulated services would be considered the most stringent, and a state with a high expenditure threshold and a low number of regulated services would be considered the least stringent.

Studies must also account for how health care payment systems have changed over time in the public sector and private sector. The incentives produced by different reimbursement structures may change the effect that capital expenditure regulations have on health care markets. For example, compared to the 1960's and 1970's when CON was first adopted in many states, the proliferation of managed care organizations has changed the relationship between insurance companies and hospitals, so it is important for studies to control for the degree of managed care penetration.

Finally, CON studies must determine which patient population to examine. Studies that use data from a specific subset of patients (i.e. Medicare patients) have findings that are less externally valid than studies that use data with broad patient populations.

The next section will review studies that examine the relationship between CON and cost, access, and quality of health care services. The studies that have been selected represent the best available evidence in consideration of the methodological features discussed above.

Would CON reduce costs in Minnesota?

CON would likely not reduce costs in Minnesota. The adoption of the prospective payment system by Medicare and the growth in managed care introduced much greater incentives for cost control in hospital care, minimizing the relevance of CON as a cost control tool. Additionally, empirical evidence consistently suggests that CON is unsuccessful in reducing overall health care spending, and has little impact on the diffusion of expensive technologies.

When CON programs were first adopted, policymakers were concerned that health care costs would skyrocket without government regulation of capital investment. These concerns were motivated by the idea that market competition in health care

seemed to lead to a “medical arms race” in which hospitals competed primarily on the basis of quality rather than price. Analysts argued that to attract skilled physicians and well-insured patients, hospitals adopted the latest medical technology, and provided hotel-like amenities to patients, leading costs to increase over time rather than decrease¹³

Hospitals also had little incentive to contain costs during the medical arms race era because hospitals received reimbursement from Medicare on a cost-plus basis.¹⁴ In 1983, Medicare’s adoption of the prospective payment system ended cost-plus reimbursement. Instead, hospitals were given a fixed fee adjusted for each patient’s diagnosis, meaning that hospitals could only earn a profit if they held costs down below the fee.¹⁵

Additionally, the liberalization of selective contracting laws for insurance companies, and the consequent growth in managed care plans, gave hospitals further incentives to hold down costs. Managed care organizations differ from traditional insurance plans by using a variety of mechanisms to intervene in the relationship between patient and provider for the purposes of controlling costs. These strategies include selective contracting with health care providers, reviewing utilization decisions by doctors and patients, required cost-sharing for patients, and defined formularies for prescription drug use. Managed care penetration remained limited prior to the mid-1980s, with only five percent of Americans enrolled in a managed care plan in 1980.¹⁶ Today, managed care organizations dominate both private and public insurance, with managed care organizations covering 99.5% of commercially insured individuals, 74.2% of Medicaid enrollees, and 26.2% of Medicare enrollees.¹⁷ Even though private sector managed care enrollment is nearly universal, public sector managed care penetration still varies significantly by state.¹⁸

The prospective payment system, coupled with the growth of managed care plans, reduced the incentives for unmitigated cost growth in the health care system, limiting the relevance of CON today. Moreover, the earliest studies of CON conducted during the medical arms race era suggested that CON was not successful in reducing cost growth. Salkever and Bice (1976) found that CON was not associated with a decrease in total investment. The study found that CON did reduce bed supply, but this reduction was more than offset by the increase in assets

¹³ *Ibid.*

¹⁴ Devers, K. J., Brewster, L. R., & Casalino, L. P. (2003). Changes in Hospital Competitive Strategy: A New Medical Arms Race? *Health Services Research*, 38(1), 447–469.

¹⁵ Gottlober, P., Brady, T., Robinson, B., & Davis, T. (2001). *Medicare Hospital Prospective Payment System: How DRG Rates Are Calculated and Updated*. Office of the Inspector General.

¹⁶ Glied, S. (1999). Managed Care. *National Bureau of Economic Research*.

¹⁷ MCOL. National Managed Care Penetration. (2013).

