

CERTIFICATE OF NEED AND THE AFFORDABLE CARE ACT: FIFTY-STATE SURVEY
AND POLICY ANALYSIS

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I. Introduction

A majority of states currently have Certificate of Need (CON) programs. CON programs are mechanisms intended to reduce unnecessary health care spending and protect access to safety net providers for medically underserved populations. CON programs are usually administered by state health planning agencies and rely on need-projecting formulas, review criteria, and methodologies established by statute, regulation, and state health plans, to limit the supply of health care facilities, services, and major medical equipment in a given region. CON programs can cover a wide variety of health care entities and activities, but where CON requirements apply, applicants follow an often lengthy and expensive process to demonstrate that the community, often a defined medical service area, needs the proposed facility, services, or major medical equipment. Most CON programs throughout the country were initiated in response to the federal *Health Planning Resources Development Act of 1974*, and many states have continued to rely on essentially the same statutory framework and policy justifications for maintaining their CON programs in spite of the vastly changed health care landscape.

CON programs are controversial, and almost half of the states have either eliminated or drastically limited their CON programs. CON supporters' main arguments are that: (1) CON programs are necessary to reach efficient outcomes since free market principles do not apply to the market for health care; (2) CON programs are needed to prevent excessive health care spending through supply-induced demand; and (3) without the protection of CON programs, specialty hospitals would cherry-pick profitable commercially insured and paying patients and render safety net providers unable to cover their costs for uncompensated care. CON opponents' main arguments are that: (1) Medicare has shifted from a cost-based to a fixed reimbursement structure, obviating the initial policy justification for CON programs; (2) there is a lack of empirical evidence that CON programs have reduced unnecessary health care spending or

increased access to health care for medically underserved population despite numerous studies; and (3) directly subsidizing safety net providers for uncompensated care is more effective and less costly than trying to accomplish this goal through CON programs.

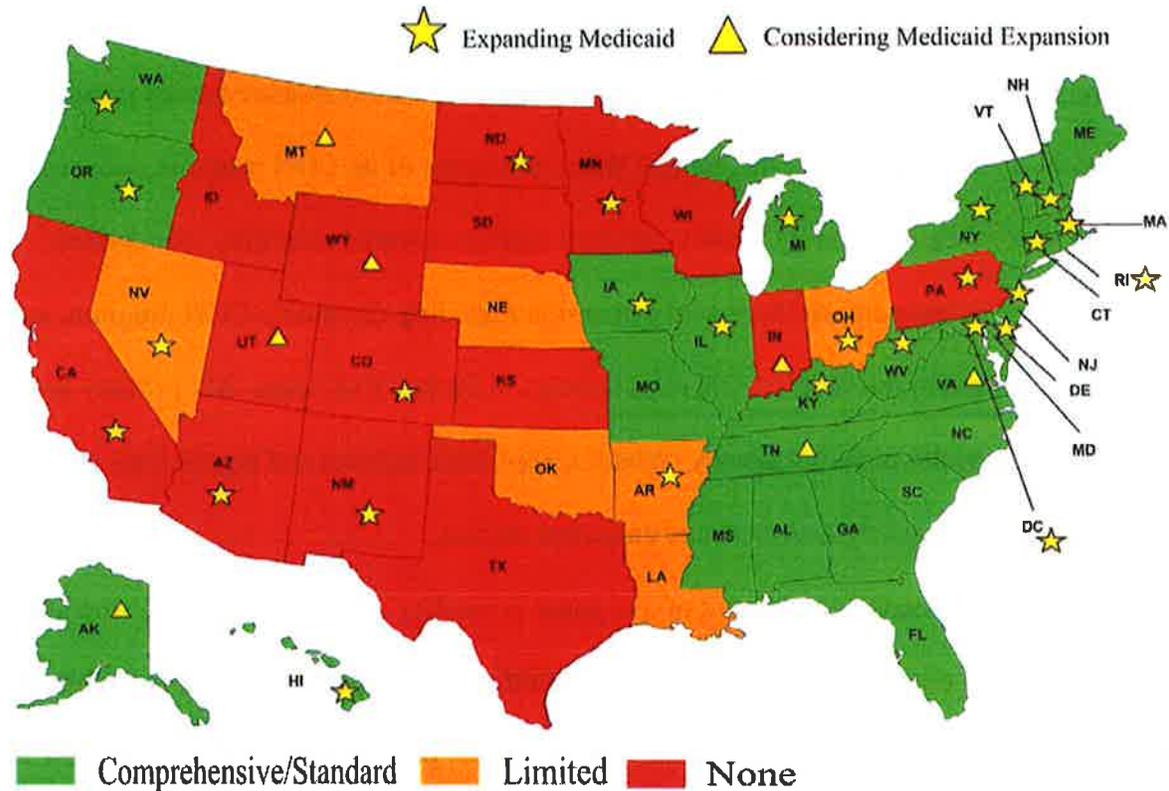
The first component of this paper is a fifty-state survey with data maps to describe the current state of CON programs throughout the country. The fifty-state survey provides information on each state about the general status and scope of its CON program, information about the state's health planning agency, covered entities, covered activities, exemptions, whether there has been any ACA-related discussion regarding the state's CON program, and any significant changes to the state's CON requirements in the last five years. My primary sources have been state health planning agency websites, applicable statutes and regulations, state health plans, news articles, policy analyses, and empirical studies.

The second component of this paper is a policy analysis evaluating whether CON programs should continue, and if so, how they should evolve, in light of the ACA. While there have been countless policy analyses on the merits of CON programs generally, only a few states and organizations have discussed how the ACA should shape the debate. The policy analysis explores seven themes for CON reform in response to the ACA, including: (1) increased consolidation of health care organizations; (2) a move toward outpatient care; (3) access to care and protection for safety net providers; (4) the shift from volume-driven to value-driven care and its impact on provider incentives; (5) comprehensive care; (6) electronic medical records and information sharing; and (7) quality and population health.

II. State CON Information

Table 1¹

Certificate of Need Status by State



1. **Alabama**

Alabama established its CON program in 1979.² Alabama’s CON program is administered by the Alabama State Health Planning and Development Agency (SHPDA).³

¹ See *Current Status of State Medicaid Expansion Decisions*, KAISER FAMILY FOUND. (Dec. 17, 2014), <http://kff.org/health-reform/slide/current-status-of-the-medicaid-expansion-decision/> (last visited Jan. 5, 2015).

² Richard Cauchi, *Certificate of Need: State Health Laws and Programs*, NAT’L CONFERENCE STATE LEGISLATURES (Jan. 2011), <http://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx> (last visited Dec. 30, 2014).

³ See ALA. STATE HEALTH PLANNING & DEV. AGENCY, <http://www.shpda.state.al.us> (last visited Dec. 29, 2014).

SHPDA is comprised of both the Alabama Certificate of Need Review Board, which handles rulemaking and determines which facilities receive CONs, and the Alabama Statewide Health Coordinating Council, which develops the Alabama State Health Plan.⁴

Alabama's CON requirements are set forth in Ala. Code § 22-21-260 *et seq.* and the regulations promulgated by SHPDA, in Ala. Admin. Code § 410-1-1 *et seq.* In Alabama, covered health care facilities and HMOs are required to undergo CON review for “the construction, development, acquisition, or other establishment of a new health care facility or [HMO]; a capital expenditure by a health care facility for major medical equipment; new annual operating costs; ‘other expenditures’ which exceed certain monetary thresholds; a change in the existing bed capacity of a health care facility or HMO; or the offering of a ‘new health service’ by a health care facility not previously offered within the prior 12 month period.”⁵

Under Ala. Code § 22-21-260, covered “health care facilities” include general and specialized hospitals and “related facilities, such as laboratories, outpatient clinics, and central service facilities operated in connection with hospitals; skilled nursing facilities; intermediate care facilities....; rehabilitation centers; public health centers; facilities for surgical treatment of patients not requiring hospitalization; kidney disease treatment centers...; community mental health centers...; alcohol and drug abuse facilities; facilities for the developmentally disabled; hospice service providers; home health agencies; and [HMOs].” Ala. Code § 22-21-260 additionally provides that “the offices of private physicians or dentists” are not covered “health care facilities” under Alabama’s CON statute.

⁴ Howard Bogard, *The Alabama CON Program*, BIRMINGHAM MED. NEWS, <http://www.birminghammedicalnews.com/news.php?viewStory=959> (last visited Dec. 29, 2014).

⁵ Quoted from *id.*; see ALA. CODE § 22-21-263.

Ala. Code § 22-21-265 states exemptions from the CON requirement for replacement of medical equipment that does not change the equipment's "purpose, use, or application" and does not "enable the health care facility to expand its health services" and for the "construction or modernization" of health care facilities that "does not allow the health care facility to provide new institutional health services subject to review."

Under Ala. Code § 22-21-264, SHPDA relies on the following CON review criteria: consistency with the Alabama State Health Plan; "the relationship of services reviewed to the long-range development plan" of the applicant; "the availability of alternative, less costly, or more effective methods of providing such services"; financial feasibility; appropriateness of location; consistency of the project with the institution's non-patient care objectives, including teaching and research; conformance with applicable laws; in the event of competing applications, whether the person applying is "the most appropriate applicant" as determined by professional capability, management capability, the availability of needed resources, and past performance; special considerations for HMOs and "those entities which provide a substantial portion of their services or resources...to individuals not residing in the health service area in which the entities are located"; and potential effects of associated construction endeavors.

Please see recent developments analyzed in the policy analysis section below.

2. **Alaska**

Alaska's CON program has been in operation since 1976.⁶ The Alaska Department of Health and Social Services, Division of Health Care Services, is responsible for

⁶ Richard Cauchi, *Certificate of Need: State Health Laws and Programs*, NAT'L CONFERENCE STATE LEGISLATURES (Jan. 2011), <http://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx> (last visited Dec. 30, 2014).

administering the state's CON program.⁷ Alaska's CON requirements are set forth in Alaska Stat. § 18.07.101 *et seq.*, 7 Alaska Admin. Code § 07.900 *et seq.*, and the *Alaska Certificate of Need Review Standards and Methodologies* updated in 2005.⁸

A CON is required before: “construction of a health care facility; alteration of the bed capacity of a health care facility; addition of a category of health services provided by a health care facility”; or conversion of “a building or part of a building to a nursing home.”⁹

Pursuant to the *Alaska Certificate of Need Review Standards and Methodologies*, the division applies the following CON review criteria: “[whether] the applicant documents need for the project by the population to be served, including, but not limited to, the needs of rural populations having distinct or unique geographic, socioeconomic, cultural, transportation, and other barriers to care; [whether] the applicant demonstrates that the project, including the applicant's long-range development plans, augments and integrates with relevant community, regional, state, and federal health planning, and incorporates or reflects evidence-based planning and service delivery...; [whether] the applicant demonstrates evidence of stakeholder participation in planning for the project and in the design and execution of services; [whether] the applicant demonstrates that they have assessed alternative methods of providing the proposed services and demonstrates that the proposed services are the most suitable approach;...the anticipated impact on existing health care systems within the project's service area...; the anticipated impact on the statewide health care system; [and whether] the project's location is

⁷ *Certificate of Need (CON) Program Summary*, ALASKA DEP'T HEALTH & SOCIAL SERV., DIV. HEALTH CARE SERV., <http://dhss.alaska.gov/dhcs/Pages/CertificateOfNeed/default.aspx> (last visited Jan. 3, 2015).

⁸ See *Alaska Certificate of Need Review Standards and Methodologies*, STATE OF ALASKA DEP'T HEALTH & SOC. SERV. (Dec. 9, 2005), available at <http://dhss.alaska.gov/dhcs/Documents/CertificateOfNeed/Standards.pdf>.

⁹ ALASKA STAT. § 18.07.031; see 7 ALASKA ADMIN. CODE § 07.900.

accessible to patients and clients, their immediate and extended families and community members, and to ancillary services.”¹⁰

Research has not disclosed any significant changes to Alaska’s CON program in the last five years.

3. **Arizona**

Arizona eliminated its CON program in the late 1980s and has not since reestablished it.¹¹ Even though Arizona no longer has a CON program, the Arizona Department of Health Services Bureau of Emergency Medical Services & Trauma System requires ambulance services to obtain a “Certificate of Necessity.”¹²

4. **Arkansas**

Arkansas has a Permit of Approval requirement that is much more limited in scope than many other states’ CON requirements.¹³

The Arkansas Health Services Permit Agency and the Arkansas Health Services Permit Commission administer the Permit of Approval process, and these entities have outlined applicable requirements in the *Arkansas Permit of Approval Rulebook*,¹⁴ published in 2012 pursuant to Ark. Code. Ann. § 20-8-101 *et seq.*

¹⁰ See *Alaska Certificate of Need Review Standards and Methodologies*, STATE OF ALASKA DEP’T HEALTH & SOC. SERV. (Dec. 9, 2005), available at <http://dhss.alaska.gov/dhcs/Documents/CertificateOfNeed/Standards.pdf>.

¹¹ Fred J. Hellinger, *The Effect of Certificate of Need Laws on Hospital Beds and Health care Expenditures: An Empirical Analysis*, 15 AM. J. MANAGED CARE 737 (2009), available at http://www.ajmc.com/publications/issue/2009/2009-10-vol15-n10/AJMC_09Oct_Hellinger_737to744/.

¹² *Bureau of Emergency Medical Services & Trauma System: Certificate of Necessity (CON) Holders*, ARIZ. DEP’T HEALTH SERV., <http://www.azdhs.gov/bems/ambulance/maps/index.php> (last visited Dec. 30, 2014).

¹³ See ARK. HEALTH SERV. PERMIT AGENCY, <http://www.arhspace.org> (last visited Dec. 30, 2014).

¹⁴ See *Arkansas Permit of Approval Rulebook*, ARK. HEALTH SERV. PERMIT AGENCY (Dec. 2012), available at http://www.arhspace.org/rules_regs/RulebookDecember2012.pdf.

The Permit of Approval requirement is limited to long-term care entities, and such entities must obtain a permit before: construction of a nursing home, expansion of LTC bed capacity, expansion or addition of home health services, and establishment of a hospice program.¹⁵ Applicants must also disclose and seek approval for “any increase in cost [of] an approved project.”¹⁶ Certain projects and entities are excluded from the Permit of Approval requirement, including nursing home capital expenditures less than \$1,000,000 that do not include the expansion of bed capacity or [the offering of] home health services; hospitals licensed in Arkansas except when expanding long-term care bed capacity or adding or expanding home health services; certain conversions or additions of services not resulting in additional bed capacity; acquisition of an existing health care facility; outpatient surgery centers; imaging centers; and freestanding radiation therapy centers.¹⁷

The Agency and Commission rely on the following Permit of Approval review criteria: “whether the proposed project is needed or projected as necessary to meet the needs of the locale or area; whether the project can be adequately staffed and operated when completed; whether the proposed project is economically feasible; and whether the project will foster cost containment through improved efficiency and productivity.”¹⁸

Research did not disclose any significant changes in Arkansas’s Permit of Approval process over the last five years.

5. **California**

¹⁵ *Id.* at 9.

¹⁶ *Id.*

¹⁷ *Id.* at 9-10.

¹⁸ *Id.* at 12.

California indefinitely suspended its CON program in the mid-1980s, and the state legislature repealed the supporting statutory authority in 1995.¹⁹ A 2006 analysis by the California Research Bureau stated the following: “California’s CON program appears to have suffered from inadequate staffing and lack of data. In addition, there were a number of exceptions to the program that made it difficult to administer, and sanctions for noncompliance were infrequently utilized.”²⁰ Reasons for abandoning the CON program included “declining federal and state support for health care facilities planning” and Medicare’s 1983 switch from “a cost-based, dollar-for-dollar fee-for service payment system to paying each hospital a flat amount for a given category of admissions.”²¹

6. **Colorado**

Colorado eliminated its CON program in 1987 and has not reestablished it since.²² Research did not disclose any significant developments in the last five years.

7. **Connecticut**

The Connecticut Office of Health Care Access (OHCA) is responsible for administering Connecticut’s CON program. The statutory provisions outlining the requirements of Connecticut’s CON program are Conn. Gen. Stat. §§ 19a-638 and 639.

Conn. Gen. Stat. § 19a-638 requires obtaining a CON prior to: the “establish[ment] of a new health care facility”; “transfer of ownership of a health care facility”;

¹⁹ Charlene W. Simmons, *Hospital Planning: What Happened to California’s Certificate of Need Program*, CAL. RESEARCH BUREAU, 13 (Aug. 2006), available at <https://www.library.ca.gov/crb/06/09/06-009.pdf>.

²⁰ *Id.* at 1.

²¹ *Id.* at 13.

²² Richard Cauchi, *Certificate of Need: State Health Laws and Programs*, NAT’L CONFERENCE STATE LEGISLATURES (Jan. 2011), <http://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx> (last visited Dec. 30, 2014).

“increase in the licensed bed capacity of a health care facility”; establishment of “an outpatient surgical facility”; “termination of services by an outpatient surgical facility”; [the acquisition of CT scanners, MRI scanners, and PET scanners]; “increase of two or more ORs within any 3 year period”; “establishment of a free-standing emergency department” or “terminat[ion] of an emergency department”; establishment of “inpatient or outpatient cardiac services; acquisition of equipment” using technologies not previously employed in the state; and “acquisition of non-hospital based linear accelerators.”²³

Conn. Gen. Stat. § 19a-638 states exemptions from the CON requirement for the establishment of private physicians’ offices; health care facilities “owned and operated by the federal government”; residential care homes and nursing homes; assisted living facilities; home health services; hospice services; outpatient rehabilitation facilities; outpatient dialysis services; transplant services; free clinics; “replacement of existing imaging equipment”; the acquisition of dental imaging equipment; and “the partial or total elimination of services provided by an outpatient surgical facility.”

Conn. Gen. Stat. § 19a-639 provides the following CON review criteria: whether there is a “clear public need for the health care facility”; how the proposal “will improve quality, accessibility, and cost effectiveness of health care delivery in the region”; and whether the proposed project will “result in any unnecessary duplication of existing or approved health care services or facilities.”

Connecticut, which has chosen to adopt Medicaid expansion, has responded to federal health care reform by making its CON requirements less onerous through the adoption of

²³ Kimberly Martone, *Connecticut’s Certificate of Need Program*, OFFICE HEALTH CARE ACCESS, available at http://www.michigan.gov/documents/mdch/Sessions_F_R_-_Other_States_CON_Models_Connecticut_334499_7.pdf (last visited Dec. 30, 2014).

its CON Reform Law in 2010.²⁴ According to the Director of Operations of OHCA, Kimberly Martone, Connecticut’s CON Reform Law of 2010 (effective October 1, 2010), Public Act 10-179, was enacted to “align health care resources with the needs of the community, align with federal health care reform in supporting the development of a patient-centered integrated delivery system, simplify CON procedural requirements, focus CON oversight to preserve access to ‘safety net’ services and potential areas of over-utilization, and improve CON criteria to address the financial stability of the health care delivery system and improve quality of patient care.”²⁵ As part of the CON Reform Law, Connecticut narrowed its definition of covered health care facility “to only include: hospitals, freestanding emergency departments, ambulatory surgery centers, mental health facilities, substance abuse facilities, and central service facilities.”²⁶

OHCA has promulgated interim Policies & Procedures for the implementation of the 2010 CON Reform statute, Public Act 10-179 §§ 87, 89-93.²⁷

I elaborate on Connecticut’s CON reform efforts in the policy analysis section below.

8. Delaware

The Delaware Certificate of Public Review program (CPR) is “a review process used to assure that there is a continuing public scrutiny of certain health care developments

²⁴ However, more recently, the Connecticut legislature has adopted certain additional provisions to protect health care accessibility for indigent and vulnerable populations (described below).

²⁵ Kimberly Martone, *Connecticut’s Certificate of Need Program*, OFFICE HEALTH CARE ACCESS, available at http://www.michigan.gov/documents/mdch/Sessions_F_R_-_Other_States_CON_Models_Connecticut_334499_7.pdf (last visited Dec. 30, 2014).