¹⁸ Kaiser Family Foundation. (2014). *Medicare Advantage Fact Sheet*.

per bed.¹⁹ Sloan and Steinwald (1980) found evidence that hospitals increased bed supply in anticipation of CON regulations, and that CON increased labor inputs per hospital bed.²⁰ These studies were conducted during the medical arms race era, so they do not show that CON would necessarily be ineffective in controlling costs in today's health care environment.

Nevertheless, the findings of more contemporary studies have largely been consistent with the findings of the earliest studies. Using 1980-1993 data from the Health Care Financing Administration, Conover and Sloan (1998) find that CON is not associated with lower total per capita health care spending, and that removing CON does not cause health care expenditures to suddenly increase.²¹ Rivers, Fottler, and Frimpong (2010) use American Hospital Association data between 1999-2003, and similarly find that CON laws are not associated with lower hospital costs per adjusted admission, and they also find that more stringent CON states actually had higher costs per admission.²²

Recent studies also suggest that CON has little impact on the diffusion of expensive technologies. Khanna et al. (2013) study CON 's impact on the diffusion of Intensity Modulated Radiation Therapy (IMRT) for prostate cancer patients. IMRT is a form of radiation therapy that is twice as expensive as other types of radiation therapy and six times as expensive as radical prostatectomy, but there's little clinical evidence to date showing that IMRT is more effective than existing therapies. Khanna and colleagues show that IMRT proliferated more quickly in CON states than in non-CON states, and that overall hospital and physician costs for prostate cancer patients were not lower in CON states.²³

Similar results have been found for robotic surgery. Jacobs et al. (2013) found that there were no statistically significant differences in the rates of adoption of robotic surgery between high-stringency CON and low-stringency CON health service areas. This is the opposite result that would be expected if CON were successfully controlling costs. CON states should have had lower rates of adoption since the purported benefits of robotic surgery have yet to be definitively proven by evidence, and because the start-up costs are high.²⁴

¹⁹ Salkever, D. S., & Bice, T. W. (1976). The Impact of Certificate-Of-Need Controls on Hospital Investment. *The Milbank Memorial Fund Quarterly. Health and Society*, 54(2), 185–214.

²⁰ Sloan, F. A., & Steinwald, B. (1980). Effects of Regulation on Hospital Cost and Input Use. *Journal of Law and Economics*, 23(1), 81–109.

²¹ Conover, C. J., & Sloan, F. A. (1998). Does removing certificate-of-need regulations lead to a surge in health care spending? *Journal of Health Politics, Policy and Law*, 23(3), 455–481.

²² Rivers, P. A., Fottler, M. D., & Frimpong, J. A. (2010). The Effects of Certificate of Need Regulation on Hospital Costs. *Journal of Health Care Finance*, 36(4), 1–16.

²³ Khanna, A., Hu, J. C., Nguyen, P. L., Lipsitz, S., & Palapattu, G. S. (2013). Certificate of need programs, intensity modulated radiation therapy use and the cost of prostate cancer care. *Journal of Urology*, 189(1), 75–79.

²⁴ Jacobs, B. L., Zhang, Y., Skolarus, T. A., Wei, J. T., Montie, J. E., Schroeck, F. R., & Hollenbeck, B. K. (2013). Certificate of Need Legislation and the Dissemination of Robotic Surgery for Prostate Cancer. *Journal of Urology*, 189(1), 80–85.

Neither of these studies can be generalized to other technologies, but their findings are consistent with broader studies demonstrating the ineffectiveness of CON in controlling health care costs. The available empirical evidence consistently indicates that CON is a weak cost control mechanism. It is therefore unlikely that strengthening the moratorium or the capital expenditure reporting law would reduce costs in Minnesota, and could potentially increase costs in the short term by encouraging anticipatory investment by providers.