²⁶ *Id.*

²⁷ *Certificate of Need Policies & Procedures for Implementation of Public Act 10-179 §§87, 89-93*, OFFICE HEALTH CARE ACCESS, available at <http://www.ct.gov/dph/lib/dph/ohca/lawsandregspdf/policiesproceduresforpublicact10-179final10-25-10.pdf>.

which could negatively affect the quality of health care or threaten the ability of health care facilities to provide services to the medically indigent.”²⁸ The Delaware CPR program is administered by the Delaware Health Resources Board, which is part of the DHHS Bureau of Health Planning & Resources Management.²⁹ The applicable statutory provisions are in 16 Del. Code Ann. § 9301 *et seq.*

A CPR is required for the following activities: the construction or development of a health care facility or acquisition of a non-profit health care facility; capital expenditures exceeding the threshold amount (unless the Board grants an exemption on the basis that expenditures are necessary for maintaining the physical structure of the facility and will not relate to direct patient care); certain changes in bed capacity; and the acquisition of major medical equipment (except for replacement purposes).³⁰

The Board relies on the following CPR criteria: “a proposal’s relationship to the Health Resources Management Plan”; “the need of the population”; “the availability of less costly and/or more effective alternatives, including the use of out of state resources”; “the relationship to the existing health care delivery system”; “the immediate and long term viability”; and “the anticipated effect on costs and charges” and on the “quality of care.”³¹

Research has not disclosed any recent changes to Delaware’s CON program, but please see a discussion of Delaware’s proposed response to the ACA in the policy analysis section below.

²⁸ DEL. HEALTH CARE COMM’N, <http://www.dhss.delaware.gov/dhss/dhcc/hrb/cprphome.html> (last visited Dec. 30, 2014).

²⁹ *Id.*

³⁰ *Id.*

³¹ *Delaware Health Resources Management Plan*, DEL. HEALTH RES. BD. 2 (Mar. 6, 2010), available at <http://dhss.delaware.gov/dph/hsm/files/hrmpupdmarch62010.pdf>.

9. District of Columbia

D.C.'s CON program has been in operation since 1977.³² The District of Columbia State Health Planning and Development Agency (SHPDA) is responsible for administering D.C.'s CON program.³³ The relevant statutory provisions are in D.C. Code § 44-401 *et seq.* (*The Health Services Planning Program Reestablishment Act of 1996*), and the applicable regulations are in D.C. Code Mun. Regs. tit. 22B, § 4000 *et seq.*

Under D.C. Code § 44-406 and D.C. Code § 44-401, covered activities include: construction or development of a new health care facility, service, or home health agency; capital expenditures exceeding the threshold amount; acquisition of major medical equipment (not for replacement purposes); bed relocation or redistribution between facilities; increase or relocation of renal dialysis stations; and acquisition of an existing health care facility. Under D.C. Code §§ 44-406 and 44-401, private physicians' offices providing non-invasive treatments are not subject to the CON requirement. D.C. Code § 44-407 states additional exemptions from the CON requirement for certain non-patient care-related capital expenditures, HMOs, and for "the acquisition of major medical equipment to be used solely for research."

D.C. Code Mun. Regs. tit. 22B, § 4050 *et seq.* provide the following considerations for CON review: consistency of the project with the goals and priorities of the State Health Plan and Annual Implementation Plan; "need for the project on a system-wide basis"; institutional need for the project; impact of the project on medical training education opportunities; "requirements of research projects and programs"; effect of the project on other physicians' and patients' access to services and facilities; reasonableness of the project's

³² Richard Cauchi, *Certificate of Need: State Health Laws and Programs*, NAT'L CONFERENCE STATE LEGISLATURES (Jan. 2011), <http://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx> (last visited Dec. 30, 2014).

³³ D.C. DEP'T HEALTH, <http://doh.dc.gov/service/certificate-need> (last visited Dec. 30, 2014).

schedule; the project’s potential impact on health care accessibility for medically underserved populations; “compliance with free care and community service requirements”; community involvement in the planning and development process; impact on the surrounding health system and community health; whether there is an adequate mechanism for protecting patient rights; quality assurance; available alternatives; effect of “operational costs of the project on costs, rates, or consumer charges”; “the effect of operational costs of the project on the applicant’s budget”; energy conservation; “effect on competition”; “efficiency and effectiveness of existing services”; financial feasibility; “compatibility with the reimbursement policies of third-party payors”; “availability of personnel”; management capability; “availability of ancillary services as required”; and “relationship of the project to the health care system.”

The District of Columbia State Health Plan has adopted a conceptual framework for CON review that encompasses the following general considerations: “the availability of the proposed service based on a needs projection that identifies gaps and unmet need; the accessibility of the proposed services; the acceptability of the proposed services; and the financial viability of the proposed services.”³⁴

Research did not disclose any changes to D.C.’s CON program in the last five years.

10. **Florida**

Florida’s CON program has been in operation since 1973.³⁵ The Florida Agency for Health Care Administration (AHCA) administers the program.³⁶

³⁴ *Addressing the District of Columbia’s Health Priorities: State Health Plan*, GOV’T D.C. iv. (2007), available at http://doh.dc.gov/sites/default/files/dc/sites/doh/publication/attachments/State_Health_%20Plan.pdf.

³⁵ Richard Cauchi, *Certificate of Need: State Health Laws and Programs*, NAT’L CONFERENCE STATE LEGISLATURES (Jan. 2011), <http://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx> (last visited Dec. 30, 2014).

Florida’s CON program “currently regulates hospices, skilled nursing facilities, intermediate care facilities for the developmentally disabled, new hospitals, and certain hospital services, [but] it does not regulate outpatient services, home health services, purchases of major medical equipment, or assisted living facilities.”³⁷

The applicable statute is *The Health Facility and Services Development Act*, Fla. Stat. §§ 408.031 through 408.045, and the associated regulations are in Fla. Admin. Code Chapter 59C-1.

Under Fla. Stat. § 408.036, the following activities are subject to CON review: “the addition of beds in community nursing homes or intermediate care facilities for the developmentally disabled...; the new construction or establishment of additional health care facilities...; the conversion from one type of health care facility to another...; the establishment of a hospice or hospice inpatient facility...; an increase in the number of beds for comprehensive rehabilitation; and the establishment of tertiary health services...”³⁸

Fla. Stat. § 408.035 sets forth the following criteria for AHCA to consider when reviewing CON applications: “the need for the health care facilities and health care services being proposed; the availability, quality of care, accessibility, and extent of utilization of existing health care facilities and health services in the service district of the applicant; the ability of the applicant to provide quality of care and the applicant’s record of providing quality of care; the availability of resources...for project accomplishment and operation; the extent to which [the project] will enhance access to health care for residents of the service district; the immediate and

³⁶ *Certificate of Need (CON) Program Overview*, FLA. AGENCY FOR HEALTH CARE ADMIN., http://ahca.myflorida.com/mchq/CON_FA/ (last visited Dec. 30, 2014).

³⁷ *Id.*

³⁸ Additional categories of activities pertaining to nursing homes and retirement communities are subject to expedited review.

long-term financial feasibility of the proposal; the extent to which the proposal will foster competition that promotes quality and cost-effectiveness; the costs and methods of proposed construction...; [and] the applicant’s past and proposed provision of health care services to Medicaid patients and the medically indigent...”

According to the Florida Hospital Association, Florida’s CON process was “significantly streamlined” through the state legislature’s 2008 revisions, which “refocused the process to be based solely on the issue of need and access to hospital care services and removed the financial viability and cost criteria from the review.”³⁹ Under the 2008 revisions, “the CON process no longer regulates all hospital projects and mainly provides oversight for the establishment of new facilities and replacement of facilities greater than one mile away from a main hospital.”⁴⁰

In January of 2014, the Health Foundation of South Florida published an in-depth analysis and critique of Florida’s CON Program entitled “Florida’s Health Care: Certificate of Need.”⁴¹ According to the analysis, “the coverage of Florida’s CON program has been substantially reduced since the program originated.”⁴² For instance “items originally subject to CON review but subsequently eliminated” include: “new or expanded obstetrical services; outpatient project capital expenditures; acquisition of medical equipment; new or expanded Medicare-certified Home Health Agencies; cost overruns of approved projects of any kind; new rural hospitals meeting certain criteria; addition or delicensure of acute care beds, neonatal

³⁹ *Certificate of Need*, FLA. HOSP. ASS’N, <http://www.fha.org/Advocacy/State-Advocacy/Legislative-Issues/Certificate-of-Need.aspx> (last visited Dec. 30, 2014).

⁴⁰ *Id.*

⁴¹ *Id.*

⁴² *Florida’s Health Care Certificate of Need*, HEALTH FOUNDATION S. FLA 2 (Jan. 2014), available at http://hfsf.org/certificate_of_need.pdf.

intensive care beds, hospital-based skilled nursing home beds, long term care hospital beds, and inpatient hospice beds at existing facilities; new or expanded adult open heart surgery programs; and new or expanded burn units.”⁴³ The Health Foundation of South Florida’s analysis elaborates that due to the “deregulatory evolution of the Florida CON program,” since 1985, AHCA has scaled back from requiring 40 to only 4 full-time employees and from reviewing 542 applications to only 29 applications annually.⁴⁴

After a 13-year moratorium on the issuance of CONs for additional community nursing home beds, Florida Senate Bill 268, introduced on October 14, 2013 (passed on April 23, 2014, with an effective date of July 1, 2014) reopens the process and amends the “CON methodology for determining the need for nursing home beds to encourage the modernization—renovation and replacement—of older nursing home facilities, the movement of beds among facilities, plus the construction of a limited number of beds.”⁴⁵ The Health Foundation of South Florida’s analysis summarizes the views of Senate Bill 268’s supporters as follows:⁴⁶

Supporters of S.B. 268 contend that financial lenders are wary about lending to builders of Medicaid nursing home beds, but that the CON program (by restricting competition from new nursing homes that will only skim off Medicare and private-pay residents) gives lenders a greater sense of security about lending to builders of Medicaid nursing home beds. Without a CON program providing a sense of security, the cost of borrowing money to renovate and replace facilities serving the Medicaid population would increase substantially. According to S.B. 268 supporters, that is what happened in Texas after elimination of CON for

⁴³ *Id.*

⁴⁴ *Id.* at 3.

⁴⁵ Quoted from *id.* at 11; *CS/CS/SB 268—Certificates of Need*, FLA. HOUSE REPRESENTATIVES, <http://www.myfloridahouse.gov/Sections/Bills/billsdetail.aspx?BillId=51290&> (last visited Dec. 30, 2014); *see also supra* note 51.

⁴⁶ *Florida’s Health Care Certificate of Need*, HEALTH FOUNDATION S. FLA 11 (Jan. 2014), *available at* http://hfsf.org/certificate_of_need.pdf.

nursing homes, resulting in many nursing homes there that served the poor being driven out of business by new facilities serving a wealthier resident population.

Please see additional discussion below in the policy analysis section regarding how Florida's CON program might respond to the ACA.

11. Georgia

Georgia's CON program has been in operation since 1979.⁴⁷ The Georgia Department of Community Health (DCH), Healthcare Facility Regulation Division (HFR), is responsible for administering the state's CON program.⁴⁸ The applicable statute is Ga. Code Ann. § 31-6-40 *et seq.*, and the regulations are in Ga. Comp. R & Regs. § 111-2-2-.01 *et seq.*

According to DHC, the following categories of projects require a CON: "new hospitals, including general, acute-care, and specialty hospitals; new or expanding nursing homes and home health agencies; all multi-specialty and certain single-specialty ambulatory surgery centers; providers in radiation therapy, Positron Emission Tomography, open heart surgery, and neonatal services; major medical equipment purchases or leases (e.g. MRI, CT scanners) that exceed the equipment threshold; major hospital renovations or other capital activities by any health care facility that exceed the capital expenditure threshold; and new health services not provided on a regular basis during the previous 12-month period"; and the addition of bed capacity.⁴⁹

⁴⁷ Richard Cauchi, *Certificate of Need: State Health Laws and Programs*, NAT'L CONFERENCE STATE LEGISLATURES (Jan. 2011), <http://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx> (last visited Dec. 30, 2014).

⁴⁸ *Certificate of Need*, GA. DEP'T CMTY. HEALTH, <https://dch.georgia.gov/certificate-need-con> (last visited Dec. 30, 2014).

⁴⁹ *Fact Sheet: Certificate of Need*, GA DEP'T CMTY HEALTH 1 (Nov. 2013), available at https://dch.georgia.gov/sites/dch.georgia.gov/files/CertificateOfNeedFY14_Final.pdf.

Under Ga. Comp. R. & Regs. § 111-2-2-.09, DHC applies the following CON review criteria: consistency with the goals and objectives of the State Health Plan; population need; availability of less costly alternatives for meeting that need; financial feasibility; effects on payors; environmental and economic implications of planned construction; accessibility to the public, especially medically underserved groups, the indigent, and Medicaid recipients; projected effects on the service area's existing health care delivery system; potential efficiency gains for the applicant health care facility; provision of services to individuals residing outside of the service area; compatibility with the "clinical needs of health professional training programs"; whether the project "fosters improvements or innovations in the financing or delivery of health services" or "promotes quality assurance"; the special needs of HMOs; and whether the project will provide an "underrepresented health service."

According to DHC and under Ga. Code Ann. § 31-6-47, the following projects are exempt from Georgia's CON process: "repairs to a facility that fall below the CON review threshold"; "replacement of existing therapeutic or diagnostic equipment that received prior CON authorization"; "cost overruns that represent less than 10 percent of the previously approved capital expenditure and do not exceed the CON review threshold, [with] all cost overruns under \$300,000...exempt from review"; a 10-bed or 10% increase of existing inventory for "a hospital that maintains an occupancy rate greater than 75% for the preceding 12-month period"; and "a joint-venture or single-specialty ambulatory surgery center, the establishment and development of which does not exceed the statutory or dollar threshold applicable to such exempt facilities."⁵⁰

⁵⁰ *Id.* at 3.

Georgia's CON program also has a request for proposal (RFP) process for "alternative health care models," which are defined as "new and/or innovative model[s] of providing new or existing institutional health service(s) delivered in or through a health care facility(ies) and/or health care services networks." Ga. Comp. R. & Regs. §. 11-2-2-.08. Under this process, "the Board may accept abstracts describing potential Alternative Health care Models, based on the recommendation of the Department," and "select a list of those categories for which Alternative Health care Model Certificate of Need applications may be submitted."⁵¹

Even though Georgia's CON program has not seen any significant reforms in the last five years, in the 2015 legislative session, physician groups are expected to advance CON reform legislation that will make it easier to establish multi-specialty ambulatory surgery centers.⁵² The last major reforms Georgia's CON program were enacted prior to the ACA in 2008, under Senate Bill 233, which "resulted in many new exceptions, new expenditure thresholds, and expanded reporting requirements."⁵³ The exemption for single-specialty ambulatory surgery centers encompasses physician-owned general surgery centers as of 2008.⁵⁴

12. **Hawaii**

⁵¹ Ga. Comp. R. & Regs. § 11-2-2-.08.

⁵² Andy Miller, *Trends and Surprises: What to Watch for This Year in Health care*, NORTHWEST GA. NEWS (Jan. 2, 2015), http://www.northwestgeorgianews.com/associated_press/news/national/trends-and-surprises-what-to-watch-for-this-year-in/article_791b586c-92bf-11e4-9b40-c74d82aae880.html (last visited Jan. 5, 2015).

⁵³ *Fact Sheet: Certificate of Need*, GA DEP'T CMTY HEALTH 1 (Nov. 2013), available at https://dch.georgia.gov/sites/dch.georgia.gov/files/CertificateOfNeedFY14_Final.pdf.

⁵⁴ Amy L. Sorrel, *Georgia Exempts General Surgery Centers from CON Rules*, AM. MED. ASS'N (Feb. 4, 2008), <http://www.amednews.com/article/20080204/government/302049981/7/> (last visited Dec. 30, 2014).

Hawaii's CON program has been in operation since 1974.⁵⁵ The State Health Planning and Development Agency (SHPDA) is responsible for administering Hawaii's CON program and implementing the state's Health Services and Facilities Plan.⁵⁶ The CON process requires initial review by Sub-area Health Planning Councils, the Certificate of Need Review Panel, and the Statewide Health Coordinating Council, which recommend approval, conditional approval, or disapproval before SHPDA issues the final decision.⁵⁷

Applicable statutes include Haw. Rev. Stat. § 323D-43, which provides the list activities subject to the CON requirement and authorizes SHPDA to develop CON review criteria, and Haw. Rev. Stat. § 323D-54, which lists exemptions from CON coverage.

Under Haw. Rev. Stat. § 323D-43, “no person, public or private, profit or non-profit shall: construct, expand, alter, convert, develop, initiate, or modify a health care facility or health care services in the state that requires a total capital expenditure in excess of [the threshold amount]; or substantially modify or increase the scope or type of health service rendered; or increase, decrease, or change the class of usage of the bed complement of a health care facility, or relocate beds from one physical facility site to another,” without first obtaining a CON from SHPDA.

Notable exemptions under Haw. Rev. Stat. § 323D-43 include the following: “offices of physicians, dentists, or other practitioners...in private practices as distinguished from organized ambulatory health care facilities, except in any case of purchase or acquisition of

⁵⁵ Richard Cauchi, *Certificate of Need: State Health Laws and Programs*, NAT'L CONFERENCE STATE LEGISLATURES (Jan. 2011), <http://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx> (last visited Dec. 30, 2014).

⁵⁶ Haw. STATE HEALTH PLANNING & DEV. AGENCY, <http://health.hawaii.gov/shpda/> (last visited Dec. 30, 2014).

⁵⁷ *Certificate of Need*, HAW. STATE HEALTH PLANNING & DEV. AGENCY, <http://health.hawaii.gov/shpda/certificate-of-need/> (last visited Dec. 30, 2014).

equipment attendant to the delivery of health care services and the instruction or supervision for any private office or clinic involving a total expenditure in excess of the expenditure minimum”; “laboratories,...except in the case of purchase or acquisition of equipment attendant to the delivery of health care service and the instruction or supervision for any laboratory involving a total expenditures in excess of the expenditure minimum”; dental clinics; development of “non-patient areas of care facilities”; “bed changes that involve ten percent or ten beds of existing licensed bed types, whichever is less, of a facility’s total existing licensed beds within a two-year period”; “replacement of existing equipment with its modern day equivalent”; primary care clinics not exceeding specified expenditure thresholds; and “extended care adult residential care homes and assisted living facilities.”

The State of Hawaii Health Services and Facilities Plan provides the following CON review considerations: “relation to the State Plan; need and accessibility; quality; costs and finances; relation to the existing health care system; and availability of resources.”⁵⁸

Research did not disclose any significant changes to Hawaii’s CON program in the last five years.

13. **Idaho**

Idaho has not had a CON program since 1983, but the Idaho Hospital Association is currently attempting to pass CON legislation that would cover “new health facilities valued at \$1,000,000 or more; purchase of major medical equipment of \$500,000 or more or CT, MRI, PET, linear accelerator, angiographic systems and surgical robotics equipment; and increases in

⁵⁸ *State of Hawaii Health Services and Facilities Plan*, STATE HEALTH PLANNING & DEV. AGENCY 16 (2009), available at <http://health.hawaii.gov/shpda/files/2013/04/shhsfp09.pdf>.

licensed acute care beds or operating room suites.”⁵⁹ Research did not disclose any further references to such proposed legislation.

14. **Illinois**

The Illinois CON program has been in operation since 1974.⁶⁰ The Health Facilities and Services Review Board is responsible for administering the Illinois CON program.⁶¹ The applicable statute is the *Health Facilities Planning Act*, 20 Ill. Comp. Stat. § 3960, and applicable regulations are in Ill. Admin. Code tit. 77, § 1110.

Covered entities include “licensed and state-operated: hospitals; long-term care facilities; dialysis centers; ambulatory surgery centers; alternative health care delivery models, free standing emergency centers, and birthing centers.”⁶² “Transactions requiring a permit include construction or modification by or on behalf of a health care facility exceeding the capital expenditure minimum that is in excess of \$12,495,668 for hospitals, \$7,062,768 for long term care facilities and for all other applicants \$3,259,740,” with the same capital expenditure thresholds applying “to the acquisition of major medical equipment.”⁶³ Covered entities must seek a “permit of exemption” for a “substantial increase” in the facility’s bed capacity or for “a

⁵⁹ *Responsible Health Planning for Idaho: Certificate of Need*, IDAHO HOSP. ASS’N, <https://www.teamiha.org/Documents/IHANews/CON%20Info%20Sheet.pdf> (last visited Dec. 30, 2014).

⁶⁰ Richard Cauchi, *Certificate of Need: State Health Laws and Programs*, NAT’L CONFERENCE STATE LEGISLATURES (Jan. 2011), <http://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx> (last visited Dec. 30, 2014).

⁶¹ *Certificate of Need Program*, ILL. HEALTH FACILITIES & SERV. REVIEW BD., <http://www.hfsrb.illinois.gov/conprocess.htm> (last visited Dec. 30, 2014).

⁶² *Id.*

⁶³ *Id.*

substantial change in the scope or functional operation of a facility and the proposed establishment or discontinuation of a facility or category of service.”⁶⁴

20 Ill. Comp. Stat. § 3960 states exemptions from the CON requirement for the offices of private health care practitioners, not subject to state health care facility licensing requirements, and for changes in ownership and closure of certain long-term care facilities.

20 Ill. Comp. Stat. § 3960 provides the following CON review criteria for the Board to consider: “the size, composition, and growth of the population of the area to be served; the number of existing and planned facilities offering similar programs; the extent of utilization of existing facilities; the availability of facilities which may serve as alternatives or substitutes; the availability of personnel necessary to the operation of the facility; multi-institutional planning and the establishment of multi-institutional systems where feasible; the financial and economic feasibility of proposed construction modification; and in the case of health care facilities established by a religious body or denomination, the needs of the members of such religious body or denomination...” Additional project-specific review criteria are provided in Ill. Admin. Code tit. 77, § 1110.

Even though the Illinois CON Program has been in operation for decades, the statute was recently updated, to avoid automatic repeal, through a sunset provision in 2009 by Illinois Senate Bill 1905. Senate Bill 1905 requires a “safety net impact statement” to the “general review criteria for substantive projects” and permits hospitals and safety net facilities to “increase the existing bed capacity over a two-year period by either adding 20 beds or an additional 10% of the facility’s capacity, whichever results in the lesser increase, as long as the project does not exceed the capital expenditure minimum for the type of facility in question.”

⁶⁴ *Id.*

Please see additional discussion of Senate Bill 1905 in the policy analysis section below.

15. **Indiana**

Indiana abandoned its CON program in 1999 and has not since reestablished it.⁶⁵ Research did not disclose any efforts to reinstate Indiana’s CON program.

16. **Iowa**

Iowa’s CON program has been in operation since 1977.⁶⁶ The Iowa State Health Facilities Council, part of the Iowa Department of Public Health, is responsible for administering Iowa’s CON program.⁶⁷ Covered entities include “hospitals, nursing homes, outpatient surgery centers, or anyone purchasing medical equipment valued above \$1.5 million.”⁶⁸ The applicable statutory provisions are in Iowa Code §§ 135.61 through 135.83, and the Iowa CON regulations are in 641 Iowa Admin. Code §§ 202 and 203.

Under Iowa Code § 135.63, a CON is required prior to offering “a new institutional health service or changed institutional health service,” which under Iowa Code §135.61 includes the following categories of activities: “the construction, development, or other establishment of a new institutional health facility...; relocation of an institutional health facility; any capital expenditure, lease, or donation by or on behalf of an institutional health facility in excess [of \$1,500,000] within a twelve-month period; a permanent change in the bed capacity

⁶⁵ Richard Cauchi, *Certificate of Need: State Health Laws and Programs*, NAT’L CONFERENCE STATE LEGISLATURES (Jan. 2011), <http://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx> (last visited Dec. 30, 2014).

⁶⁶ *Id.*

⁶⁷ *Certificate of Need: State Health Facilities Council*, IOWA DEP’T OF PUB. HEALTH, http://www.idph.state.ia.us/adper/cert_of_need.asp (last visited Dec. 30, 2014).

⁶⁸ *Id.*

[meaning intended for one year or more], as determined by the department, of an institutional health facility; any expenditure in excess [of \$500,000] by or on behalf of an institutional health facility for... [the initiation of new health care services];...[the termination of previously offered health care services]; any acquisition by or on behalf of a health care provider or a group of health care providers of any piece of replacement equipment with a value in excess [of \$1,500,00]...; any acquisition by or on behalf of a health care provider or group of health care providers of any piece of equipment with a value in excess [of \$1,500,000] whether acquired by purchase, lease, or donation, which results in the offering or development of a health service not previously provided; any acquisition by or on behalf of an institutional health care facility or HMO of any piece of replacement equipment with a value in excess of [\$1,500,000], whether acquired by purchase, lease, or donation...; any air transportation service for transportation of patients or medical personnel [that was not offered within the prior year]; [establishment of] any mobile health service with a value in excess [of \$1,500,000]...; cardiac catheterization service[s]; open heart surgical service[s]; organ transplantation service[s]; and radiation therapy service[s]...”

Iowa Code § 135.63 states exclusions from the CON requirement for: private offices and clinics of individual physicians, dentists, or other private groups of health care providers not acquiring or replacing major medical equipment and not offering cardiac catheterization, open heart surgery, organ transplants, or radiation therapy; HMOs engaging in certain limited activities; residential care facilities; reductions in bed capacity under certain conditions; and termination of health care services under certain conditions.

Iowa Code § 135.64 provides the following CON review criteria: “the contribution of the proposed institutional health service in meeting the needs of the medically

underserved...; the relationship of the proposed institutional health services to the long-range development plan...of the [applicant]; the need of the population served or to be served [by the applicant]; the distance, convenience, cost of transportation, and accessibility to health services for persons who live outside metropolitan areas; the availability of alternative, less costly, or more effective methods of providing the proposed institutional health services; the immediate and long-term financial feasibility, as well as the probable impact of the proposal on the costs of and charges...by the [applicant] proposing the new institutional health service; the relationship of the proposed institutional health services to the existing health care system of the area..; the appropriate and efficient use or prospective use of the proposed health service, and of any existing similar services, including but not limited to the capacity of the sponsor's facility to provide the proposed service, and possible sharing or cooperative arrangements among existing facilities and providers; [the availability of necessary resources]; [relationship of the proposed service to ancillary or support services]; special needs and circumstances of HMOs [and research endeavors]; [impact of potential construction projects]...; and the recommendations of [agency personnel].”

Research did not disclose any changes to Iowa's CON program in the last five years.

17. **Kansas**

Kansas abandoned its CON program in 1985, and research did not disclose any attempts to reinstate the CON program in the last five years.⁶⁹

⁶⁹ Richard Cauchi, *Certificate of Need: State Health Laws and Programs*, NAT'L CONFERENCE STATE LEGISLATURES (Jan. 2011), <http://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx> (last visited Dec. 30, 2014).

18. **Kentucky**

The Kentucky Cabinet for Health and Family Services, Division of Certificate of Need, administers the state's CON program, which has been in effect since 1972.⁷⁰ The applicable statute and regulations are in Ky. Rev. Stat. Ann. § 216B and 900 Ky. Admin. Regs., respectively.

Under Ky. Rev. Stat. Ann § 216B.061, the following activities require a CON: “establish[ing] a health facility; obligat[ing] a capital expenditure which exceeds the capital expenditure minimum; mak[ing] a substantial change in the bed capacity of a health facility; mak[ing] a substantial change in a health service; mak[ing] a substantial change in a project; acquir[ing] major medical equipment; alter[ing] a geographical area or alter[ing] a specific location which has been designated on a certificate of need or license; and transfer[ring] an approved certificate of need for the establishment of a new health facility or the replacement of a licensed facility.”

Ky. Rev. Stat. Ann. § 216B.020 exempts the activities of most “private offices and clinics of physicians, dentists, and other practitioners [not operating ambulatory surgical centers]...” from the CON requirement.

Under 900 Ky. Admin. Regs. 6:070, the Cabinet applies the following CON review criteria: consistency of the proposed project with the State Health Plan; health care needs of the applicable geographic service area; accessibility; the proposed project's impact on and compatibility with the existing health care system; “costs, economic feasibility, and resource availability”; and quality of the proposed services.

⁷⁰ *Certificate of Need*, KY. CABINET FOR HEALTH & FAMILY SERV. DIV. CERTIFICATE OF NEED, <http://chfs.ky.gov/ohp/con/> (last visited Dec. 30, 2014).

In response to controversial litigation, in 2012, the state legislature passed Kentucky House Bill 458, which requires ambulatory surgical centers (ASCs) to obtain a CON even if such facilities would have otherwise qualified for the physician office exemption.⁷¹ Under House Bill 458, performing outpatient surgical procedures does not disqualify non-ASC private physician practices from qualifying for the CON exemption, but such practices may not seek insurance reimbursement as ASCs.⁷²

Kentucky is currently modernizing its CON program in response to the ACA, but this process is still very much in the initial stages, and regulatory language has not yet been amended. The Cabinet issued its *Certificate of Need Modernization: Core Principles and Request for Stakeholder Input* through Special Memorandum on October 8, 2014, and the Cabinet advanced the following “core principles”: (1) “supporting the evolution of care delivery”; (2) “incentivizing development of a full continuum of care”; (3) incentivizing quality”; (4) “improving access to care”; (5) “improving value of care”; (6) “promoting adoption of efficient technology”; and (7) “exempting services for which CON is no longer necessary.”⁷³ From these core principles, it remains unresolved whether Kentucky will effectively strengthen its CON requirements or make them more lenient, but the above goals make it clear that the Cabinet considers Kentucky’s CON program to be an integral component of effectuating health care reform.

⁷¹ Joe Ardery & Lindsay Kemp, *Kentucky Certificate of Need—Here and Now and What the Future Holds*, KY. HOSP. ASSOC. & FROST BROWN TODD LLC (May 24, 2012), available at <http://info.kyha.com/Convention12/Documents/CONPresentation.pdf>.

⁷² *Id.*

⁷³ *Special Memorandum: Certificate of Need Modernization: Core Principles: Request for Stakeholder Input*, CABINET FOR HEALTH & FAMILY SERV. OFFICE HEALTH POLICY (Oct. 8, 2014), available at <http://chfs.ky.gov/ohp/con/> (last visited Dec. 30, 2014).

Please see further elaboration on Kentucky’s CON modernization process in the policy analysis section below.

19. Louisiana

Louisiana has not had a CON program for decades, but it does have a limited Facility Need Review (FNR) process administered by the state’s Department of Health & Hospitals that “specific provider types must complete prior to applying for initial licensure in the state of Louisiana.”⁷⁴ The FNR program has been in operation since 1991.⁷⁵

The Department defines FNR as “a review conducted for nursing facility beds (including skilled beds, IC-I and IC-II beds), intermediate care facilities for the developmentally disabled beds, Home and Community Based Services (Supervised Independent Living, Personal Care Attendant Services and Respite), Adult Day Care facilities, and Adult Residential Care units to determine whether there is a need for additional beds and/or providers to be licensed and/or to be enrolled to participate in the Medicaid Program.”⁷⁶

20. Maine

Health Care Oversight, which is part of Maine’s Department of Licensing and Regulatory Services, is responsible for implementing the state’s CON program, which has been in operation since 1978.⁷⁷ The *Certificate of Need Act* is in Me. Rev. Stat. Ann. tit. 22 § 327,

⁷⁴ *Facility Need Review*, DEP’T HEALTH & HOSP., <http://new.dhh.louisiana.gov/index.cfm/directory/detail/717> (last visited Dec. 30, 2014).

⁷⁵ Richard Cauchi, *Certificate of Need: State Health Laws and Programs*, NAT’L CONFERENCE STATE LEGISLATURES (Jan. 2011), <http://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx> (last visited Dec. 30, 2014).

⁷⁶ *Facility Need Review*, DEP’T HEALTH & HOSP., <http://new.dhh.louisiana.gov/index.cfm/directory/detail/717> (last visited Dec. 30, 2014).

⁷⁷ HEALTH CARE OVERSIGHT, LICENSING & REGULATORY SERV.: ME. DEP’T HEALTH & HUMAN SERV., http://www.maine.gov/dhhs/dlrs/c_on/#rules (last visited Dec. 30, 2014); Richard Cauchi, *Certificate of Need: State Health Laws and Programs*, NAT’L CONFERENCE STATE LEGISLATURES (Jan. 2011), <http://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx> (last visited Dec. 30, 2014).

and in 2002, the state legislature passed *An Act to Strengthen the Certificate of Need Law*, Me. Rev. Stat. Ann. tit. 22 § 326, *et seq.*, in response to a legislative finding that “unnecessary construction or modification of health care facilities and duplication of health services are substantial factors in the cost of health care and the ability of the public to obtain necessary medical services.”⁷⁸

Under Me. Rev. Stat. Ann. tit. 22 § 329, a CON is required for: “transfer of ownership by lease, donation, transfer, or acquisition of control; acquisitions of major medical equipment [above the threshold amount]; capital expenditures [above the threshold amount]; new health services; [increases in bed capacity]; and capital expenditures of nursing facilities exceeding the threshold amount].”

Me. Rev. Stat. Ann. tit. 22 § 330 lists exemptions for certain HMO activities and acquisitions; home health care services; hospice; assisted living programs and services; and ambulatory surgical facilities existing prior to 1998, as long as such facilities have not since expanded their capacity.

The *Certificate of Need Procedures Manual* lists the determinations the Commissioner must make before issuing a CON: “that the applicant is fit, willing and able to provide the proposed services at the proper standard of care as demonstrated by, among other factors, whether the quality of any health care provided in the past by the applicant or a related party under the applicant’s control meets industry standards; [the project is economically feasible]...; there is a public need for the proposed services...; that the proposed services are

⁷⁸ 10-144 Me. Code R. 503, entitled *Maine Certificate of Need Procedures Manual (for Health Care Facilities other than Nursing Care Facilities)*, DEP’T HEALTH & HUMAN SERV. DIV. LICENSING & REGULATORY SERV. (April 11, 2012), available at http://www.maine.gov/dhhs/dlrs/c_o_n/#rules.

consistent with the orderly and economic development of health facilities and health resources for the State...; and [that the project] is consistent with the State Health Plan.”⁷⁹

According to a 2013 news article, there was recently an extensive (although apparently, unsuccessful) attempt to repeal Maine’s CON program, and Governor LePage was a large supporter of that push.⁸⁰

21. **Maryland**

Maryland’s CON program has been in operation since 1973.⁸¹ The Maryland Department of Health and Mental Hygiene is responsible for administering the state’s CON program.⁸² Maryland’s CON requirements are in Md. Code Ann. § 10-42-01-00 *et seq.*

Pursuant to Md. Code. Ann. § 10-4-01-02, “with certain exceptions, a certificate of need is required to build, develop, or establish a new health care facility; move an existing health care facility to another site; change the bed capacity of a health care facility; change the type or scope of any health care service offered by a health care facility; or make a health care facility capital expenditure that exceeds [the threshold amount].”⁸³

Under Md. Code Ann. §10-24-01-04, the Commission may exempt the following actions from CON review: “merger or consolidation of two or more hospitals or other health care facilities...; relocation of an existing health care facility owned or controlled by a merged asset

⁷⁹ *Id.*

⁸⁰ Andis Robeznieks, *On the Chopping Block: Eyes on Maine as It Looks to Toss Certificate of Need*, MODERN HEALTH CARE, (Mar. 2, 2013) <http://www.modernhealthcare.com/article/20130302/MAGAZINE/303029975> (last visited Dec. 30, 2014).

⁸¹ Richard Cauchi, *Certificate of Need: State Health Laws and Programs*, NAT’L CONFERENCE STATE LEGISLATURES (Jan. 2011), <http://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx> (last visited Dec. 30, 2014).

⁸² *Certificate of Need: Overview of CON*, MARYLAND DEP’T HEALTH & MENTAL HYGIENE, <http://mhcc.dhnh.maryland.gov/certificateofneed/pages/overview.aspx> (last visited Dec. 30, 2014).

⁸³ Quoted from *id.*

system...; a change in the bed capacity of an existing health care facility pursuant to the consolidation or merger of two or more health care facilities, or conversion of a health care facility or part of a facility to a non-health-related use...; a change in the type or scope of health care services offered by a health care facility...pursuant to the consolidation or merger of two or more health care facilities, conversion of all or part of a health care facility to a non-health-related use, or conversion of a hospital to a limited service hospital; a capital expenditure that exceeds the review threshold for capital expenditures made as part of a consolidation or merger of two or more health care facilities...; [and] the closure of an acute general hospital or part of a hospital, in a jurisdiction with fewer than three acute general hospitals.”

The Commission must consider the following six criteria when reviewing CON applications: compatibility with the State Health Plan; whether there is an unmet need for the proposed services in the target population; “the availability of more cost-effective alternatives”; economic feasibility and availability of needed resources; “compliance with conditions of previous certificates of need”; and the potential “impact on existing providers and the health care delivery system.”⁸⁴

Research did not disclose any CON reforms in the last five years, but it should be noted that Maryland’s all-payer rate setting system likely makes the state more invested than others in maintaining a comprehensive CON program.⁸⁵

22. **Massachusetts**

Massachusetts has had a Determination of Need (DoN) process since 1972.⁸⁶ The Massachusetts’ Office of Health Policy and Planning, part of the Massachusetts Department of

⁸⁴ *Id.*

⁸⁵ *Certificate of Need*, PDA, <http://www.pdaconsultants.com/emerging-trends/certificate-of-need> (last visited Dec. 30, 2014).

Public Health, is responsible for administering Massachusetts' DoN process.⁸⁷ The applicable statutory provisions are in Mass. Gen. Laws ch. 111, §§ 25B to 25G, §§ 51 through 53, § 51A, and § 71, and the accompanying regulations are in 105 Mass. Code Regs. 100.001 *et seq.*

Pursuant to Mass. Gen. Laws ch. 111, § 25C and under 105 Mass. Code Regs. 100.011, “no person or government agency may make a substantial capital expenditure for construction of a health care facility or substantial change in the services of any such facility, unless the Department has determined that there is a need for such substantial capital expenditure or substantial change in services.”

105 Mass. Code Regs. 100.020 defines “substantial change in service” for acute care hospitals to include “new technology, innovative service, or ambulatory surgery service, regardless of whether an expenditure *minimum* is exceeded; or any services which may be provided by facilities which are not acute care hospitals.” 105 Mass. Code Regs. 100.020 defines “substantial change in service” for other health care facilities to mean: “the addition of a service or increase in staff which entails annual operating costs in excess of the expenditure minimum; any increase in bed capacity...exceeding 12 beds...; the addition or expansion of, or conversion to, a new technology or innovative service regardless of whether an expenditure minimum is exceeded; the addition or expansion of or conversion to ambulatory surgery; or [certain bed conversions].”

Under the Office of Health Policy and Planning's “Determination of Need Program Informational Bulletin on Innovative Services and New Technology,” “innovative

⁸⁶ Richard Cauchi, *Certificate of Need: State Health Laws and Programs*, NAT'L CONFERENCE STATE LEGISLATURES (Jan. 2011), <http://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx> (last visited Dec. 30, 2014).

⁸⁷ *Determination of Need*, MASS. DEP'T HEALTH & HUMAN SERV., PUB. HEALTH DIV. OFFICE HEALTH POLICY & PLANNING, <http://www.mass.gov/eohhs/gov/departments/dph/programs/admin/ohpp/don/> (last visited Dec. 30, 2014).

services” include air ambulance, ECMO, open-heart surgery and left ventricular assistive devices, Neonatal Intensive Care Units, organ transplantation, and megavoltage radiation therapy.⁸⁸ “New technology” includes PET, extracorporeal shock wave lithotripter, and MRI scanners.⁸⁹

105 Mass. Code Regs. 100.011 states exceptions to the CON requirement for biomedical and medical research; certain activities of HMOs; and long-term care facilities, including nursing homes.

Under 105 Mass. Code Regs. 100.533, the Department considers the following DoN review considerations: whether the project “is the product of a sound health planning process”; whether the project will address the health care needs of the applicable service area; whether “the project will produce a facility or service which is capable of operating efficiently and effectively, and which relates to other facilities and services so as to promote and further coordination and consolidation of facilities and services within the applicable service area”; compliance of the with relevant legal standards; “reasonableness of expenditures and cost”; “financial feasibility and capability”; whether the project “on balance, is superior to alternative and substitute methods”; the potential “environmental impact”; and whether the project promotes “primary/preventative health care services and community contributions.” The Boston Alliance for Community Health explains that this last factor plays an especially critical role in Massachusetts’ DoN process for Boston-based hospitals:⁹⁰

⁸⁸ *Determination of Need Program Information Bulletin on Innovative Services and New Technology*, ASS. DEP’T HEALTH & HUMAN SERV., PUB. HEALTH DIV. OFFICE HEALTH POLICY & PLANNING, available at <http://www.mass.gov/eohhs/docs/dph/health-planning/don/infobull.pdf>.

⁸⁹ *Id.*

⁹⁰ *Determination of Need*, BOS. ALLIANCE FOR CMTY HEALTH, <http://www.bostonalliance.org/determination-of-need/> (last visited Dec. 30, 2014).

When a health care institution intends to build a new facility or make a major capital purchase, it is required to file a DoN application with the Massachusetts Department of Public Health (MDPH). If the application is approved, the applicant facility then provides the equivalent of 5% of the capital outlay to support community health and prevention needs. Once this amount is set, a planning group, which includes the MDPH, the applicant Boston-based hospital, BACH and other local partners, work together to determine the best use of the funds based on priorities identified through a community assessment process. Thus, the DoN is intended to foster collaborations between hospitals and community-based partners as well as improve the health status of vulnerable populations.