Some Minnesota policymakers may still have concerns about health care cost growth. Rural Minnesota is a particular area of concern for cost growth because rural hospitals do not face the same cost constraints that urban hospitals face. Many rural hospitals are sole-source providers for their community, reducing the extent to which competition can reduce costs. Additionally, many rural hospitals are designated as Critical Access Hospitals. Medicare provides cost-based reimbursement instead of prospective payments to Critical Access Hospitals, further reducing incentives for cost control at rural hospitals.²⁵ Rural health care is a significant concern in Minnesota. Indeed, 79 of Minnesota's 137 hospitals are designated Critical Access Hospitals.²⁶

There is no evidence to date that CON would be more effective at controlling costs in rural health care settings compared to urban areas. But because rural hospitals do not face the same cost control incentives as urban hospitals, Minnesota should carefully monitor cost growth for these hospitals. Minnesota already has data systems in place to monitor costs in both rural and urban hospitals. The Minnesota Health Care Cost Information Act requires acute care hospitals, psychiatric and specialty hospitals, free-standing outpatient surgical centers, and diagnostic imaging facilities to provide financial, utilization, and services data to the Minnesota Department of Health in a "Hospital Annual Report."²⁷ Minnesota policymakers can use this data to evaluate cost trends in rural hospitals.

Some analysts remain concerned about cost growth in urban areas where managed care is more prevalent and where hospitals are prospectively paid. They argue that the medical arms race is still ongoing due to recent changes in health care markets. Following the managed care backlash in the late 1990s and early 2000s, managed care plans opted to offer relatively broad provider networks, reducing the risk that high-cost providers would be excluded from insurance company networks. Additionally, managed care plans reduced the "gatekeeping" functions of primary care physicians, allowing patients to see a specialist without primary care

²⁵ Rosko, M. D., & Mutter, R. L. (2010). Inefficiency Differences Between Critical Access Hospitals and Prospectively Paid Rural Hospitals. *Journal of Health Politics, Policy and Law*, 35(1).

²⁶ Minnesota Department of Health. (2013). *Minnesota's Critical Access Hospitals*.

²⁷ Minnesota Department of Health. (2014). *2014 Hospital Annual Report-Instructions*.

approval²⁸. The loosening of managed care controls may have reduced the effectiveness of managed care as a cost control mechanism.

Additionally, Medicare's prospective payment system has developed imperfect reimbursement methodologies, causing some specialties to receive reimbursements that may exceed the cost of providing care. Differential reimbursement rates may be contributing to a medical arms race in particular specialties that are profitable. An increasingly common strategy for hospitals is to create well-branded specialty service lines for care that are reimbursed at a relatively high rate, such as cancer care, cardiac care, and orthopedic care.²⁹

In response to the financial incentives for specialty care, many physicians have also entered the market to compete with hospitals by opening physician-owned ambulatory surgery centers or specialty hospitals. Physician-owned specialty services have received criticism for disproportionately treating well-insured, low-acuity patients, and because physician-ownership and investment in facilities they refer to may present strong incentives for overutilization.³⁰ The Stark Laws prohibit Medicare reimbursement to physicians for patient referrals that they own, but the in-office ancillary services exception allows physicians to self-refer patients within their own practices and for services that they personally provide.³¹

However, these market trends are nevertheless benefitting many patients. The proliferation of physician-owned ambulatory surgery centers often provide more convenient locations for patients, reduced waiting times, lower cost-sharing, and a friendly non-institutional environment.³²

If policymakers remain concerned about these market trends, a CON would likely provide little assistance to Minnesota in addressing the new medical arms race. In some ways, CON may actually accelerate competition along specialty service lines and for well-insured patients by giving providers strong incentives to use CON to "claim territory" in a particular service area or in a particular service line, blocking prospective competitors from entering the market in that specialty.³³

²⁸ Fox, P. D., & Kongstvedt, P. R. (2013). A History of Managed Health Care and Health Insurance in the United States. In *Essentials of Managed Health Care*(6th ed.). Burlington, MA: Jones & Bartlett.