In 2014, the Massachusetts Department of Public Health issued proposed amendments to the DoN regulations under which hospitals must obtain DoN approval before establishing or expanding ambulatory surgery centers.⁹¹ Before, there was somewhat of a loophole for hospitals, as “the DoN formula for Ambulatory Surgery Centers (ASC) provided that no freestanding ASC could be established or expanded without DoN approval, while at the same time, hospitals could expand ambulatory surgery capacity without DoN approval if the project cost was under \$25 million.”⁹²

23. **Michigan**

Michigan started its CON program in 1972.⁹³ The Michigan Department of Community Health is responsible for administering Michigan’s CON Program. The applicable statutory provisions are in Mich. Comp. Laws § 333.22201 *et seq.*, and the CON regulations are in Mich. Admin. Code r. 325.9101 *et seq.*

⁹¹ Andrew Levine, *Department of Public Health Proposes Changes to Determination of Need Regulations*, DONOGHUE BARRETT & SINGAL (Mar. 18, 2014), <http://dbslawfirm.com/news/department-of-public-health-proposes-changes-to-determination-of-need-regulation> (last visited Dec. 30, 2014).

⁹² *Id.*

⁹³ Richard Cauchi, *Certificate of Need: State Health Laws and Programs*, NAT’L CONFERENCE STATE LEGISLATURES (Jan. 2011), <http://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx> (last visited Dec. 30, 2014).

The statutes and regulations are quite cumbersome and difficult to navigate, but the Michigan Department of Community Health provides the following summary in its 2014 explanatory brochure:⁹⁴

An entity (health facility, physician, group practice, etc.) proposing any of the following types of projects must obtain a CON, regardless of the capital expenditure proposed: increase in the number of licensed bed or the relocation of licensed beds from one site to another; acquisition of an existing health facility; operation of a new health facility; initiation, replacement, or expansion of covered clinical services [which include air ambulance services, cardiac catheterization services, CT scanner services, hospital beds, MRI services, MRT services, neonatal intensive care units, nursing home/hospital long-term care beds, open heart surgery services, PET scanner services, psychiatric beds and services, surgical services, transplantation services, and urinary lithotripter services]; short-term nursing care program (swing beds).

In addition capital expenditure projects (construction, renovation, etc.) that involve a health care facility require a CON. The capital expenditure threshold is...\$3,160,000 for clinical service areas.

For purposes of a CON, a health facility is defined as a: hospital; psychiatric hospital or unit; nursing home; Freestanding Outpatient Surgical Facility; [or an] HMO.

The Michigan Department of Community Health performs three different types of review processes: non-substantive, substantive, and comparative.⁹⁵ Non-substantive review is appropriate for projects like equipment replacements that require limited information and do not significantly change the scope of services offered or alter the existing health care provider landscape.⁹⁶ Projects meriting substantive review require “a full review, but on an individual

⁹⁴ *Michigan's Certificate of Need Program: Balancing Cost, Quality, & Access*, MICH. DEP'T CMTY. HEALTH (2014), http://michigan.gov/documents/mdch/2013_Brochure_409310_7.pdf (last visited Dec. 30, 2014).

⁹⁵ *Id.*

⁹⁶ *Id.*

basis.”⁹⁷ Comparative review is for “applications competing for project types for which the need is limited.”⁹⁸

Please see the policy analysis section below for recent developments in Michigan’s CON program.

24. **Minnesota**

Minnesota has not had a CON program since 1985.⁹⁹ However, in 2004, the Minnesota Legislature “passed a law establishing a public interest review process for hospitals seeking exceptions to the state’s hospital bed moratorium law.”¹⁰⁰ This process is more limited than many other states’ CON programs and is called “Hospital Public Interest Review.” Under Hospital Public Interest Review, “a hospital seeking to increase its number of licensed beds or an organization seeking to obtain a hospital license must submit a plan to the Minnesota Department of Health (MDH).¹⁰¹ MDH is required to review the plan and issue a finding on whether the plan is in the public interest.”¹⁰²

As part of Hospital Public Interest Review, MDH is required to consider the following issues: “whether the new hospital or hospital beds are needed to provide timely access to care or access to new or improved services; the financial impact of the new hospital or hospital beds on existing acute-care hospitals that have emergency departments in the region;

⁹⁷ *Id.*

⁹⁸ *Id.*

⁹⁹ Richard Cauchi, *Certificate of Need: State Health Laws and Programs*, NAT’L CONFERENCE STATE LEGISLATURES (Jan. 2011), <http://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx> (last visited Dec. 30, 2014).

¹⁰⁰ *Hospital Public Interest Review*, MINN. DEP’T HEALTH, <http://www.health.state.mn.us/divs/hpsc/hep/moratorium/> (last visited Dec. 30, 2014); see Minn. Stat. §144.552.

¹⁰¹ *Id.*

¹⁰² *Id.*

how the new hospital or hospital beds will affect the ability of existing hospitals in the region to maintain existing staff; the extent to which the new hospital or hospital beds will provide services to non-paying or low-income patients relative to the level of services provided to these groups by existing hospitals in the region; and the views of affected parties.”¹⁰³

Research did not disclose any attempts to reinstate Minnesota’s CON program or any changes to the Hospital Public Interest Review process in the last five years.

25. Mississippi

Mississippi started its CON program in 1979.¹⁰⁴ The Mississippi State Department of Health is responsible for administering Mississippi’s CON program.¹⁰⁵

The applicable statutory provisions are in Miss. Code Ann. § 41-7-171 *et seq.*, and the regulations can be found in the *CON Review Manual*, Title 15, Part IX, Subpart 91.¹⁰⁶

Under Miss. Code Ann. § 41-7-191(1), a CON is required prior to: “the construction, development or other establishment of a new health care facility...; the relocation of a health care facility or portion thereof, or major medical equipment...; [changes in bed capacity]; [introduction] of the following health services: open-heart surgery services, cardiac catheterization inpatient rehabilitation services, licensed psychiatric services, licensed chemical dependency services, radiation therapy services, diagnostic imaging services of an invasive nature, nursing care..., home health services, swing-bed services, ambulatory surgical services,

¹⁰³ *Id.*

¹⁰⁴ Richard Cauchi, *Certificate of Need: State Health Laws and Programs*, NAT’L CONFERENCE STATE LEGISLATURES (Jan. 2011), <http://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx> (last visited Dec. 30, 2014).

¹⁰⁵ *Certificates of Need*, MISS. STATE DEP’T HEALTH, http://msdh.ms.gov/msdhsite/_static/30,0,84.html (last visited Jan. 1, 2015).

¹⁰⁶ *CON Review Manual*, MISS. STATE DEP’T HEALTH, *available at* http://msdh.ms.gov/msdhsite/_static/30,0,84,301.html.

[MRI] services, long term care hospital services, [or] [PET] services; the relocation [of health services]; the acquisition or otherwise control of any major medical equipment for the provision of medical services...; changes of ownership of existing health care facilities...; and [capital expenditures according to the statutory definition]...”

The *CON Review Manual*, Chapter 2, lists exemptions from the CON requirement for construction, renovation, and expansion of state-owned facilities under a number of circumstances, in addition to an exemption for “replacement or relocation of a health care facility designated as a critical access hospital.”¹⁰⁷

The *CON Review Manual*, Chapter 8, provides the following CON review considerations: “the relationship of the health services being reviewed to the applicable State Health plan...; the relationship of services reviewed to the long range development plan, if any, of the institution providing or proposing the services...; the availability of less costly or more effective alternative methods of providing the service to be offered, expanded, or relocated...; the immediate and long-term financial feasibility of the proposal, as well as the probable effect of the proposal on the costs and charges...by the institution or service...; need for the project...; the contribution of the proposed service in meeting the health related needs of members of medically underserved groups which have traditionally experienced difficulties in obtaining equal access to health services...; relationship of the services proposed to be provided to the existing health care system...; the availability of resources (including health personnel, management personnel, and funds for capital and operating needs) for the services proposed to be provided and the need for

¹⁰⁷ *Id.* at 20.

alternative uses of the resources...; relationship to ancillary or support services...; access by health professional schools...; [and the impact of proposed construction].”¹⁰⁸

Mississippi’s CON Program has not seen any significant changes in the last five years.

26. **Missouri**

Missouri started its CON program in 1979.¹⁰⁹ The Missouri Health Facilities Review Committee, a division of the Missouri Department of Health & Senior Services, is responsible for administering the state’s CON program.¹¹⁰

The applicable statute is “the Missouri Certificate of Need Law,” found in Mo. Rev. Stat. § 197.300 *et seq.*, and the associated regulations are in Mo. Code Regs. Ann. tit. 19, § 60-50.010 *et seq.*

Under Mo. Rev. Stat. § 197.315, “any person who proposes to develop or offer a new institutional health service within the state must obtain a [CON] from the committee prior to the time such services are offered.” More specifically, a helpful summary compiled by Research Planning Consultants, L.P., explains that the following activities require a CON: “development of a new hospital costing \$1,000,000 or more (unless exempt under chapter 197, [Mo. Rev. Stat.]); acquisition or replacement of major medical equipment costing \$1,000,000 or more by a health facility not licensed under Chapter 198, [Mo. Rev. Stat.]; acquisition or replacement of major medical equipment for a health care facility licensed under Chapter 198, [Mo. Rev. Stat.],

¹⁰⁸ *Id.* at 52-55.

¹⁰⁹ Richard Cauchi, *Certificate of Need: State Health Laws and Programs*, NAT’L CONFERENCE STATE LEGISLATURES (Jan. 2011), <http://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx> (last visited Dec. 30, 2014).

¹¹⁰ *Certificate of Need*, MO. DEP’T HEALTH & HUMAN SERV., <http://health.mo.gov/information/boards/certificateofneed/> (last visited Jan. 1, 2015).

costing \$400,000 or more; acquisition of any equipment or beds in a long-term care hospital [meeting certain requirements]...; a capital expenditure for renovation, modernization, or replacement (not additional beds) by or on behalf of an existing health care facility...costing \$600,000 or more; additional LTC (licensed or certified residential care, assisted living, intermediate care, or skilled nursing facility) beds or LTC bed expansions or replacements...costing \$600,000 or more; [and] expansion of an existing health care facility...that either costs \$600,000 or more, or exceeds 10 beds or 10% of the facility's licensed capacity, whichever is less.”¹¹¹

Mo. Rev. Stat. § 197.315 provides that a CON is not required for “facilities operated by the state” or “for the transfer of ownership of an existing and operational health facility in its entirety.”

The Missouri Health Facilities Review Committee does not employ a list of general guiding principles but engages in CON review through applying need formulas that vary depending on the covered activity, in addition to conducting financial feasibility reviews.¹¹²

Research did not disclose any changes to Missouri's CON program in the last five years.

27. **Montana**

Montana started its CON program in 1975.¹¹³ The License Bureau of the Quality Assurance Division of the Department of Public Health and Human Services (DPHHS) is

¹¹¹ *CON Services/Missouri Certificate of Need Process (CON)*, RESEARCH & PLANNING CONSULTANTS, L.P. (Feb. 2014), <http://www.rpccconsulting.com/missouri-certificate-of-need-process-con.htm> (last visited Jan. 1, 2015).

¹¹² *Certificate of Need*, MO. DEP'T HEALTH & HUMAN SERV., <http://health.mo.gov/information/boards/certificateofneed/> (last visited Jan. 1, 2015).

responsible for administering the program.¹¹⁴ DPHHS explains that in Montana, “CON requires that individuals or health care facilities seeking to initiate or expand services submit applications to the State,” with prior approval required “before initiating projects that require capital expenditures above certain dollar thresholds.”¹¹⁵

Applicable laws include Mont. Code Ann. § 50-5-301 *et seq.*; Mont. Admin. R. 37.106.101-140; and the current State Health Care Facilities Plan.¹¹⁶

Montana’s CON program is more limited in scope than the CON programs of many other states.¹¹⁷ “The facilities and services subject to review include: ambulatory surgical facilities proposed for counties with populations less than 20,000; home health agency services; inpatient chemical dependency facilities; intermediate care facilities for persons with mental retardation or developmental disabilities...; [and] nursing home services.”¹¹⁸

Projects subject to the CON requirement include: “capital expenditures over \$1,500,000; changes in bed capacity of a facility through an increase in number, or relocation of beds; addition of health services associated with annual operating expenses of \$150,000 or more; construction, development, or establishment of a facility; establishment of a home health agency

¹¹³ Richard Cauchi, *Certificate of Need: State Health Laws and Programs*, NAT’L CONFERENCE STATE LEGISLATURES (Jan. 2011), <http://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx> (last visited Dec. 30, 2014).

¹¹⁴ *Certificate of Need*, MONT. DEP’T PUB. HEALTH & HUMAN SERV., [http://www.dphhs.mt.gov/qad/Licensure/Health careFacilityLicensure/CertificateofNeed.aspx](http://www.dphhs.mt.gov/qad/Licensure/Health%20careFacilityLicensure/CertificateofNeed.aspx) (last visited Jan. 1, 2015).

¹¹⁵ *Id.*

¹¹⁶ *See State Health Care Facilities Plan*, MONT. DEP’T PUB. HEALTH & HUMAN SERV., [http://www.dphhs.mt.gov/qad/Licensure/Health careFacilityLicensure/CertificateofNeed/LBSHCFP.aspx](http://www.dphhs.mt.gov/qad/Licensure/Health%20careFacilityLicensure/CertificateofNeed/LBSHCFP.aspx) (last visited Jan. 1, 2015).

¹¹⁷ *Certificate of Need*, MONT. DEP’T PUB. HEALTH & HUMAN SERV., [http://www.dphhs.mt.gov/qad/Licensure/Health careFacilityLicensure/CertificateofNeed.aspx](http://www.dphhs.mt.gov/qad/Licensure/Health%20careFacilityLicensure/CertificateofNeed.aspx) (last visited Jan. 1, 2015).

¹¹⁸ *Id.*

or expansion to another service area; and use of hospital beds (more than five) to produce skilled nursing care (swing beds).”¹¹⁹

DPHHS presents the following list of projects that may “forego the full CON review [i]f the facility informs the Department of its intentions in advance”: “initial establishment of five or fewer swing beds...; addition of 10 beds, or 10% of licensed beds, whichever is less...(provided there has been no change in the facility’s license in two years); and changes of ownership...”¹²⁰ Mont. Code Ann. § 50-5-309 additionally provides that “construction of a state-owned facility” and repair and replacement of facilities damaged by natural disasters are exempt from the CON requirement.

Pursuant to Mont. Code Ann. § 50-5-304, DPHHS considers the following review criteria: population need; the availability of less costly or more effective alternatives; financial feasibility; “the probable impact of the proposal on the costs of and charges for providing health services”; “the relationship and financial impact” to the existing health care system; “consistency of the proposal with joint planning efforts by health care providers in the area”; availability of needed resources “and the availability of alternative uses of the resources for the provision of health services”; “the relationship, including the organizational relationship, of the health services proposed to be provided to ancillary or support services”; impacts of proposed construction; and “accessibility of health services for persons who live outside urban areas.”

Research did not disclose any changes to Montana’s CON program in the last five years.

¹¹⁹ *Id.*; see Mont. Code Ann. § 50-5-301.

¹²⁰ *Certificate of Need*, MONT. DEP’T PUB. HEALTH & HUMAN SERV., [http://www.dphhs.mt.gov/qad/Licensure/Health careFacilityLicensure/CertificateofNeed.aspx](http://www.dphhs.mt.gov/qad/Licensure/Health%20careFacilityLicensure/CertificateofNeed.aspx) (last visited Jan. 1, 2015).

28. Nebraska

Nebraska started its CON program in 1979.¹²¹ The Nebraska Department of Health & Human Services, Division of Public Health, is responsible for administering the state's CON program.¹²² Applicable statutes include the *Nonprofit Hospital Sale Act* (Neb. Rev. Stat. § 71-20,102 *et seq.*) and the *Nebraska Health Care Certificate of Need Act* (Neb. Rev. Stat. § 71-5801 *et seq.*). Nebraska's CON program is not particularly extensive since it primarily regulates acquisitions by and of non-profit hospitals and changes to bed capacity, including bed transfers and does not regulate capital expenditures or purchases of major medical equipment.

Under the *Nonprofit Hospital Sale Act*, “no person shall engage in the acquisition of a hospital owned by a nonprofit corporation without first having applied for and received approval of the department, [and]...no person shall engage in the acquisition of a hospital not owned by a nonprofit corporation without first having applied for a received the approval to the department pursuant to the Act unless such person is a non-profit...”¹²³ This approval process is tied to the state's CON process since “for acquisitions which require approval from the department under the *Nonprofit Hospital Sale Act* and a certificate of need under the *Nebraska Health Care Certificate of Need Act*,” there is a “single unified review process,” under which the

¹²¹ Richard Cauchi, *Certificate of Need: State Health Laws and Programs*, NAT'L CONFERENCE STATE LEGISLATURES (Jan. 2011), <http://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx> (last visited Dec. 30, 2014).

¹²² *Certificate of Need*, NEB. DEP'T HEALTH & HUMAN SERV., http://dhhs.ne.gov/publichealth/Pages/cr1_need.aspx (last visited Jan. 1, 2015).

¹²³ Neb. Rev. Stat. § 71-20,104.

agency issues a simultaneous decision.”¹²⁴ Review criteria for acquisitions under the *Non-Profit Hospital Sale Act* can be found in Neb. Rev. Stat. §§ 71-20,108 and 71-20,109.¹²⁵

Under the *Nebraska Health Care Certificate of Need Act*, Neb. Rev. Stat. § 71-5829.03, the following bed capacity and transfer-related activities require a CON: “the initial establishment of long-term care beds or rehabilitation beds...; an increase in the long-term care beds of a health care facility by more than ten long-term care beds or more than ten percent of the total long-term care bed capacity of such facility, whichever is less, over a two-year period; an increase in the rehabilitation beds of a health care facility by more than ten rehabilitation beds or more than ten percent of the total rehabilitation bed capacity of such facility, whichever is less; any initial establishment of long-term care beds through conversion by a hospital of any type of hospital beds to long-term care beds if the total beds converted by the hospital are more than ten beds or more than ten percent of the total bed capacity of such hospital, whichever is less, over a two-year period; any initial establishment of rehabilitation beds through conversion by a hospital of any type of hospital beds to rehabilitation beds if the total beds converted by the hospital are more than ten beds or more than ten percent of the total bed capacity of such hospital, whichever is less, over a two-year period; or any relocation of rehabilitation beds in Nebraska from one health care facility to another health care facility, except that no certificate of need is required for relocation or transfer of rehabilitation beds from a health care facility to another health care facility owned and operated by the same entity.”

Under the *Nebraska Health Care Certificate of Need Act*, Neb. Rev. Stat. § 71-5830.01, a CON is not required for “a change in classification between an intermediate health

¹²⁴ Neb. Rev. Stat. § 71-20,105.

¹²⁵ Description of review criteria omitted since statutes do not apply more onerous standards than the Nebraska Health Care Certificates of Need Act.

care facility, a nursing facility, or a skilled nursing facility” or for “a transfer or relocation of long-term care beds from one facility to another entity in the same health planning region.”

Research did not disclose any changes to Nebraska’s CON program in the last five years.

29. Nevada

Nevada started its CON program in 1972.¹²⁶ Nevada’s Department of Health and Human Services and the Health Planning and Primary Care Office are responsible for administering the program.¹²⁷ The applicable statute is Nev. Rev. Stat. § 439A.100, and the state’s CON regulations are in Nev. Admin. Code §§ 439A.010 through 439A.675.

Under Nevada’s CON process, new construction of “health facilities at a cost of over \$2 million in counties in Nevada where the population is less than 100,000 requires a letter of approval from the...Department of Health and Human Services.”¹²⁸ Under Nev. Rev. Stat. § 439.015, health facilities include “hospitals, ambulatory surgery centers, and skilled nursing facilities,” but not the “office of a practitioner used solely to provide routine services to patients.”¹²⁹ New construction is defined as “a new health facility or construction which increases the square footage in an existing facility or the redesign or renovation of an existing

¹²⁶ Richard Cauchi, *Certificate of Need: State Health Laws and Programs*, NAT’L CONFERENCE STATE LEGISLATURES (Jan. 2011), <http://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx> (last visited Dec. 30, 2014).

¹²⁷ *Certificate of Need*, NEV. DEP’T HEALTH & HUMAN SERV.: NEV. DIV. PUB. & BEHAVIORAL HEALTH (Nov. 26, 2014), http://health.nv.gov/BFHS_CertificateOfNeed.htm (last visited Jan. 1, 2015).