²⁹ Berenson, R. A., Bodenheimer, T., & Pham, H. H. (2006). Specialty-service lines: salvos in the new medical arms race. *Health Affairs*,25(5), 337–343.

³⁰ Kahn III, C. N. (2006). Intolerable Risk, Irreparable Harm: The Legacy Of Physician-Owned Specialty Hospitals. *Health Affairs*,25(1), 130–133.

³¹ *Ibid.*

³² Federal Trade Commission. (2004). *Improving Health Care: A Dose of Competition*.

³³ Yee, T., Stark, L. B., Bond, A. M., & Carrier, E. (2011). *Health Care Certificate-of-Need (CON) Laws: Policy or Politics?* National Institute for Health Care Reform.

Would CON improve the quality of care in Minnesota?

CON would likely not improve health care quality in Minnesota. CON has been shown to promote regionalization of certain health care services for which there is a strong correlation between volume and patient outcomes, but the evidence does not suggest a direct link between CON and improved patient outcomes. Additionally, regionalization would likely increase patient travel times, and provide perverse incentives for providers to meet volume benchmarks.

Proponents of CON believe that CON may improve the quality of care by ensuring that incumbent providers perform a higher volume of certain procedures. Indeed, the Minnesota Department of Health has recommended that the state “should discourage unnecessary duplication of services, particularly those that require high levels of capital investment and those for which health outcomes may be improved through the use of high-volume centers of excellence.”³⁴

The “practice-makes-perfect” hypothesis stipulates that high-volume providers achieve better quality because higher patient volumes increase provider experience levels. Physicians that treat many patients may be better able to maintain and improve their skill level than physicians that treat relatively few patients.³⁵ Additionally, hospitals with high patient volumes may learn to change their clinical environments to improve patient safety.³⁶ If this explanation is accurate, it may justify using CON to promote regionalization of medical services for which there is a strong correlation between volume and improved outcomes.

On the other hand, the correlation between volume and quality may instead reflect selective referral patterns. High-volume hospitals may receive high volumes of patients because the quality of the hospital is perceived to be high. In other words, quality may be inducing greater patient volume instead of the other way around.³⁷

While many studies have documented the volume-outcome correlation, far fewer studies have examined whether the “practice-makes-perfect” hypothesis or the “selective referral” hypothesis is correct. Robinson and Luft (1987) try to determine which explanation is more important, and they find that it depends on the procedure. For acute myocardial infarction, cholecystectomy, stomach operations, and intestinal operations volume is an important predictor of quality. However, for cardiac bypass graft, transurethral prostatectomy, ulcers, femur fractures, and aneurysms, selective referral patterns are more predictive when controlling for

³⁴ *Ibid.*

³⁵ Luft, H. S., Hunt, S. S., & Maerki, S. C. (1987). The Volume-Outcome Relationship: Practice-Makes-Perfect or Selective-Referral Patterns? . *Health Services Research*, 22(2), 157–182.

³⁶ Billingsley, K. G., Morris, A. M., Dominitz, J. A., Matthews, B., Dobie, S., Barlow, W., ... Baldwin, L.-M. (2007). Surgeon and Hospital Characteristics as Predictors of Major Adverse Outcomes Following Colon Cancer Surgery: Understanding the Volume-Outcome Relationship. *Journal of the American Medical Association*, 142(1), 23–31.

³⁷ Luft, H. S., Hunt, S. S., & Maerki, S. C. (1987). The Volume-Outcome Relationship: Practice-Makes-Perfect or Selective-Referral Patterns? . *Health Services Research*, 22(2), 157–182.

volume.³⁸ Hannan et al. (1992) find that in New York state, low-mortality surgeons performing abdominal aortic aneurysm resections received a larger increase in referrals over time than high-mortality surgeons, suggesting that the selective referral hypothesis explains the volume outcome association.³⁹ Because the causal mechanism underlying volume-outcome relationships is not well understood, studies examining the impact of CON should try to measure a direct relationship between CON and quality.