¹²⁸ *Id.*

¹²⁹ Michael Willden, *Certificate of Need (CON): Overview for Nevada*, NEV. DEP’T HEALTH & HUMAN SERV. (Apr. 13, 2006), available at https://www.leg.state.nv.us/73rd/Interim/StatCom/Health_care/exhibits/20009N.pdf.

building which is not currently being used as a health facility.”¹³⁰ The CON program used to be more extensive, but in 1995, the Nevada state legislature narrowed its scope to “cover only the construction of new health facilities involving capital expenditures over \$2 million.”¹³¹

Pursuant to Nev. Admin Code §§ 439A.605 through 439A.637, the department considers the following criteria in deciding whether to grant a CON: “whether a need for the proposed project exists in the community; whether the proposed project is financially feasible; the effect of the proposed project on the cost of health care; and the appropriateness of the proposed project in the community.”¹³²

Research did not disclose any changes to Nevada’s CON program in the last five years.

30. **New Hampshire**

New Hampshire started its CON program in 1979.¹³³ The Health Services Planning and Review Board is responsible for administering the CON program.¹³⁴ The applicable statute is N.H. Rev. Stat. Ann. § 151-C, and the Health Services Planning and Review Rules provide additional guidance.¹³⁵

¹³⁰ *Certificate of Need*, NEV. DEP’T HEALTH & HUMAN SERV.: NEV. DIV. PUB. & BEHAVIORAL HEALTH (Nov. 26, 2014), http://health.nv.gov/BFHS_CertificateOfNeed.htm (last visited Jan. 1, 2015).

¹³¹ *Id.*

¹³² *Id.*

¹³³ Richard Cauchi, *Certificate of Need: State Health Laws and Programs*, NAT’L CONFERENCE STATE LEGISLATURES (Jan. 2011), <http://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx> (last visited Dec. 30, 2014).

¹³⁴ *Health Services Planning and Review*, N.H. DEP’T HEALTH & HUMAN SERV., <http://www.dhhs.nh.gov/DPHS/hspr/index.htm> (last visited Jan. 2, 2015).

¹³⁵ *See Health Planning and Review Rules*, N.H. DEP’T HEALTH & HUMAN SERV., *available at* <http://www.dhhs.nh.gov/dphs/hspr/rules.htm>.

Under New Hampshire law, “a CON is required to construct or modify health care facilities; acquire new medical equipment; or offer new inpatient care beds and services, subject to statutory thresholds.”¹³⁶ “The following health care services facilities, and diagnostic/therapeutic equipment items are regulated by the CON program and require [CON] review and approval by the Health Services Planning and Review Board: acute care (general) hospital beds and services, ambulatory surgery centers, cardiac catheterization and cardiac surgery services, extracorporeal shock wave lithotripsy (ESWL) services, inpatient physical rehabilitation beds and services, inpatient adult psychiatric beds and services, long term care (nursing home) beds and services..., MRI equipment and services..., PET equipment and services, and transfer of ownership of Non-Medicare/Medicaid certified facilities.”¹³⁷

The following facilities and services are not subject to the CON requirement: “assisted living, home health, hospice, kidney dialysis, medical office buildings, outpatient services, parking garages, residential care, residential treatment and rehabilitation, sheltered care, [and] supportive residential care.”¹³⁸

Under N.H. Rev. Stat. Ann § 151-C:7, the board considers the following criteria in reviewing CON applications: “the immediate and long range financial feasibility of the proposed project, including the probable impact on costs and charges of the facility on the health insurance premiums and personal health expenditures in the state or the region of the state; the availability of resources for the proposed project including health and management personnel and funds, capital, and operating needs; the degree to which the proposed project will be

¹³⁶ *Health Services Planning and Review*, N.H. DEP’T HEALTH & HUMAN SERV., <http://www.dhhs.nh.gov/DPHS/hspr/index.htm> (last visited Jan. 2, 2015).

¹³⁷ *Id.*

¹³⁸ *Id.*; see N.H. Rev. Stat. Ann. § 151-C:13.

accessible to persons who are medically underserved, including, but not limited to, persons with a disability and indigent persons; in the case of existing facilities or entities with other facilities, records of the quality of care...[and] in the case of new entities, assurance of the quality of care stated in measureable terms; the utilization and the financial impact of increased utilization; the effect on the average cost of a procedure; whether total health care costs of the state will be increased, not just whether unit costs will be decreased; and health outcomes.”

Pursuant to N.H. Rev. Stat. Ann. § 151-C:8, the Health Services Planning and Review Board issues requests for applications (RFAs) when it determines that additional health care services are needed.

In 2012, there was an extensive effort to repeal the CON program in its entirety, and the House voted to dismantle the board, but the House Finance Committee voted to save the program in 2013 before repeal could be effectuated.¹³⁹

31. **New Jersey**

New Jersey started its CON program in 1971.¹⁴⁰ The New Jersey Department of Health, Division of Health Facilities Evaluation and Licensing, is responsible for administering the state’s CON program.¹⁴¹ Applicable statutes include the *Health Care Facilities Planning Act*, P.L. 1971, c.136, as amended by P.L 1978, c. 83, the *Health Care Cost Reduction Act*, P.L. 1991, c. 187, the *Health Care Reform Act*, P.L. 1992, c. 160, and the *Certificate of Need Reform*

¹³⁹ Rachel Gotbaum, *Why the House Voted to Dismantle the Certificate of Need Board*, NPR (Mar. 15, 2012), available at <http://stateimpact.npr.org/new-hampshire/2012/03/15/why-the-house-voted-to-dismantle-the-certificate-of-need-board/>; Grant Bosse, *House Finance Wants to Use Budget Bill to Revive the CON Board*, N. H. WATCHDOG.ORG (Mar. 27, 2013), <http://newhampshire.watchdog.org/11817/house-finance-wants-to-use-budget-bill-to-revive-con-board/> (last visited Jan. 2, 2015).

¹⁴⁰ Richard Cauchi, *Certificate of Need: State Health Laws and Programs*, NAT’L CONFERENCE STATE LEGISLATURES (Jan. 2011), <http://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx> (last visited Dec. 30, 2014).

¹⁴¹ *About Us*, STATE OF N.J. DEP’T HEALTH: DIV. HEALTH FACILITIES EVALUATION, http://www.nj.gov/health/healthfacilities/about_us.shtml (last visited Jan. 2, 2015).

Act, P.L. 1998, c. 43.¹⁴² The regulations can be found in N.J. Admin. Code § 8:33: “Certificate of Need: Application and Review Process.”¹⁴³

Pursuant to N.J. Admin. Code §§ 8.33-3.1 through 8.33-3.7, the following activities are subject to the CON requirement: “initiation of [a] health care service...; termination/discontinuance of [a] service or facility and/or reduction of licensed bed capacity...; transfer of a health care service/facility...; changes in licensed beds and/or services...; [buildings]; [and] major moveable medical equipment.” “Health care facilities” and “health care services” encompass a wide range of categories under N.J. Admin. Code § 8:33-1.3.

But many activities and services are exempt from New Jersey’s CON requirements. Under N.J. Admin. Code § 8:33-6.1, “the following specific health care services or projects are exempt from the certificate of need requirement: community-based primary care centers...which provide preventative, diagnostic, treatment, management, and reassessment services exclusively on an outpatient basis to individuals with acute or chronic illnesses in a location and manner that is accessible to individuals; outpatient drug and alcohol services which include drug-free and methadone maintenance services and day treatment alcohol services; ambulance and valid coach services...; mental health services which are non-bed related outpatient services including outpatient centers, partial hospitalization programs and case management programs; residential health care facilities; transfer of ownership interest, except in the case of a general hospital; change of site for an unimplemented certificate of need within the same county; relocation or replacement of a health care facility within the same county, except

¹⁴² Janelle Sagness, *Certificate of Need Laws: Analysis and Recommendations for the Commission on Rationalizing New Jersey’s Health Care Resources*, N.J. DEP’T HEALTH 11 (Jan. 12, 2007), available at http://www.nj.gov/health/rhc/documents/con_laws.pdf.

¹⁴³ N.J. Admin. Code § 8.33: “Certificate of Need: Application and Review Process,” available at http://www.nj.gov/health/healthfacilities/documents/ac/reg8_33.pdf.

for a general hospital; continuing care retirement communities...; [MRI]; adult day health care facilities; pediatric day health care facilities; [dialysis]...; capital improvements and renovations to health care facilities; addition of medical/surgical, adult intensive care, adult critical care beds in general hospitals; replacement of existing major moveable medical equipment; inpatient operating rooms...; hospital-based sub-acute care; ambulatory care facilities...; basic obstetric and pediatric services and birth centers, including addition of obstetric and pediatric beds in general hospitals; linear accelerators; new technology...; extracorporeal shock wave lithotripter; hyperbaric chamber; [PET]...; ambulatory surgical facilities; same day surgery operating rooms; long-term care facilities proposing to increase their total number of licensed long-term care beds by no more than 10 beds or 10 percent of their licensed long-term care capacity, whichever is less, within a period of five years; [and] satellite emergency department...”

Under N.J. Admin. Code § 8:33-1.2, “no certificates of need shall be issued unless the action proposed in the application...is necessary to provide required health care in the area(s) to be served, can be financially accomplished and maintained, licensed in accordance with applicable licensure regulations, will not have an adverse economic or financial impact on the delivery of or access to health care services in the region or Statewide, and will contribute the orderly development of adequate and effective health care services.” To make such determinations, the department considers “the availability of facilities or services which serve as alternatives or substitutes, the need for special equipment and services in the area, the adequacy of financial resources in the several professional disciplines, [and] the accessibility and availability of health care services to low-income persons.”¹⁴⁴

¹⁴⁴ See also N.J. Admin. Code § 8:33-4.10.

New Jersey’s CON program also allows the Commissioner to “announce additional or special calls for certificate of need applications” under N.J. Admin. Code § 8:33-4.1.

Research did not disclose any changes to New Jersey’s CON program in the last five years.

32. **New Mexico**

New Mexico has not had a CON program since 1983.¹⁴⁵ Research did not disclose any efforts to reinstate New Mexico’s CON program.

33. **New York**

New York started its CON program in 1966.¹⁴⁶ The Public Health and Health Planning Council (PHHPC), part of the New York Department of Health, manages the state’s CON program.¹⁴⁷ New York’s CON process “governs establishment, construction, renovation, and major medical equipment acquisitions of health care facilities, such as hospitals, nursing homes, home care agencies, and diagnostic and treatment centers.”¹⁴⁸ The applicable statutory authority can be found in the New York Code, Public Health Law, Articles 28, 36, 40, and 7.

The following entities are considered covered “health care facilities” for purposes of New York’s CON program: hospitals, nursing homes, diagnostic and treatment centers, and ambulatory surgery centers, as regulated under Article 28; certified home health agencies and

¹⁴⁵ Richard Cauchi, *Certificate of Need: State Health Laws and Programs*, NAT’L CONFERENCE STATE LEGISLATURES (Jan. 2011), <http://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx> (last visited Dec. 30, 2014).

¹⁴⁶ *Id.*

¹⁴⁷ *Certificate of Need*, N.Y. DEP’T HEALTH, <https://www.health.ny.gov/facilities/cons/> (last visited Jan. 2, 2015).

¹⁴⁸ *Id.*

long term home health care programs, as regulated under Article 36; hospices, as regulated under Article 40; and adult care facilities under Article 7.¹⁴⁹ Private physician offices are currently not considered covered health care facilities since New York’s CON requirements are tied to licensure.¹⁵⁰ HMOs are currently exempt from New York’s CON requirements.¹⁵¹

The following types of projects require CON review: “establishing and/or constructing new facilities, agencies, programs, or hospices; renovating existing facilities, agencies, programs or hospices; acquiring major medical equipment; adding or deleting services; changing ownership of facilities, agencies, programs or hospices; [and] modifying service areas for agencies or hospices.”¹⁵² Under New York’s CON program, whether a full review, administrative review, or in some cases, limited review, is required depends on the type of facility and scope of the project.¹⁵³

“Certificate of need applications are reviewed against the following criteria: public need; financial feasibility; character and competence; and [effects of proposed] construction.”¹⁵⁴

¹⁴⁹ *How to Determine if CON Submission is Required: Types of Health Care Facilities Subject to CON Process*, N.Y. STATE DEP’T HEALTH, https://www.health.ny.gov/facilities/cons/more_information/ (last visited Jan. 2, 2015).

¹⁵⁰ *But see Report of the Public Health and Planning Council on Redesigning Certificate of Need and Health Planning*, PUB. HEALTH & PLANNING COUNCIL 38 (Dec. 6, 2012), available at https://www.health.ny.gov/facilities/public_health_and_health_planning_council/docs/con_redesign_report.pdf (recommending increased CON regulation of private physician offices, discussed below).

¹⁵¹ *Id.* at 36.

¹⁵² *How to Determine if CON Submission is Required: Types of Health Care Facilities Subject to CON Process*, N.Y. STATE DEP’T HEALTH, https://www.health.ny.gov/facilities/cons/more_information/ (last visited Jan. 2, 2015).

¹⁵³ *Id.*

¹⁵⁴ *Certificate of Need Review Criteria*, N.Y. STATE DEP’T HEALTH, https://www.health.ny.gov/facilities/cons/more_information/review_criteria.htm (last visited Jan. 2, 2015).

In addition to provider-initiated CON applications, the Department of Health also issues requests for applications (RFAs).¹⁵⁵

The December 2012 “Report of the Public Health and Health Planning Council on Redesigning Certificate of Need and Health Planning” states that in response to the goals of the ACA and related efforts of New York’s Medicaid Redesign Team, Governor Cuomo has “charged the Public Health and Health Planning Council with redesigning the state’s CON program.”¹⁵⁶ In its report, PHHPC “recommends the creation of Regional Health Improvement Collaboratives (RHICs) to convene and actively engage stakeholders, analyze data, and develop a consensus around strategies to promote the Triple Aim” in 11 “geographic planning regions.”¹⁵⁷ Additionally, PHHPC recommendations include “eliminat[ing] CON for primary care facilities” while retaining licensure requirements; “exempt[ing] projects funded with State Department of Health grants from public need review and provid[ing] for limited review”; “reconsider[ing] the utility of CON for hospital beds in the next three to five years...given the growth of payment incentives that discourage admissions”; “consider[ing] the use of ACO certification in lieu of CON for certain facilities”; “updat[ing] the criteria that trigger the facility licensure requirement [for CON coverage] and equaliz[ing] the treatment of physician practices

¹⁵⁵ *Report of the Public Health and Planning Council on Redesigning Certificate of Need and Health Planning*, PUB. HEALTH & PLANNING COUNCIL 34 (Dec. 6, 2012), available at https://www.health.ny.gov/facilities/public_health_and_health_planning_council/docs/con_redesign_report.pdf (recommending increased CON regulation of private physician offices, discussed below).

¹⁵⁶ *Report of the Public Health and Planning Council on Redesigning Certificate of Need and Health Planning*, PUB. HEALTH & PLANNING COUNCIL 7 (Dec. 6, 2012), available at https://www.health.ny.gov/facilities/public_health_and_health_planning_council/docs/con_redesign_report.pdf (recommending increased CON regulation of private physician offices, discussed below).

¹⁵⁷ *Report of the Public Health and Planning Council on Redesigning Certificate of Need and Health Planning*, PUB. HEALTH & PLANNING COUNCIL 9, 11 (Dec. 6, 2012), available at https://www.health.ny.gov/facilities/public_health_and_health_planning_council/docs/con_redesign_report.pdf (defining the “Triple Aim” as encompassing “better care, including improvements in safety, effectiveness, patient-centeredness, timeliness, efficiency and equity; better health for populations; and lower per capita costs”).

and [already covered] facilities with respect to CON...”; and “updat[ing] the CON process for hospice [to facilitate increased utilization].”¹⁵⁸

On October 15, 2014, the New York Department of Health publicized proposed changes to simplify its CON process by “requir[ing] prior notice, rather than a CON application, for certain construction projects involving non-clinical infrastructure, the replacement of medical equipment, and facility repair and maintenance.”¹⁵⁹

Please see further discussion on the proposed reforms below in the policy analysis section.

34. North Carolina

North Carolina started its CON program in 1978.¹⁶⁰ The North Carolina Division of Health Service Regulation (DHSR) Certificate of Need Section, part of the state’s Department of Health and Human Services, is responsible for administering the program.¹⁶¹ The State Medical Facilities Plan “lists the determined needs for health care facilities, beds, services, etc. across the state, and aspiring providers send in applications competing to win state approval for

¹⁵⁸ *Report of the Public Health and Planning Council on Redesigning Certificate of Need and Health Planning*, PUB. HEALTH & PLANNING COUNCIL 9-10, 35 (Dec. 6, 2012), available at https://www.health.ny.gov/facilities/public_health_and_health_planning_council/docs/con_redesign_report.pdf (recommending increased CON regulation of private physician offices, discussed below).

¹⁵⁹ Theresa Carnegie, *NYS Department of Health Proposes Changes to Certificate of Need Process*, MINTZ LEVIN COHN FERRIS GLOVSKY & POMPEO PC (Oct. 28, 2014), <http://www.healthlawpolicymatters.com/2014/10/28/nys-department-of-health-proposes-changes-to-certificate-of-need-process/> (last visited Jan. 22, 2015).

¹⁶⁰ Richard Cauchi, *Certificate of Need: State Health Laws and Programs*, NAT’L CONFERENCE STATE LEGISLATURES (Jan. 2011), <http://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx> (last visited Dec. 30, 2014).

¹⁶¹ *Certificate of Need*, N.C. DIV. HEALTH SERV. REGULATION, <http://ncdhhs.gov/dhsr/coneed/index.html> (last visited Jan. 2, 2015).

filling those needs.”¹⁶² The applicable statutory provisions are N.C. Gen. Stat. § 131E-175 *et seq.*, and the regulations are in tit. 10A N.C. Admin. Code 14C.

North Carolina’s CON law provides that “no person shall offer or develop a new institutional health service [or change bed capacity] without first obtaining a certificate of need.”¹⁶³ Under N.C. Gen. Stat. § 131E-175, new institutional health services include “bone marrow transplantation; burn intensive care services; neonatal intensive care services; open-heart surgery services; and cardiac catheterization services.”¹⁶⁴ Pursuant to N.C. Gen. Stat. § 131E-176(16), a CON is required prior to acquisition of any of the following equipment: “cardiac catheterization equipment; gamma knife equipment; heart-lung bypass machine; linear accelerator; lithotripter; [MRI] scanner; [PET] scanner; and simulator.” A CON is also required before any “upgrading or expansion of existing health [care] facilities or services, which involves a capital expenditure above the specified minimums.”¹⁶⁵

Wes Cleveland, a CON regulatory expert affiliated with the AMA, has described North Carolina’s CON program, which covers 25 services, as among “the most restrictive CON programs in the nation,” paralleled only by the Alaska and New York CON programs.¹⁶⁶

Covered entities include “all new hospitals, psychiatric facilities, chemical dependency treatment facilities, nursing home facilities, adult care homes, kidney disease

¹⁶² *Certified: The Need to Repeal CON*, JOHN LOCKE FOUND. 5 (Oct. 25, 2013), available at <http://www.insideronline.org/summary.cfm?id=21036>.

¹⁶³ *Certificate of Need*, N.C. DIV. HEALTH SERV. REGULATION, <http://ncdhhs.gov/dhsr/coneed/index.html> (last visited Jan. 2, 2015); N.C. Gen. Stat. § 131E-175.

¹⁶⁴ *Certificate of Need*, N.C. DIV. HEALTH SERV. REGULATION, <http://ncdhhs.gov/dhsr/coneed/index.html> (last visited Jan. 2, 2015).

¹⁶⁵ *Id.*; N.C. Gen. Stat. § 131E-175.

¹⁶⁶ *Certified: The Need to Repeal CON*, JOHN LOCKE FOUND. 3 (Oct. 25, 2013), available at <http://www.insideronline.org/summary.cfm?id=21036>.

treatment facilities, home health agencies, hospices, diagnostic centers, and ambulatory surgical facilities.”¹⁶⁷

N.C. Gen. Stat. § 131E-184 provides exemptions from CON review for “conversion of existing acute care beds to psychiatric beds” (under certain circumstances); development of new substance abuse treatment facilities; capital expenditures used to renovate, replace, or expand certain long term care facilities; and the replacement of certain medical equipment. In 2005, Session Law 2005-36 additionally granted an exemption for gastroenterologists performing colonoscopies in their own endoscopy units.¹⁶⁸

Pursuant to N.C. Gen. Stat. § 131E-183, the Department applies the following review considerations in deciding whether to issue a CON: consistency with the State Medical Facilities Plan; population need; whether the project is the most effective alternative; financial feasibility; whether the proposed project will lead to unnecessary duplication; availability of needed resources; special needs of HMOs; effects of proposed construction; accessibility for the elderly, the indigent, and other medically-underserved groups; effects on the medical education system; and effects on competition.