Some studies directly examine the impact of CON on both provider volume and quality, but many of these studies focus on a single procedure. Recent studies of the impact of CON on the quality of care have particularly focused on outcomes for cardiac care, such as coronary artery bypass graft (CABG) surgery, or percutaneous coronary interventions (PCI). Generalizations about CON should not be made on the basis of these studies because cardiac care differs from other specialty service lines in important ways. For example, CABG programs have very high fixed costs, with the average start-up costs for each program ranging from \$12-\$14 million. Additionally, cardiac care is general reimbursed well by Medicare and private insurance.⁴⁰

Studies of the impact of CON on cardiac care consistently find that CON is successful in concentrating procedures among high volume providers. Cutler, Huckman, and Colstad (2009) estimate that CON removal in Pennsylvania resulted in a 5 percent reduction average hospital volume for CABG. ⁴¹ Ho, Ku-Goto, and Jollis (2009) estimate that providers in states without CON have on average 31% lower procedure volume for CABG and 29% lower volume for PCI.⁴² Disesa et al. (2006) estimate that the average number of CABG procedures per hospital is 271 in CON states compared to 188 in non-CON states. They also find that in 2003 3.0% of hospitals in CON states were low-volume hospitals, compared to 7.4% of hospitals in non-CON states.⁴³ These consistent volume results are likely due to minimum procedure volume requirements imposed by state CON programs.⁴⁴

³⁸ *Ibid.*

³⁹ Hannan, E. L., Kilburn, Jr., H., O'Donnell, J. F., Bernard, H. F., Shields, E. P., Lindsey, M. L., & Yazici, A. (1992). A Longitudinal Analysis of the Relationship between In-Hospital Mortality in New York State and the Volume of Abdominal Aortic Aneurysm Surgeries Performed. *Health Services Research*, 27(4), 517-542.

⁴⁰ Cutler, David M., Robert S. Huckman, and Jonathan T. Kolstad. 2010. Input constraints and the efficiency of entry: lessons from cardiac surgery. *American Economic Journal: Economic Policy* 2(1): 51-76.

⁴¹ Cutler, David M., Robert S. Huckman, and Jonathan T. Kolstad. 2010. Input constraints and the efficiency of entry: lessons from cardiac surgery. *American Economic Journal: Economic Policy* 2(1): 51-76.

⁴² Ho, V., Ku-Goto, M.-H., & Jollis, J. G. (2009). Certificate of Need (CON) for Cardiac Care: Controversy over the Contributions of CON. *Health Services Research*, 44(2), 483-500.

⁴³ Disesa, V. J., O'Brien, S. M., Welke, K. F., Beland, S. M., Haan, C. K., Vaughan-Sarrazin, M., & Peterson, E. D. (2006). Contemporary Impact of State Certificate-of-Need Regulations for Cardiac Surgery: An Analysis Using the Society of Thoracic Surgeons' National Cardiac Surgery Database. *Circulation*, 114, 2122-2129.

⁴⁴ Ho, V. (2007). Does Certificate Of Need Affect Cardiac Outcomes And Costs? *International Journal of Health Care Finance and Economics*, 6(4), 300-324.

Despite the consistent success of CON laws in increasing hospital cardiac procedure volumes, CON laws do not appear to consistently improve quality. Disesa et al. (2006) find no significant association between CON and CABG operative mortality or morbidity.⁴⁵ Ho (2007) estimates that a lack of CON marginally affected CABG quality in non-CON states, but did not find any impact of CON on PCI outcomes.⁴⁶ Some studies even find that CON reduces quality for CABG. Cutler, Huckman, and Colstad (2009) estimate that removal of CON provided an estimated 79 additional quality-adjusted life years for CABG patients over the study period.⁴⁷ Ho, Ku-Goto, and Jollis (2009) similarly find that CON removal is associated with declines in CABG mortality.⁴⁸

These results contradict the practice-makes perfect hypothesis. The authors offer many explanations for these findings. Cutler estimates that CON removal resulted in a 44 percent to 53 percent increase in market share for surgeons with the lowest risk-adjusted mortality.⁴⁹ Ho explains that Ohio and Pennsylvania, two of the seven states that removed CON in her study, required outcome reporting for all CABG providers following CON removal, and that poor outcomes could have resulted in the revoking of CABG licensure for providers.⁵⁰ Disesa concludes that “CON regulations can have an impact on the allocation of resources but cannot ensure the skills, judgment, and evidence-based practice applied in the delivery of care.” He and his coauthors believe “the adoption of evidence-based treatment algorithms and guideline-based clinical best practices may be responsible for the decreasing importance of volume effects on outcomes.”⁵¹

The current evidence suggests that CON is successful at increasing hospital procedure volumes for cardiac care, but is not associated with improved quality. The external validity of the evidence is limited because it focuses on cardiac care. It is still plausible that CON could positively impact quality for procedures for which CON studies have not been conducted.

However, even if regionalization successfully improves quality for some procedures, the policy would come with significant tradeoffs. Regionalization may undermine access by increasing the distance between patients and available providers. Studies of patient preferences have determined that many patients are willing to accept lower quality if they can be treated by a local provider. Finlayson, Birkmeyer, Tosteson, and Nease (1999) find that among veterans waiting for elective surgery that 45 percent of respondents would prefer to see a local provider even if the

⁴⁵ Disesa et al. (2006)

⁴⁶ Ho (2007)

⁴⁷ Cutler et al. (2010)

⁴⁸ Ho et al. (2009)

⁴⁹ *Ibid.*

⁵⁰ *Ibid.*

⁵¹ *Ibid.*

relative risk of complications was twice as high with the local provider.⁵² Though actual patient behavior may not be consistent with their responses, these surveys suggest that location is an important factor for patients in determining their preferences for medical care.

Regionalization could also substantially increase the market power of high volume providers relative to insurers. Providers with more negotiating power may be able to extract higher prices from insurance companies, raising the cost of health care. Additionally, minimum procedure volume requirements may create perverse incentives by encouraging providers to promote utilization to meet the volume benchmark instead of according to patient needs. Physicians retain considerable discretion in clinical decision-making, giving them leverage to encourage a procedure even if the procedure is only marginally necessary or even not in the best interests of the patient.⁵³

Proponents of regionalization argue that regionalization may increase economies of scale for certain medical services, reducing overall societal costs for medical care. However, these cost savings would be greatest for procedures for which there are very high fixed costs. Since most medical services do not have high fixed costs, the ultimate gains from economies of scale may be limited. Regionalization may also reduce costs if high volume providers have fewer expensive complications for their patients, reducing lengths of stay or readmission. However, current evidence does not suggest there is any relationship between volume and length of stay or readmission rates.⁵⁴

Regionalization may not be necessary in Minnesota because the state already employs a number of strategies to improve and promote health care quality. In 2008, the state passed health care reform legislation that required the Minnesota Department of Health to develop a standardized set of quality of care measures to be reported by all providers in the state. The Statewide Quality Reporting and Measurement System (SQRMS) requires physicians, hospitals, and ambulatory surgical centers to report on a standard set of quality measures.⁵⁵ The legislation also required the creation of the “provider peer grouping system,” which will rank providers and place them in groups based on measures of risk-adjusted cost and quality.⁵⁶

⁵² Finlayson, S., Birkmeyer, J. D., Tosteson, A. N., & Nease, R. F. (1999). Patient preferences for location of care: implications for regionalization. *Medical Care*, 37(2), 204–209.

⁵³ Birkmeyer, J. D., Skinner, J. S., & Wennberg, D. E. (2002). Will Volume-Based Referral Strategies Reduce Costs Or Just Save Lives? *Health Affairs*, 21(5), 234–241.