In 2011, members of the state legislature formed the House Select Committee on the Certificate of Need Process and Related Hospital Issues, and “at the end of 2012, [the] legislative committee recommended several reforms for CON, including allowing ‘market driven competition in the provision of health services,’ [but the] bills based on those recommendations [including House Bill 177: ‘Amend Certificate of Need Laws’ and House Bill 83: ‘Enact CON

¹⁶⁷ *Certificate of Need*, N.C. DIV. HEALTH SERV. REGULATION, <http://ncdhhs.gov/dhsr/coneed/index.html> (last visited Jan. 2, 2015); N.C Gen. Stat. § 131E-175.

¹⁶⁸ *See Bill to Revise Hospital Rules Dies in Subcommittee*, N.C. HEALTH NEWS (Apr. 24, 2014), <http://www.northcarolinahealthnews.org/2014/04/24/bill-to-revise-hospital-rules-dies-in-subcommittee/> (last visited Jan. 2, 2015).

Committee Recommendations,'] failed in 2013.”¹⁶⁹ The committee additionally recommended “a ‘full and complete review of all new institutional health services regulated under Certificate of Need law to determine the need and rationale for each included service regulation’; ‘exempting diagnostic centers from Certificate of Need Review and amending the Certificate of Need laws pertaining to single-specialty ambulatory surgery rooms’; several adjustments to ‘statutory expenditure thresholds regarding expedited reviews, major medical equipment, and replacement equipment’; [and] several changes ‘to streamline the appeals process, to redefine the parties having standing to appeal, and to deter the bringing of frivolous, harassing, or meritless appeals.’”¹⁷⁰

In April of 2014, Representative Marilyn Avila, co-chair of the state legislature’s Committee on Market Based Solutions and Elimination of Anti-Competitive Practices in Health Care proposed a bill to the committee that “would have eliminated limits on the creation of ambulatory surgery centers,” but the bill failed to obtain “the needed votes to proceed to the full House.”¹⁷¹

State legislators, including Representative Avila, plan to advocate for CON reform legislation again in the 2015 session, in response to concerns that hospitals have been unfairly circumventing CON requirements for operating rooms by building unregulated procedure rooms to the same standards, unfairly choking out competition by prospective physician-owned ASCs by making need for operating rooms appear artificially lower under the

¹⁶⁹ *Certified: The Need to Repeal CON*, JOHN LOCKE FOUND. 1 (Oct. 25, 2013), available at <http://www.insideronline.org/summary.cfm?id=21036>.

¹⁷⁰ *Id.* at 6.

¹⁷¹ *See Bill to Revise Hospital Rules Dies in Subcommittee*, N.C. HEALTH NEWS (Apr. 24, 2014), <http://www.northcarolinahealthnews.org/2014/04/24/bill-to-revise-hospital-rules-dies-in-subcommittee/> (last visited Jan. 2, 2015).

prevailing State Medical Facilities Plan methodology.¹⁷² In 2013 “policymakers sought to relax regulations for applicants interested in building single specialty ASCs... and push aside the ‘needs’ projected by the State Medical Facilities Plan [under the condition that] physicians would provide [7%] charity care and perform 800 surgeries each year.”¹⁷³

35. **North Dakota**

North Dakota cancelled its CON program in 1995, and research did not disclose any attempts to reinstate the program.¹⁷⁴

36. **Ohio**

Ohio’s CON program only regulates long-term care facilities and is more limited in scope than many other states’ CON programs.

Ohio’s CON requirements are in Ohio Rev. Code Ann. § 3702.01 *et seq.* and Ohio Admin. Code 3702-2-01 *et seq.* Reviewable activities include “the development of new long term care facilities (including the reopening of a facility not currently providing care), replacement of existing long term care facilities, increases in the capacity of a long term care facility, the relocation of long term care beds to another site, the renovation and/or addition to a long term care facility with a capital cost of more than \$2 million, and any change related to a granted CON application within 5 years including a cost overrun of 110% of the approved

¹⁷² Katherine Restrepo, *North Carolina’s Certificate of Need Law: A High Wall for Competitors to Scale*, FORBES (Dec. 8, 2014), <http://www.forbes.com/sites/katherinerestrepo/2014/12/08/north-carolinas-certificate-of-need-law-a-high-wall-for-competitors-to-scale/> (last visited Jan. 5, 2014); see Katherine Restrepo, *Certificate of Need Under Fire in North Carolina*, HEARTLAND (Dec. 16, 2014), <http://news.heartland.org/newspaper-article/2014/12/16/certificate-need-under-fire-north-carolina> (last visited Jan. 5, 2014).

¹⁷³ *Id.*

¹⁷⁴ Richard Cauchi, *Certificate of Need: State Health Laws and Programs*, NAT’L CONFERENCE STATE LEGISLATURES (Jan. 2011), <http://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx> (last visited Dec. 30, 2014).

cost.”¹⁷⁵ The Ohio Department of Health is responsible for administering the program.¹⁷⁶ There is currently a moratorium prohibiting the addition of new long-term care beds under Ohio Rev. Code Ann. § 3702.59.¹⁷⁷

Research did not disclose any significant changes in the last five years.

37. **Oklahoma**

Oklahoma has CON programs for long-term care facilities and psychiatric and chemical dependency treatment facilities, both of which are administered by the Oklahoma State Department of Health (OSDH).¹⁷⁸

The applicable statute for Oklahoma’s Long Term Care CON program is Okla. Stat. tit. 63 § 1-850 *et seq.*, and OSDH has also promulgated “Unofficial Certificate of Need Rules.”¹⁷⁹ Under the Long-Term Care CON program, “nursing facilities, specialized facilities for developmentally disabled clients, and hospital-based skilled nursing units must be approved [or granted an exemption] before: establishing a new facility; increasing the number of beds at an existing facility; acquiring ownership or operation of a facility; or spending \$1,000,000 or more

¹⁷⁵ Quoted from *Frequently Asked Questions*, OHIO DEP’T HEALTH (Jan. 1, 2014), <http://www.odh.ohio.gov/~media/ODH/ASSETS/Files/dspc/certificate%20of%20need/frequentlyaskedquestions.aspx> (last visited Jan. 2, 2015) (citing Ohio Admin. Code 3701-12-05).

¹⁷⁶ *Certificate of Need Program*, OHIO DEP’T HEALTH, <http://www.odh.ohio.gov/odhprograms/dspc/certn/certneed1.aspx> (last visited Jan. 2, 2015).

¹⁷⁷ *Frequently Asked Questions*, OHIO DEP’T HEALTH (Jan. 1, 2014), <http://www.odh.ohio.gov/~media/ODH/ASSETS/Files/dspc/certificate%20of%20need/frequentlyaskedquestions.aspx> (last visited Jan. 2, 2015).

¹⁷⁸ *Long-term Care Certificate of Need*, OKLA. STATE DEP’T HEALTH, http://www.ok.gov/health/Protective_Health/Health_Resources_Development_Service/Health_Facility_Systems/_Long_Term_Care_Certificate_of_Need/ (last visited Jan. 2, 2015); *Psychiatric and Chemical Dependency Treatment Facilities Certificate of Need*, OKLA. STATE DEP’T HEALTH, http://www.ok.gov/health/Protective_Health/Health_Resources_Development_Service/Health_Facility_Systems/_Psychiatric_and_Chemical_Dependency_Treatment_Facilities_Certificate_of_Need/index.html (last visited Jan. 2, 2015).

¹⁷⁹ *Id.*

on any project.”¹⁸⁰ Long-term care facilities may apply for an exemption for replacement or relocation, for certain change of ownership transactions, and for an expansion of licensed bed capacity not exceeding ten beds or ten percent.¹⁸¹

The applicable statute for Oklahoma’s Psychiatric and Chemical Dependency Treatment CON program is Okla. Stat. tit. 63 § 1-880.1 *et seq.* Under the Psychiatric and Chemical Dependency Treatment Facilities CON program, “psychiatric hospitals, psychiatric units, and chemical dependency units in general acute hospitals must receive approval under Oklahoma’s [CON] laws before establishing a new facility, [which includes] transferring ownership or operation of a facility.”¹⁸² OSDH has also promulgated unofficial rules, which may be found on the agency’s website.¹⁸³

Research did not disclose any changes to Oklahoma’s CON programs in the last five years.

38. **Oregon**

Oregon’s CON program has been in operation since 1971.¹⁸⁴ The Oregon Health Authority, Public Health Division is responsible for administering the state’s CON program.¹⁸⁵

¹⁸⁰ *Long-term Care Certificate of Need*, OKLA. STATE DEP’T HEALTH, http://www.ok.gov/health/Protective_Health/Health_Resources_Development_Service/Health_Facility_Systems_/Long_Term_Care_Certificate_of_Need/ (last visited Jan. 2, 2015).

¹⁸¹ *Id.*

¹⁸² *Psychiatric and Chemical Dependency Treatment Facilities Certificate of Need*, OKLA. STATE DEP’T HEALTH, http://www.ok.gov/health/Protective_Health/Health_Resources_Development_Service/Health_Facility_Systems_/Psychiatric_and_Chemical_Dependency_Treatment_Facilities_Certificate_of_Need/index.html (last visited Jan. 2, 2015).

¹⁸³ *Id.*

¹⁸⁴ Richard Cauchi, *Certificate of Need: State Health Laws and Programs*, NAT’L CONFERENCE STATE LEGISLATURES (Jan. 2011), <http://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx> (last visited Dec. 30, 2014).

The applicable statutory provisions are in Or. Rev. Stat. § 442.015 *et seq.*, and the regulations are in Or. Admin. R. 333-545 *et seq.*

Under Or. Rev. Stat. § 442.215, “any new hospital or new skilled nursing or intermediate care facility...shall obtain a certificate of need from the Oregon Health Authority prior to an offering or development,” where Or. Rev. Stat. § 430.620 defines “offer” as to “hold itself out as capable of providing, or as having the means for the provision of, specified health services,” and Or. Rev. Stat. § 442.015 defines “develop” as to “undertake those activities that on their completion will result in the offer of a new institutional health service or the incurring of a financial obligation...in relation to the offering of such a health service.” Under Or. Rev. Stat. § 442.315, covered services include “[MRI] scanners, [PET] scanners; cardiac catheterization equipment; megavoltage radiation therapy equipment; extracorporeal shock wave lithotrippers; neonatal intensive care; burn care; trauma care; inpatient psychiatric services; inpatient chemical dependency services; inpatient rehabilitation services; open heart surgery; [and] organ transplant services.”

Under Or. Rev. Stat. § 442.325, a CON is also “required for the development and establishment of a health care facility or any new [HMO].” Under Or. Rev. Stat. § 430.620, “health care facility means a hospital; a long term care facility; an ambulatory surgical center; a freestanding birthing center; or an outpatient dialysis center.”

Or. Rev. Stat. § 442.315 states an exemption from the CON requirement for “any hospital, skilled nursing, or immediate care service facility that seeks to replace equipment with

¹⁸⁵ *Certificate of Need*, OR. HEALTH AUTH., <https://public.health.oregon.gov/ProviderPartnerResources/HealthcareProvidersFacilities/CertificateNeed/Pages/index.aspx> (last visited Jan. 2, 2015).

equipment of similar basic technological function or an upgrade that improves quality or cost-effectiveness of the service provided.”

Or. Admin. R. 333-580-0040 provides general review criteria pertaining to the project’s capacity to address the needs of the population, the availability of necessary resources weighed against potential alternative uses of such resources, in addition to economic considerations, including the financial feasibility of the project.

Research did not disclose any changes to Oregon’s CON program in the last five years.

39. **Pennsylvania**

Pennsylvania’s CON program ended in 1996.¹⁸⁶

In November of 2009, State Representative Phyllis Mundy sponsored the *Health Care Facilities Act* (HB 247) to “rein in the escalating costs of health care,” stating that “one of the significant health care cost drivers is unnecessary duplication of expensive technology and services.”¹⁸⁷ HB 247 would have “establish[ed] local review committees to review CON applications and provide recommendations to the Department of Health; require[d] applicants to demonstrate that there is not a more cost-effective alternative to providing their proposed services; require[d] applicants to demonstrate that their proposed service would not adversely affect health care costs; [and] involve[d] the Pennsylvania Health Care Cost Containment Council in the review process.”¹⁸⁸ In support of the bill, Mundy noted that “since the state’s

¹⁸⁶ Richard Cauchi, *Certificate of Need: State Health Laws and Programs*, NAT’L CONFERENCE STATE LEGISLATURES (Jan. 2011), <http://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx> (last visited Dec. 30, 2014).

¹⁸⁷ *Medical Certificate of Need Process Could Return to PA*, REAL REPORTING.ORG/NEWSLANC.COM (Nov. 5, 2009), <http://newslanc.com/2009/11/05/medical-certificate-of-need-process-could-return-to-pa/> (last visited Jan. 2, 2015).

¹⁸⁸ *Id.*

CON program expired in 1996,...the number of licensed ambulatory surgery centers in Pennsylvania increased 400%, from 44 to more than 230.”¹⁸⁹

In 2012, state Senator Jim Ferlo advanced legislation that would bring back Pennsylvania’s CON program to address “duplication, unnecessary facilities, and a lack of primary care.”¹⁹⁰ “Ferlo’s proposed law [Senate Bill 809: Reenacting a Certificate of Need Program] would require the Department of Health to draft a State Health Improvement Plan to identify areas of need and saturation, establish an 11-member review board, and make health care providers obtain approval for any hospital expenditure above \$2 million, any new equipment or improvements for an ambulatory surgical facility above \$1 million, and any new high-cost technology above \$500,000.”¹⁹¹ Senate Bill 809 was referred to the Senate Public Health & Welfare Committee on April 4, 2013.¹⁹² When interviewed about Senate Bill 809, Bill Maruca, an attorney working for Fox Rothschild, a firm in Philadelphia, responded that reviving CON might not be such a “cure-all” since insurance companies in Philadelphia have become much more powerful than they were before CON was repealed and are increasingly restricting who they contract with.¹⁹³

The above efforts to reinstate Pennsylvania’s CON program have not yet succeeded.

¹⁸⁹ *Id.*

¹⁹⁰ Andrew Conte & Luis Fábregas, *Medical Facility Curbs Proposed in Pennsylvania*, TRIBLIVE | STATE (May 7, 2012), <http://triblive.com/state/pennsylvania/1473689-74/health-care-certificate-ferlo-review-facilities-hospital-state-equipment-law#axzz3MgffUCnB> (last visited Jan. 2, 2015)(quoting state Senator Jim Ferlo).

¹⁹¹ *Id.*

¹⁹² *2013 Senate Bill 809: Reenacting a Certificate of Need Program*, PENNSYLVANIAVOTES.ORG, <http://pennsylvaniavotes.org/2013-SB-809> (last visited Jan. 2, 2015).

¹⁹³ Andrew Conte & Luis Fábregas, *Medical Facility Curbs Proposed in Pennsylvania*, TRIBLIVE | STATE (May 7, 2012), <http://triblive.com/state/pennsylvania/1473689-74/health-care-certificate-ferlo-review-facilities-hospital-state-equipment-law#axzz3MgffUCnB> (last visited Jan. 2, 2015)(quoting state Senator Jim Ferlo).

40. Rhode Island

Rhode Island started its CON program in 1968.¹⁹⁴ The Department of Health (DOH) administers the CON program, in addition to a separate but related Change in Effective Control (CEC) process.¹⁹⁵

Applicable statutes governing Rhode Island's CON process are in R.I. Gen. Laws § 23-15, and the regulations are in R.I. Code R. § 23-15. A CON, "is required for...the following activities: construction, development, or establishment of a new health care facility (including, freestanding ambulatory surgical centers, home care providers, home nursing care providers, hospitals, nursing facilities, hospice providers, inpatient rehabilitation centers, multi-practice physician ambulatory surgery centers, [and] multi-practice podiatry ambulatory surgery centers); a capital expenditure for: health care equipment in excess [of the threshold amount]..., construction or renovation of a health care facility [in excess of the threshold amount], [or] acquisition of an existing health care facility, if the services or the bed capacity of the facility will be changed...; any capital expenditure which results in an increase in bed capacity of a hospital and inpatient rehabilitation centers...; any capital expenditure which results in an increase in bed capacity of a nursing facility in excess of 10 beds or 10% of [the] facility's licensed bed capacity...; the offering of a new health service [above the threshold amount]; predevelopment activities not part of a proposal [exceeding the threshold amount]; establishment of an additional inpatient premise of an existing inpatient health care facility; [and] tertiary or

¹⁹⁴ Richard Cauchi, *Certificate of Need: State Health Laws and Programs*, NAT'L CONFERENCE STATE LEGISLATURES (Jan. 2011), <http://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx> (last visited Dec. 30, 2014).

¹⁹⁵ *Office of Health Systems Development*, STATE OF R.I. DEP'T HEALTH, <http://www.health.ri.gov/programs/healthsystemsdevelopment/> (last visited Jan. 2, 2015).

specialty care services [including] full body MRI, CT, cardiac catheterization, [PET], linear accelerators, open heart surgery, organ transplantation, and neonatal intensive care services.”¹⁹⁶

Under R.I. Code R. § 23-15-4.3, to demonstrate public need, the applicant must “demonstrate the current service and target population involved and where appropriate, the projected population change; delineate the health needs of the above populations; inventory the facilities or services currently available or proposed capable of meeting [such] health needs; determine that portion of need which is not satisfied; identify and evaluate alternative proposals to satisfy the unmet need; and delineate the justification for the specific alternative proposed, including the scope thereof.”

The applicable statutes governing Rhode Island’s CEC process are in R.I. Gen. Laws § 23-17. Under Rhode Island’s CEC process, “a change in ownership, control, or lease of a health care facility in [Rhode Island] requires approval by the Department of Health as a [CEC]...This includes hospitals, nursing homes, organized ambulatory care facilities, freestanding emergency care facilities, [and] home health care providers.”¹⁹⁷

DOH provides the following statutory review criteria for the CEC process: “the character, commitment, competence, and standing in the community of the proposed owner or operator; the extent to which the facility will continue to provide care without effect on the viability of the facility; the extent to which the facility will continue to provide safe and adequate treatment for the individuals receiving health care provided by the facility; [and] the extent to

¹⁹⁶ Quoted from *Certificate of Need: Summary of the Statutory Review and Decision Process*, R.I. DEP’T HEALTH, <http://www.health.ri.gov/publications/processsummaries/HealthSystemsCertificateOfNeed.pdf> (last visited Jan. 2, 2015); R.I. Gen. Laws § 23-15.

¹⁹⁷ Quoted from *Change in Effective Control: Summary of the Statutory Review and Decision Process*, R.I. DEP’T HEALTH, <http://www.health.ri.gov/publications/processsummaries/HealthSystemChangeInEffectiveControl.pdf> (last visited Jan. 2, 2015); R.I. Gen. Laws § 23-17.

which the facility will continue to provide access to underserved populations, in consideration of the proposed continuation or termination of services provided by the facility.”¹⁹⁸

In July of 2014, the Rhode Island passed new legislation, 2014-H 7368, that “helps expedite...the certificate of need process for domestic ‘medical tourism’ companies looking to locate in Rhode Island.”¹⁹⁹ The law provides “a provision for an exemption from the certificate of need requirements [for] the domestic medical tourism industry and multi-practice health facilities” and was enacted in response to the experience of a Pennsylvania-based in-home care company that sought to open a Rhode Island office but abandoned its efforts and terminated its services in Rhode Island after “spending about \$100,000 and seven months to obtain a home nursing care provider’s license.”²⁰⁰

41. **South Carolina**

South Carolina established its CON program in 1971, and the South Carolina Department of Health and Environmental Control, with the advice of the South Carolina State Health Planning Committee, is responsible for administering the program.²⁰¹ The applicable statutory provisions are in S.C. Code Ann. § 44-7-110 *et seq.*, and the regulations are in S.C. Code Ann. Regs. 61-15-101 *et seq.*

Pursuant to S.C. Code Ann. § 44-7-160, “health care facilities” are required to obtain a CON from the department “before undertaking any of the following: the construction or

¹⁹⁸ *Id.*

¹⁹⁹ *Bills Aimed at Expediting Certificate of Need Signed*, PROVIDENCE BUS. NEWS (Jul. 14, 2014), <http://pbn.com/Bills-aimed-at-expediting-certificate-of-need-signed,98465> (last visited Jan. 2, 2015).