⁵⁴ *Ibid.*

⁵⁵ McCabe, D. (2014). *The Minnesota Statewide Quality Reporting and Measurement System (SQRMS): An Overview*. Minnesota Department of Health: Health Economics Program.

⁵⁶ Gauthier, A., & Cullen, A. (2010). *Reforming Health Care Delivery Through Payment Change and Transparency: Minnesota's Innovations*. Commonwealth Fund.

Given the lack of direct evidence showing that CON improves quality, as well as the potential downsides of regionalization, CON would be a weak tool for promoting health care quality in Minnesota.

Would CON improve access to care in Minnesota?

CON would likely have little impact on access to care in Minnesota. There is little empirical evidence to support the argument the safety net hospitals are more financially secure in CON states compared to non-CON states.

Proponents of CON often contend that CON increases access to care by improving the financial viability of safety net hospitals. If competition were unrestrained by CON, safety net hospitals could lose their most profitable patients to new providers that strategically locate themselves to serve well-insured patient populations. The most profitable categories of service, like cardiac care, orthopedics, and diagnostic imaging, are used by hospitals to cross-subsidize unprofitable services like emergency room care, mental health, or chemical dependency.⁵⁷ Safety net hospitals claim that they especially need these profitable patients these because they provide disproportionate levels of care to the uninsured, Medicaid enrollees, and other patients that provide hospitals with limited reimbursement.

The growth of surgical centers and diagnostic imaging centers in recent years has potentially undermined the capacity of safety net hospitals to cross-subsidize care for the indigent. In Minnesota, the number of free-standing ambulatory surgery centers has increased six-fold since 1997. The Minnesota Department of Health has concluded that “rapid growth in the number of ambulatory surgery centers in Minnesota in recent years has likely had a financial impact on hospitals and their ability to cross-subsidize money-losing services.”⁵⁸

These concerns about safety net hospitals are receiving special attention in Minnesota and elsewhere as a result of policy changes in the ACA that substantially affect the financial status of safety net hospitals. Hospitals that serve large numbers of Medicaid patients and uninsured patients receive Disproportionate Share Hospital allotments to supplement normal reimbursement rates from Medicaid. Minnesota’s disproportionate share hospitals received \$79.7 million in FY 2014 from the DSH program.⁵⁹ The ACA substantially cut these payments in future years because the law assumed that rate of uninsured would decline, reducing the costs of uncompensated care for safety net hospitals.⁶⁰ It is not clear yet whether the

⁵⁷ Minnesota Department of Health. (2007). *Factors and Incentives Driving Investment in Medical Facilities*.

⁵⁸ Minnesota Department of Health. (2007). *Factors and Incentives Driving Investment in Medical Facilities*.

⁵⁹ Kaiser Family Foundation. (2014). *State Health Facts: Federal Medicaid Disproportionate Share Hospital (DSH) Allotments*.

⁶⁰ Kaiser Family Foundation. (2013). *How Do Medicaid Disproportionate Share Hospital (DSH) Payments Change Under the ACA?*

financial benefits of reduced uncompensated care are large enough to offset reductions in disproportionate share payments.

However, compared to hospitals in other states, Minnesota hospitals absorb significantly less uncompensated care, helping to keep safety net hospitals financially afloat. In 2012, uncompensated care accounted 2.2% of the total operating expenses of Minnesota's hospitals, compared to the national average of 6.1%.⁶¹ Indeed, of the ten largest providers of uncompensated care in the state, who provide a nearly 50% of all of the state's uncompensated care, eight of those providers earned revenue in excess of expenses in 2013.⁶²

Despite the generally healthy financial profile of Minnesota's safety net hospitals, some individual hospitals do consistently struggle to stay afloat. Hennepin County Medical Center, the largest provider of uncompensated care in the state, had an operating loss in two of the last three years, including a \$22.0 million loss in 2013.⁶³ These losses will mount if decreasing disproportionate share payments are not outweighed by decreases in the rate of uninsured.

A CON law would potentially address these developments in the health care marketplace and ACA policy changes by only permitting capital projects that do not threaten access to care for the needy. Indeed, many CON laws require an analysis on the impact of new investments on the capacity of the system to serve the poor. In Illinois, for example, the CON law actually can prevent hospitals from being closed if they are too important to serving the poor. And many state CON laws require some provision of charity care by hospitals.⁶⁴

There's little systematic evidence that measures the impact of CON laws on safety net hospitals, but the evidence that does exist does not favor CON. The Lewin Group's 2007 analysis of CON in Illinois determined that safety net hospitals in non-CON states had higher margins than safety net hospitals in CON states. Their analysis concludes that "realistically, the greatest effect that CON laws have is that it retards the shift of relatively profitable services from the inner-city into the suburbs."⁶⁵ Similarly, Stratman and Russ (2014) find that CON is not associated with increased levels of uncompensated care at hospitals.⁶⁶

It is not clear why CON laws appear to provide limited protection to safety net hospitals. One possible explanation is that CON laws may restrict the flexibility of safety net hospitals seeking to improve their financial position. Many safety net

⁶¹ Minnesota Department of Health: Health Economics Program. (2014). *Uninsurance and the Safety Net*.

⁶² Minnesota Department of Health: Hospital Annual Reports (2011-2013)

⁶³ *ibid.*

⁶⁴ Dobson, A., Welch, W. P., Bender, D., Ko, K. D., Sen, N., El-Gamil, A., Kirby, T. (2007). *An Evaluation of Illinois' Certificate of Need Program*. The Lewin Group.

⁶⁵ *Ibid.*

⁶⁶ Stratmann, T., & Russ, J. (2014). *Do Certificate-of-Need Laws Increase Indigent Care?* The Mercatus Center.

hospitals are seeking to employ many of the same strategies as their non-safety-net counterparts to stay afloat, including facility renovations and specialty service line expansions to attract more patients that are well-insured. Indeed, the community tracking survey of hospital strategy indicated that safety net hospitals in states with CON took fewer offensive and defensive actions to protect and expand their market share.⁶⁷ Though this evidence is qualitative, it does suggest that CON might impede the ability of safety net hospitals to take steps to become more profitable.

Discussion

Strengthening capital expenditure regulations in Minnesota by reinstating a CON program would likely not achieve its intended goals, and may be associated with unintended consequences.

Many studies have examined the impact of CON laws on health care costs, and these studies consistently find that CON is unable to significantly reduce costs. CON does not appear to reduce total per capita health care costs. The evidence suggests that CON may impact spending patterns, but fails to reduce total spending because health providers reallocate resources to unregulated or less stringently regulated services. CON may also increase costs in the short run by encouraging providers to accelerate their investment plans. CON also appears to do little to reduce the dissemination of expensive technologies with little proven clinical benefit.

CON also does not appear to be a promising avenue for improving health care quality. The evidence on this question is narrower because it focuses mostly on cardiac surgery, but it nevertheless consistently suggests that CON has little impact on quality. It is possible CON may have a stronger impact on quality for services that have received little formal study. Nonetheless, even if CON could bring modest quality improvements from regionalization of services with a strong volume-outcome association, regionalization could impose significant costs. Regionalization would likely increase patient travel times, and could create perverse incentives for providers to meet volume benchmarks. Ultimately, Minnesota would likely be better served by building on its current efforts to provide standardized quality measurement and reporting for hospitals and physicians.

Finally, CON would not substantially improve access to care for the indigent in Minnesota. This is the least well-studied impact of CON, but the evidence to date does not favor CON. The state should continue to monitor the financial health of safety net hospitals as ACA implementation moves forward. Based on these findings, this report recommends that Minnesota does not reinstate a CON program.

⁶⁷ Cunningham, P. J., Bazzoli, G., & Katz, A. (2008). Caught In The Competitive Crossfire: Safety-Net Providers Balance Margin And Mission In A Profit-Driven Health Care Market. *Health Affairs*, 27(5), 374–382.

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