²⁰⁰ *Id.*

²⁰¹ Richard Cauchi, *Certificate of Need: State Health Laws and Programs*, NAT’L CONFERENCE STATE LEGISLATURES (Jan. 2011), <http://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx> (last visited Dec. 30, 2014); *Certificate of Need Program*, S.C. DEP’T HEALTH & ENVTL. SERV., <http://www.scdhec.gov/Health/FHPP/HealthFacilityRegulationsLicensing/CertificateOfNeed/> (last visited Jan. 3, 2015).

other establishment of a new health care facility; a change in the existing bed complement of a health care facility through the addition of one or more beds or change in the classification of licensure of one or more beds; [capital expenditures over the threshold amount]; [a capital expenditure associated with] the addition or substantial expansion of a [covered] health service; [the offering of a new health service]; [and] the acquisition of medical equipment which is to be used for diagnosis or treatment if the total project cost [exceeds the threshold amount].”

According to S.C. Code Ann. § 44-7-130, “health care facility means acute care hospitals, psychiatric hospitals, alcohol and substance abuse hospitals, nursing homes, ambulatory surgical facilities, hospice facilities, radiation therapy facilities, rehabilitation facilities, residential treatment facilities for children and adolescents, intermediate care facilities for persons with intellectual disability, [and] narcotic treatment programs.”

S.C. Code Ann. § 44-7-170 states exemptions from the CON requirement for “the acquisition...of medical equipment to be used solely for research, the offering of an institutional health service...solely for research, or the obligation of a capital expenditure...to be made solely for research; the offices of a licensed private practitioner whether for individual or group practice...; [and] the replacement of like equipment for which a [CON] has been issued which does not constitute a material change in service or new service.” S.C. Code Ann. § 44-7-170 further provides that the CON requirement “does not apply to” capital expenditures for non-medical projects, “community-based housing designed to promote independent living,” and kidney dialysis centers.

S.C. Code Ann. § 44-7-190 requires the department to consider the following criteria when reviewing CON applications: “need for health care facilities, beds, services, and equipment, including demographic needs, appropriate distribution, and utilization; accessibility

for underserved groups; availability of facilities and services without regard to ability to pay; absence of less costly and more effective alternatives; appropriate financial considerations, including method of financing, financial feasibility, and cost containment; consideration of the impact on health systems resources; site and building suitability;...[and] quality of care.” Under S.C. Code Ann. § 44-7-210, “the department may not issue a [CON] unless an application complies with the South Carolina Health Plan.”

Elaborating on the above statutory requirements, the associated regulations, in S.C. Code Ann. Regs. 61-15-802, provide the following criteria for project review: “community need; accessibility; acceptability [meaning support of local providers and target population]; [financial viability]; projected revenues; projected expenses; beginning cash flow; net income; debt service; methods of financing; [ability to obtain the desired capital]; record of the applicant; ability to complete the project; financial feasibility; cost containment; efficiency; physical design; alternative methods; staff resources; support services and equipment; distribution, adverse effects on other facilities; adverse effects on training programs; access [for medical education purposes]; zoning; utilities; site size; environmental hazard; square footage; medically underserved groups; other entities; [and] elimination of safety hazards.”

In July of 2013, South Carolina’s CON program was temporarily suspended when Governor Nikki Haley vetoed the funding needed for the program’s operation, and the House sustained the veto.²⁰² When Governor Haley issued the line-item veto, she commented: “The CON program is an intensely political one through which bureaucratic policymakers deny health

²⁰²Cassie Cope, *SC House Panel Begins Review of Certificate of Need Program*, THE STATE (Sept. 24, 2014), http://www.thestate.com/2014/09/24/3702843_sc-house-panel-begins-review-of.html?sp=/99/132/312/169/&rh=1 (last visited Jan. 3, 2015); *South Carolina Certificate of Need Law Remains in Force*, MCGUIRE WOODS (Apr. 15, 2014), <http://www.mcguirewoods.com/Client-Resources/Alerts/2014/4/South-Carolina-Certificate-of-Need-Law-Remains-in-Force.aspx> (last visited Jan. 3, 2015).

care providers from offering treatment. We should allow the market to work rather than politics.”²⁰³

The CON program resumed in April of 2014 when the South Carolina Supreme Court ruled that DHEC could not legally suspend the program, reasoning that while “the Governor or South Carolina has a constitutional right to a line-item veto over specific items contained in an appropriations act..., DHEC also ha[d] a statutory obligation under the CON Act to administer the CON program.”²⁰⁴ While the CON program was dormant, “about 70 projects went forward that would have required a [CON],” the majority of which were home health providers, and it appears likely that the involved companies will be required to engage in the CON process.²⁰⁵ Now, a panel of representatives from the state legislature, including Rep. Murrell Smith and Rep. Jim Merrill, is exploring how the state might reform its CON program in response to the controversy surrounding it, and recent reports indicate “opinions are all over the board.”²⁰⁶ For instance, while the South Carolina Hospital Association and the South Carolina Health Care Association “think the answer is to streamline the process so expansion projects do [not] get put on extensive hold” and to raise “the threshold for new equipment purchases or

²⁰³ *South Carolina Certificate of Need Law Remains in Force*, MCGUIRE WOODS (Apr. 15, 2014), <http://www.mcguirewoods.com/Client-Resources/Alerts/2014/4/South-Carolina-Certificate-of-Need-Law-Remains-in-Force.aspx> (last visited Jan. 3, 2015).

²⁰⁴ *Id.*

²⁰⁵ Cassie Cope, *SC House Panel Begins Review of Certificate of Need Program*, THE STATE (Sept. 24, 2014), http://www.thestate.com/2014/09/24/3702843_sc-house-panel-begins-review-of.html?sp=/99/132/312/169/&rh=1 (last visited Jan. 3, 2015); Bill Poovey, *Some Health Care Providers Stuck in Regulatory Mess*, GSA BUS. (Nov. 17, 2014), <http://www.gsabusiness.com/news/53046-some-health-care-providers-stuck-in-regulatory-mess> (last visited Jan. 3, 2015).

²⁰⁶ Cassie Cope, *SC House Panel Begins Review of Certificate of Need Program*, THE STATE (Sept. 24, 2014), http://www.thestate.com/2014/09/24/3702843_sc-house-panel-begins-review-of.html?sp=/99/132/312/169/&rh=1 (last visited Jan. 3, 2015); Joey Holleman, *Does SC Health Care Need Certificate of Need?*, THE STATE (Oct. 21, 2014), http://www.thestate.com/2014/10/21/3760233_does-sc-health-care-need-certificate.html?rh=1 (last visited Jan. 3, 2015).

major capital expenditures,” a number of “physician groups and ambulatory surgical centers would like to see the program ended, or at least its scope tremendously reduced.”²⁰⁷

At the agency level, on November 13, 2014, the Department advanced, and the Board later “granted initial approval to,” proposed revisions to the CON regulations, and “several changes of significance have some providers questioning whether the Department is attempting to accomplish through regulation what could not be accomplished through limiting the program’s funding. For example, the revisions significantly raise the monetary threshold for projects to trigger the requirement to obtain a CON to \$50 million for a capital expenditure and to \$10 million for medical equipment,” and the regulations would also create a streamlined online application process.²⁰⁸

42. **South Dakota**

South Dakota discontinued its CON program in 1988.²⁰⁹ Research did not disclose any attempts to restore the program.

43. **Tennessee**

Tennessee’s CON program started in 1973.²¹⁰ The Tennessee Health Services and Development Agency (THSDA) is responsible for administering the state’s CON

²⁰⁷ Joey Holleman, *Does SC Health Care Need Certificate of Need?*, THE STATE (Oct. 21, 2014), http://www.thestate.com/2014/10/21/3760233_does-sc-health-care-need-certificate.html?rh=1 (last visited Jan. 3, 2015).

²⁰⁸ Amber Carter, *Potential Changes in the South Carolina Certificate of Need Application and Review Process*, PARKER POE ADAMS & BERNSTEIN LLP (Dec. 9, 2014), <http://www.jdsupra.com/legalnews/potential-changes-in-the-south-carolina-05702/> (last visited Jan. 5, 2015).

²⁰⁹ Richard Cauchi, *Certificate of Need: State Health Laws and Programs*, NAT’L CONFERENCE STATE LEGISLATURES (Jan. 2011), <http://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx> (last visited Dec. 30, 2014).

²¹⁰ *Id.*

program.²¹¹ Applicable statutory provisions can be found in Tenn. Code Ann. § 68-11-1601 *et seq.*, and regulations are in Tenn. Comp. R. & Regs. 0720-9-.01 *et seq.*

Under Tenn. Code Ann. § 68-11-1607, a CON is required for the following activities: “the construction, development, or other establishment of any type of health care institution; the modification, renovation, or addition to a hospital in excess of \$5 million and other institutions in excess of \$2 million; any change in the bed complement of a health care institution [including the relocation of beds to another facility or site]; [initiation of a covered health care service]; change in location or replacement of existing or certified facilities providing health care services, major medical equipment, or health care institutions; change of parent office of a home health or hospice agency from one county to another county; acquisition of major medical equipment in which the cost exceeds \$2 million; discontinuation of obstetrics; [and] the closing of any hospital that has been designated as a critical access hospital under the Medicare rural flexibility program or the elimination in such hospital of any services for which a certificate of need is required.”²¹²

The following entities must obtain a CON “prior to establishment, licensure, or certification: hospital; nursing home; recuperation center; ambulatory surgical treatment center; mental health hospital; intellectual disability institutional habilitation facility; home care organization (home health and hospice); outpatient diagnostic center; rehabilitation facility; residential hospice; nonresidential substitution-based treatment center for opiate addiction; [and] birthing center.”²¹³ A CON is required before initiating the following types of services: “burn

²¹¹ *Certificate of Need Program*, TENN. HEALTH SERV. & DEV’T AGENCY, http://tennessee.gov/hsda/cert_need_sum.html (last visited Jan. 3, 2015).

²¹² *Certificate of Need Program; Health Services and Development Agency CON Basics*, TENN. HEALTH SERV. & DEV’T AGENCY, http://tennessee.gov/hsda/cert_need_basics.html (last visited Jan. 3, 2015).

²¹³ *Id.*

unit; neonatal intensive care unit; open heart surgery; [PET]; swing beds; home health; psychiatric (inpatient); rehabilitation (inpatient); hospital-based alcohol and drug treatment for adolescents provided under a program of care longer than 28 days; extracorporeal lithotripsy; [MRI]; cardiac catheterization; linear accelerator; hospice; [and] opiate addiction treatment provided through a facility licensed as a nonresidential substitution-based treatment center for opiate addiction.”²¹⁴

The following actions do not require the full CON process but merely a “notice or prior approval by the THSDA: persons replacing existing major medical equipment with the same or similar major medical equipment or upgrading such equipment; hospitals with fewer than 100 beds increasing by 10 beds over a one-year period; newly licensed health care institutions changing ownership within two years of obtaining the initial license; [and] any health care facility proposing to change conditions that were placed on its [CON] when approved and subsequently made a condition of the license.”²¹⁵

Under Tenn. Comp. R. & Regs. 0720-11-.01, THSDA considers three factors in the CON review process: “need, economic feasibility, and contribution to the orderly development of adequate and effective health care facilities and/or services.”²¹⁶ To assess need, THSDA considers: “the relationship of the proposal to any existing applicable plans (e.g., the State Health Plan); the population served by the proposal; the existing or certified services or institutions in the area; the reasonableness of the service area; the special needs of the service area population, including the accessibility to consumers, particularly women, racial and ethnic

²¹⁴ *Id.*

²¹⁵ Quoted from *id.*; Tenn. Comp. R & Regs. 0720-10-.02.

²¹⁶ *Certificate of Need Program; Health Services and Development Agency CON Basics*, TENN. HEALTH SERV. & DEV’T AGENCY, http://tennessee.gov/hsda/cert_need_basics.html (last visited Jan. 3, 2015).

minorities, and low-income groups; comparison of utilization/occupancy trends and services offered by the other area providers; [and] the extent to which Medicare, Medicaid, and medically indigent patients will be served by the project.”²¹⁷ To assess economic feasibility, THSDA considers: “whether adequate funds are available to the applicant to complete the project; the reasonableness of the proposed project costs; anticipated revenue from the proposed project and impact on existing patient charges; participation in state/federal revenue programs; alternatives considered; and the availability of less costly or more effective alternative methods of providing the benefits intended by the proposal.”²¹⁸ To assess “contribution to the orderly development of adequate and effective health care facilities and/or services,” THSDA considers: “the relationship of the proposal to the existing health care system (for example, transfer agreements, contractual agreements for health services, affiliation of the project with health professional schools); the positive or negative effects attributed to duplication competition; the availability and accessibility of human resources required by the proposal, including consumers and related providers; [and] the quality of the proposed project in relation to applicable governmental or professional standards.”²¹⁹

In 2011, state Sen. Mike Bell and state Rep. Judd Matheny, sponsored a Tennessee bill that would “eliminate the [CON] requirements for health care services and equipment” while maintaining CON requirements for “health care facilities” as defined by the statute.²²⁰ If the bill were approved, it would have “had the greatest impact on physicians

²¹⁷ *Id.*

²¹⁸ *Id.*

²¹⁹ *Id.*

²²⁰ April Wortham, *Tennessee Bill Would Curb State Approval for Medical Services*, NASHVILLE BUS. JOURNAL (Mar. 4, 2011), available at <http://www.bizjournals.com/nashville/print-edition/2011/03/04/tennessee-bill-state-medical-services.html?page=all>.

because many of the [CON] applications submitted by hospitals involve facilities along with services and equipment.”²²¹ There is no indication that this bill made it past the committee stage.

44. **Texas**

Texas eliminated its CON program in 1985.²²² Research did not disclose any efforts to reinstate the program.

45. **Utah**

Utah abandoned its CON program in 1984, and research did not disclose any attempts to reinstate the program.²²³

46. **Vermont**

Vermont’s CON program has been in operation since 1979.²²⁴ The Green Mountain Care Board (GMCB) is responsible for administering the state’s CON program.²²⁵ Under Vermont’s new health care reform bill, GMCB has also been charged with creating the state’s single payer system.²²⁶ The statutory provisions for Vermont’s CON program are in Vt. Stat. Ann. tit. 18, § 9401 *et seq.*, and GMCB’s CON rule, GMCB Rule 4.00, provides additional guidance.²²⁷

²²¹ *Id.*

²²² Richard Cauchi, *Certificate of Need: State Health Laws and Programs*, NAT’L CONFERENCE STATE LEGISLATURES (Jan. 2011), <http://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx> (last visited Dec. 30, 2014).

²²³ Richard Cauchi, *Certificate of Need: State Health Laws and Programs*, NAT’L CONFERENCE STATE LEGISLATURES (Jan. 2011), <http://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx> (last visited Dec. 30, 2014).

²²⁴ *Id.*

²²⁵ *Certificate of Need*, GREEN MOUNTAIN CARE BD., <http://gmcbboard.vermont.gov/certificateofneed> (last visited Jan. 3, 2015).

²²⁶ *What is Vermont Single Payer?*, VERMONT LEADS, <http://www.vermontleads.org/what-is-vermont-single-payer.html> (last visited Jan. 3, 2015).

²²⁷ *Available at* <http://gmcbboard.vermont.gov/sites/gmcbboard/files/12%2012%2014%20CON%20Rule.pdf>.

Under Vt. Stat. Ann. tit. 18, § 9434(a), “health care facilities” other than hospitals are required to obtain a CON before: “the construction, development, purchase, renovation, or other establishment of a health care facility, or any capital expenditure [exceeding \$1.5 million]; [a change in bed capacity through addition, conversion, or relocation]; the offering of any home health service...; the transfer or conveyance of more than a 50 percent ownership interest in a health care facility other than a hospital; [acquisition of major medical equipment with a cost or value exceeding \$1 million]; [the offering of a new health care service with annual operating costs exceeding \$500,000]; [and] the construction, development, purchase, lease, or other establishment of an ambulatory surgical center.” Covered health care facilities under Vt. Stat. Ann. tit. 18, § 9432 include hospitals, birthing centers, “nursing homes, [HMOs], home health agencies, outpatient diagnostic or therapy programs, kidney disease treatment centers, mental health agencies or centers, diagnostic imaging facilities, independent diagnostic laboratories, cardiac catheterization laboratories, radiation therapy facilities, or any inpatient or ambulatory surgical, diagnostic, or treatment center.”

Under Vt. Stat. Ann. tit. 18, § 9434(b), “hospitals” must obtain a CON before: “the construction, development, purchase, renovation or other establishment of a health care facility, or any capital expenditure [exceeding \$3 million]; [acquisition of major medical equipment with a cost or value exceeding \$1 million]; [the offering of a new health care service with annual operating costs exceeding \$500,000]; [and a change in bed capacity through addition, conversion, or relocation].”

Vt. Stat. Ann. tit. 18, § 9435 states an exclusion from the CON requirement for “offices of physicians, dentists, or other practitioners of the healing arts,” clarifying that this exclusion does not apply to “offices owned, operated, or leased by a [hospital entity]; outpatient

diagnostic or therapy programs; kidney disease treatment centers; independent diagnostic libraries; cardiac catheterization laboratories; radiation therapy facilities; ambulatory surgical centers; and diagnostic imaging facilities and similar facilities.”

Pursuant to Vt. Stat. Ann. tit. 18, § 9437, a CON “shall be granted if the applicant demonstrates and the board finds that: the application is consistent with the health resource allocation plan; the cost of the project is reasonable; there is an identifiable, existing, or reasonably anticipated need for the proposed project which is appropriate for the applicant to provide; the project will improve the quality of health care in the state or provide greater access to health care for Vermont’s residents, or both; the project will not have an undue adverse impact on any other existing services provided by the applicant; the project will serve the public good; the applicant has adequately considered the availability of affordable, accessible patient transportation services to the facility; and if the application is for the purchase or lease of new health care information technology, it conforms with the health information technology plan.”

Research did not disclose any significant changes to Vermont’s CON program in the last five years.

47. **Virginia**

The Virginia Department of Health’s Division of Certificate of Public Need (DCOPN) is responsible for administering Virginia’s Certificate of Public Need (COPN) program.²²⁸ Virginia’s COPN process originally included additional review by regional Health Planning Agencies (HPAs), but HPAs have largely fallen into disuse due to a lack of funding. The applicable statutory provisions for Virginia’s COPN process are in Va. Code Ann. § 32.1-102.1 *et seq.*, and the regulations are in 12 Va. Admin. Code § 5-230.

²²⁸ *The Certificate of Need Program*, VA. DEP’T HEALTH, <http://www.vdh.virginia.gov/OLC/copn/> (last visited Jan. 3, 2015).

Va. Code Ann. § 32.1-102.1 provides that the following medical care facilities are subject to COPN review: “general hospitals; sanitariums; nursing homes; intermediate care facilities...; extended care facilities; mental hospitals; facilities for individuals with intellectual disability; psychiatric hospitals and intermediate care facilities established primarily for the medical, psychiatric, or psychological treatment and rehabilitation of individuals with substance abuse disorders; specialized centers or clinics or that portion of a physician’s office developed for the provision of outpatient or ambulatory surgery, cardiac catheterization, [CT] scanning, stereotactic radiosurgery, lithotripsy, [MRI scanning], [MSI], [PET] scanning, radiation therapy, sterotactic radiotherapy, proton beam therapy, nuclear medicine imaging, except for the purpose of nuclear cardiac imaging, or any such other specialty services as may be designated by the Board by regulation.”

Under Va. Code Ann. § 32.1-102.3, “no person shall commence any project without first obtaining a certificate.” Va. Code Ann. § 32.1-102.1 defines “project” to include: “establishment of a medical care facility; an increase in the total number of beds or operating rooms in an existing medical care facility; relocation of beds from one existing facility to another...; introduction into an existing medical care facility of any new nursing home service...; introduction into an existing medical care facility any new [listed specialty service]...; conversion of beds in an existing medical care facility to medical rehabilitation beds or psychiatric beds; the addition by an existing medical care facility of any medical care equipment [for the provision of listed specialty services]...; any capital expenditure [exceeding the threshold amount]; [and] conversion in an existing medical care facility of psychiatric beds approved pursuant to a Request for Application (RFA) to non-psychiatric inpatient beds.”

Pursuant to Va. Code Ann. § 32.1-102.3, “in determining whether a public need for a project has been demonstrated, the Commissioner shall consider: the extent to which the proposed service or facility will provide or increase access to needed services for residents of the area to be served...; the extent to which the project will meet the needs of the area to be served, as demonstrated by...the level of community support for the project..., the availability of reasonable alternatives..., any recommendation or report of the regional health planning agency..., any costs and benefits of the project; the financial accessibility of the project to residents of the area to be served, including indigent residents; the extent to which the application is consistent with the State Medical Facilities Plan; the extent to which the proposed service or facility fosters institutional competition that benefits the area to be served while improving access to essential health care services for all persons in the area to be served; the relationship of the project to the existing health care system of the area to be served, including the utilization and efficiency of existing services or facilities; the feasibility of the project, including the financial benefits of the project to the applicant, the cost of construction, the availability of financial and human resources, and the cost of capital; the extent to which the project provides improvements or innovations in the financing and delivery of health services...; [and effects on medical training and education].” Even though the Commissioner is required to consider whether the application is consistent with the State Medical Facilities Plan, under Va. Code Ann. § 32.1-102.3, “if the Commissioner finds, upon presentation of appropriate evidence, that the provisions of such plan are not relevant to a rural locality’s needs, inaccurate, outdated, inadequate, or otherwise inapplicable, the Commissioner, consistent with such finding, may issue or approve the issuance of a certificate.”

As provided in Va. Code Ann. § 32.1-102.3.2, the Commissioner issues Requests for Applications (RFAs) for projects that would “result in an increase in the number of beds in a planning district in which nursing facility or extended care services are provided.” The Commissioner also issues RFAs for psychiatric beds.²²⁹

As of this writing, COPN reform is under consideration by the Virginia General Assembly and the administration.

48. **Washington**

Washington started its CON program in 1971.²³⁰ The Washington State Department of Health is responsible for administering the program.²³¹ The applicable statutory provisions are in Wash. Rev. Code § 70.38.015 *et seq.*, and the regulations are in Wash. Admin. Code § 246-310-001 *et seq.*

In Washington, a CON “is required for: construction, development, or establishment of the following health care facilities: hospitals, nursing homes, kidney dialysis centers, Medicare or Medicaid home health agencies, ambulatory surgical centers, and hospice care centers; increases in the number of stations at a kidney dialysis center; sale, purchase, or lease of all or part of an existing hospital, regardless of profit/non-profit status; increases in the number of licensed beds at a hospital, nursing home, or hospice care center; offering a new tertiary service [including]: level I rehabilitation programs, open heart surgery, therapeutic cardiac catheterization, organ transplantation specialty burn services, intermediate care nursery

²²⁹ See Va. Code Ann. § 32.1-102.3.

²³⁰ Richard Cauchi, *Certificate of Need: State Health Laws and Programs*, NAT’L CONFERENCE STATE LEGISLATURES (Jan. 2011), <http://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx> (last visited Dec. 30, 2014).

²³¹ *Certificate of Need*, WASH. STATE DEP’T HEALTH, <http://www.doh.wa.gov/LicensesPermitsandCertificates/FacilitiesNewReneworUpdate/CertificateofNeed> (last visited Jan. 3, 2015).

and/or obstetric services, Level II neonatal intensive care nursery and/or obstetric services, [and] Level III specialized inpatient pediatric services; a capital expenditure made by a nursing home exceeding [the threshold amount]; nursing home bed banking transactions; [and] nursing home replacements.”²³²

Wash. Rev. Code § 70.38.105 excludes certain non-patient care-related capital expenditures from the CON requirement, including those made solely for: “communications and parking facilities; mechanical, electrical, ventilation, heating, and air conditioning systems; energy conservation systems...; acquisition of equipment, including data processing equipment, which is not or will not be used in the direct provision of health services; [certain renovations of existing nursing homes]; acquisition of land; and refinancing of existing debt.” Wash. Rev. Code § 70.38.111 lists exemptions from the CON requirement for certain HMO-related activities and transactions; “for the construction, development, or other establishment of a nursing home, or the addition of beds to an existing nursing home that is owned and operated by [certain] continuing care retirement communit[ies]; [for certain activities of rural health care facilities]; [for] a nursing home that voluntarily reduces the number of its licensed beds to provide assisted living, licensed assisted living facility care, adult day care, adult day health, respite care, hospice, outpatient therapy services, congregate meals, home health, or senior wellness clinic, or to reduce to one or two the number of beds per room to otherwise enhance the quality of life for residents in the nursing home...; [for the establishment of hospice agencies under certain conditions]; [and for certain conversions of licensed beds for psychiatric services].”

Wash. Rev. Code § 70.38.115 provides the following CON review criteria: “the need that the population served or to be served has for such services; the availability of less

²³² *Id.*

costly or more effective alternative methods of providing such services; the financial feasibility and the probable impact of the proposal on the cost of and charges for providing health services in the community to be served; in the case of health services to be provided, the availability of alternative uses of project resources for the provision of other health services, the extent to which such proposed services will be accessible to all residents of the area to be served, the need for and the availability in the community of services and facilities for osteopathic physicians and surgeons and allopathic physicians and their patients, [and the project's] impact on existing and proposed institutional training programs for doctors of osteopathic medicine and surgery and medicine at the student, internship, and residency training levels; in the case of a construction project, the costs and methods of the proposed construction...; the special needs and circumstances of osteopathic hospitals, non-allopathic services, and children's hospitals; improvements or innovations in the financing and delivery of health services which foster cost containment and serve to promote quality assurance and cost-effectiveness; in the case of health services proposed to be provided, the efficiency and appropriateness of the use of existing services and facilities similar to those proposed; in the case of existing services or facilities, the quality of care provided by such services or facilities in the past; in the case of hospital [CON] applications, whether the hospital meets or exceeds the regional average level of charity care...; and in the case of nursing home applications, the availability of other nursing home beds in the planning area to be served and the availability of other services in the community to be served.”

Please see a discussion of recent developments in Washington's CON program in the policy analysis section below.

49. **West Virginia**

West Virginia started its CON program in 1977.²³³ The West Virginia Health Care Authority is responsible for administering the program.²³⁴ West Virginia's CON requirements are described in W. Va. Code § 16-2D.

Under W. Va. Code § 16-2D-3, a CON is required prior to: “the construction, development, acquisition, or other establishment of a new health care facility or [HMO]; the partial or total closure of a health care facility or [HMO] with which a capital expenditure is associated; [exceeding the capital expenditure threshold]...; a substantial change in the bed capacity of a health care facility...; the addition of health care services...[by] a health care facility or [HMO]; the addition of ventilator services to any nursing facility bed by any health care facility or [HMO]; the deletion of one or more health services previously offered...[by] a health care facility or [HMO]...; the acquisition of major medical equipment; a substantial change in an approved new institutional health service...; [and] an expansion of the service area for hospice or home health service.”

W. Va. Code § 16-2D-2 defines “health care facility” to include the following types of entities: “hospitals; skilled nursing facilities; kidney disease treatment centers, including free-standing hemodialysis units; intermediate care facilities; ambulatory health care facilities; ambulatory surgical facilities; home health agencies; hospice agencies; rehabilitation facilities; [HMOs]; and community mental health and intellectual disability facilities.”

W. Va. Code § 16-2D-4 states an exemption from the CON requirements for private office practices of licensed health professionals “provided that such private office

²³³ Richard Cauchi, *Certificate of Need: State Health Laws and Programs*, NAT'L CONFERENCE STATE LEGISLATURES (Jan. 2011), <http://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx> (last visited Dec. 30, 2014).

²³⁴ *Certificate of Need*, W. VA. HEALTH CARE AUTH., <http://www.hca.wv.gov/certificateofneed/Pages/default.aspx> (last visited Jan. 3, 2015).

practices shall not be construed to include such practices where major medical equipment otherwise subject to review...is acquired, offered or developed,” and the exemption does not apply to “the acquisition, offering or development of one or more health services, including ambulatory surgical facilities or centers, lithotripsy, [MRI], and radiation therapy.” W. Va. Code §16-2D-4 states additional exemptions for certain primary care centers and birthing centers offered for underserved communities, for the acquisition of major medical equipment solely for research purposes, as further delineated in the statute, for electronic medical record systems, and for certain non-patient care-related capital expenditures.

W. Va. Code § 16-2D-6 provides the following CON review criteria: “the relationship of the health service being reviewed to the state health plan; the relationship of services reviewed to the long-range development plan of the [applicant]; the need [of the population] for the services proposed to be offered or expanded, and the extent to which all residents of the area, and in particular low income persons, racial and ethnic minorities, women, handicapped persons, other medically underserved populations, and the elderly, are likely to have access to those services; the availability of less costly or more effective alternative methods...; the immediate and long-term financial feasibility of the proposal as well as the probable impact of the proposal on costs of and charges for providing health services...; the relationship of the services proposed to the existing health care system...; [availability of necessary resources]...; [cost, methods, and probable impact of proposed construction];...clinical needs of health professional training programs in the area...; improvements or innovations in the financing and delivery of health services which foster competition...and serve to promote quality assurance and cost effectiveness...; [and] the contribution of the proposed service in meeting the

health-related needs of members of medically underserved populations which have traditionally experienced difficulties in obtaining equal access to health services...”

Research did not disclose any changes to West Virginia’s CON program in the last five years.

50. Wisconsin

Wisconsin eliminated its CON program in 2011, but research did not disclose why the state legislature made this decision.²³⁵ Prior to 2011, Wisconsin’s CON program was limited in scope, applying primarily to nursing homes and long-term care facilities.²³⁶

51. Wyoming

Wyoming abandoned its CON program in 1989, and research did not disclose any attempts to reinstate the program.²³⁷

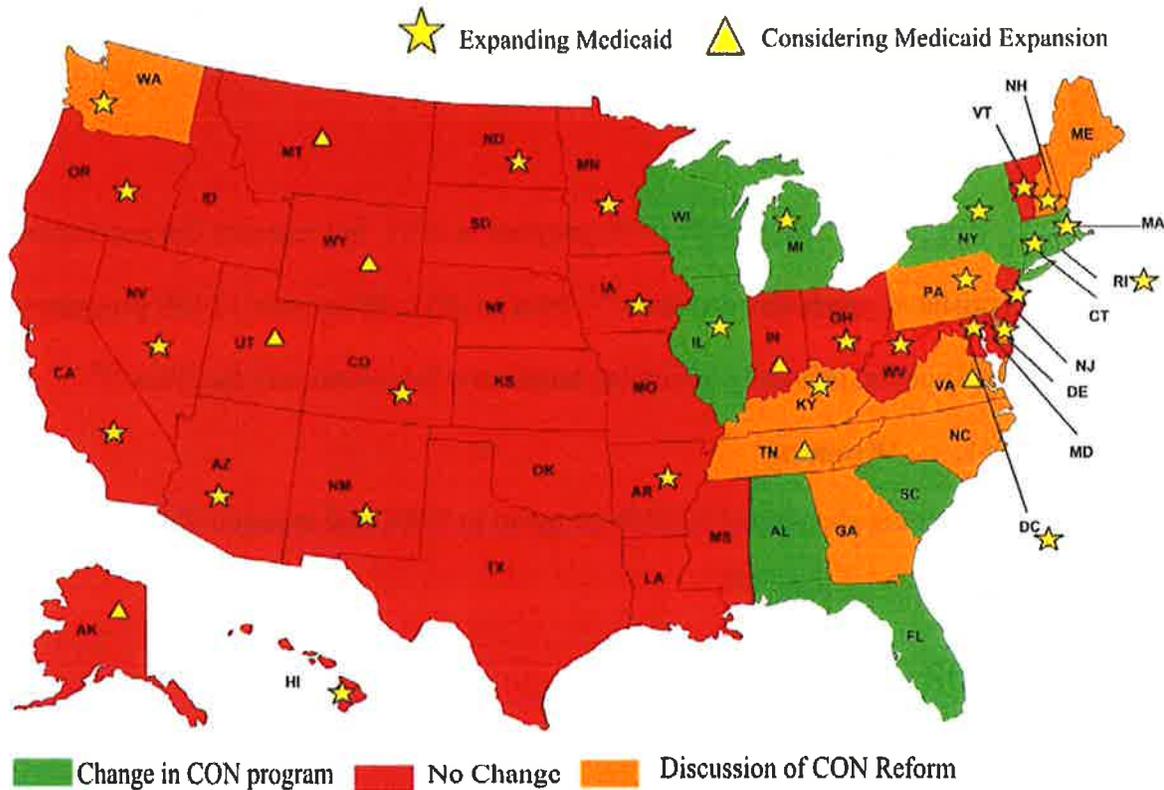
²³⁵ Richard Cauchi, *Certificate of Need: State Health Laws and Programs*, NAT’L CONFERENCE STATE LEGISLATURES (Jan. 2011), <http://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx> (last visited Dec. 30, 2014).

²³⁶ James P. Leute, *Health Care Needs Aren’t Easily Measured*, GAZETTEXTRA (Dec. 11, 2011), <http://www.gazetteextra.com/news/2011/dec/11/health-care-needs-arent-easily-measured/> (last visited Jan. 3, 2015).

²³⁷ Richard Cauchi, *Certificate of Need: State Health Laws and Programs*, NAT’L CONFERENCE STATE LEGISLATURES (Jan. 2011), <http://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx> (last visited Dec. 30, 2014).

Table 2

Change and Discussion of Change in CON Programs by State



III. Policy Analysis

A. General Arguments in Favor of CON Programs

1. **CON Programs are Necessary to Reach Efficient Outcomes Since Free Market Principles do not Apply to the Market for Health Care**

CON supporters argue that the laissez-faire policy of allowing market forces to operate unconstrained in the health care sector will consistently fail to generate socially and economically efficient outcomes because health care “market” falls short of the necessary conditions for a free market, including (1) many buyers and sellers, (2) perfect information, (3)

consumer rationality, and (4) a lack of externalities.²³⁸ As the argument proceeds, CON regulation is justified on the basis that “when the necessary conditions of the ideal free market are not met, there can be market failures some of which are not easily corrected by the market and therefore require interventions from outside the market.”²³⁹

To support the argument that health care markets with CON programs generate more efficient outcomes than less regulated health care markets, in October of 2012, the Michigan Manufacturers’ Association published a legislative primer describing a “recent cost comparison analysis for the Big 3 automakers” as follows:²⁴⁰

In 2009, the combined CT scan and MRI costs for Chrysler, Ford, and General Motors in Michigan (excluding HMO and Medicare members) totaled about \$41 million. In eight car-making states with without Certificate of Need, the cost of those same CT and MRI scans would have been \$18 million more. The cost per covered life for CT scans was 67% higher in states without Certificate of Need, due to higher utilization and cost per scan; the cost per covered life for MRI was 20% higher in non-CON states.

However, the Antitrust Division of the DOJ does not find this “health care is different” argument to be particularly compelling, noting, “similar arguments made by engineers and lawyers that competition fundamentally does not work and, is in fact harmful to public policy goals, have been rejected by the courts.”²⁴¹ The Antitrust Division rather maintains, “market forces improve the quality and lower the costs of health care services.”²⁴²

²³⁸ See Ari Mwachofi & Affaf F. Al-Assaf, *Health Care Market Deviations from the Ideal Market*, 11 SULTAN QABOOS UNIV. MED. J. 328-337 (2011), available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3210041/>.

²³⁹ *Id.*

²⁴⁰ *Certificate of Need: Michigan’s Health Care Blueprint Balances Cost, Quality, and Access*, MICH. MFR. ASS’N 3 (Oct. 2012), available at https://mimfg.org/Portals/0/Documents/GA/hr_conprimertimeless032613.pdf (last visited Dec. 30, 2014).

²⁴¹ Joseph Miller, *Competition in Health care and Certificates of Need: Statement of the Antitrust Division, US Department of Justice Before the Florida Senate Committee on Health and Human Services Appropriations*,

2. CON Programs are Necessary to Prevent Excessive Health Care Duplication and Spending through Supply-Induced Demand

Closely related to the first argument, another argument in support of CON regulation is that without CON programs to constrain the supply of health care services, health care providers would offer more health care services, establish more facilities, and acquire more expensive medical equipment than would be socially and economically efficient, leading providers with excess capacity to encourage patients to receive, and insurers to cover, unnecessary care. Under this theory, providers “have a strong influence over demand, by virtue of ordering the services that their patients consume,” and patients “generally lack the expertise or the opportunity to become prudent consumers of health care services.”²⁴³

Ohio largely abandoned its CON program, except for long-term care facilities, in 1998, and a 2012 study found the following:²⁴⁴

Ohio experienced an explosion of new ambulatory surgery centers and imaging centers immediately after the CON requirements for these services were eliminated. After removing most CON coverage in Ohio, the state has seen construction of 150 additional surgery centers and 300 additional diagnostic imaging centers.

A 2011 study on the opening of 301 new cardiac surgery programs between 1993 and 2004 found that “new programs were much more likely to open in states that did not require them to [obtain] a certificate-of-need,” with 42% of the cardiac surgery programs opening in

U.S. DEP’T JUSTICE ANTITRUST DIV. (Mar. 25, 2008), *available at* <http://www.justice.gov/atr/public/comments/233821.htm>.

²⁴² *Id.*

²⁴³ *Report of the Public Health and Planning Council on Redesigning Certificate of Need and Health Planning*, PUB. HEALTH & PLANNING COUNCIL 29 (Dec. 6, 2012), *available at* https://www.health.ny.gov/facilities/public_health_and_health_planning_council/docs/con_redesign_report.pdf.

²⁴⁴ *Florida’s Health Care Certificate of Need*, HEALTH FOUNDATION S. FLA 10 (Jan. 2014), *available at* http://hfsf.org/certificate_of_need.pdf.

“communities that already had access to cardiac surgery.”²⁴⁵ The researchers found that “new specialty programs opened in an especially inefficient pattern,” with all of these programs opening “within twenty miles of an existing program, and 80%” opening “within five miles of an existing program,” and that “these new specialty programs opened only in states that did not require a certificate of need.”²⁴⁶ Even though the overall rates for cardiac surgery did not increase in response to the increased supply, researchers were concerned that “the rates of associated procedures such as angioplasties and stents have increased dramatically” and that “increasing the number of hospitals that perform cardiac surgery when the demand for such surgeries is decreasing results in a higher proportion of procedures being done in hospitals where they are seldom performed, potentially adversely affecting the outcomes.”²⁴⁷ The researchers concluded, “certificate of need requirements may help avoid unnecessary duplication of services by preventing new programs opening in close proximity to existing ones,”²⁴⁸ stating the following:²⁴⁹

Flawed though it may be, the certificate-of-need process is one way for society to avoid spending money to needlessly duplicate a service that already exists, in some cases within the same ZIP code. If the nation is serious about restraining the rate of growth of health spending, such programs may need to be reinvigorated or reinstated in states that have dismantled them.

²⁴⁵ Frances Leslie Lucas, Andrea Siewars, David C. Goodman, Dongmei Want, & David E. Wennberg, *New Cardiac Surgery Programs Established from 1993 to 2004 Led to Little Increased Access, Substantial Duplication of Services*, 30 HEALTH AFFAIRS 8, 1569 (2011).

²⁴⁶ *Id.*

²⁴⁷ *Id.* at 1572.

²⁴⁸ *Id.* at 1569.

²⁴⁹ *Id.* at 1573.

Research also indicated that, “following repeal of Texas’ CON law, the state saw a surge of new ‘boutique’ and physician-owned hospitals that spawned a dramatic rise in costs.”²⁵⁰

3. Without CON Programs, Hospitals would Cherry-pick Profitable Patients and Render Safety Net Providers Unable to Cover their Costs for Uncompensated Care

The last, and likely most compelling, argument for CON supporters is that safety net providers need the protection of CON programs to survive. The argument is that without CON programs to restrict the supply of competing health care services in a given region, safety net providers would be left without enough income from commercially insured and other paying patients to cross-subsidize the expenses of providing uncompensated care.

The Kansas Department of Health and Environment’s Center for Health and Environmental Statistics issued a report in February of 2004, stating the following:²⁵¹

The Kansas Health Institute, in an Issue Brief called “The Growth of Specialty Hospitals in Kansas: What Effect Do they Have on Community Health Services,” reviews the impact of this new kind of health care facility that provides services for a particular specialty, like cardiology or orthopedics. The institute reports that the [concentration of] nine specialty hospitals in five Kansas communities is more than one would expect based on the nationwide total. Rapid growth of these facilities is fueled by their profitability and the ease of establishing new hospitals in Kansas. KHI concludes that competition from specialty hospitals threatens the revenue base that general hospitals have traditionally used to subsidize unprofitable community health services such as uncompensated care.

The growth of specialty hospitals may present some policy issues for the state. Kansas will have to weigh the desire for innovation and market-based solutions against the threat that specialty

²⁵⁰ *Florida’s Health Care Certificate of Need*, HEALTH FOUNDATION S. FLA 10 (Jan. 2014), available at http://hfsf.org/certificate_of_need.pdf.

²⁵¹ *Kansas Health Statistics Report*, 20 KAN. DEP’T & ENV’T—CENT. FOR HEALTH & ENVYL. STUDIES 4 (Feb. 2004), available at <http://www.kdheks.gov/phi/khsnews/khs20.pdf> (last visited Dec. 30, 2014).

hospitals pose to community health services at general hospitals. The Institute notes that avoiding the trade-off may require a more explicit source of funding for such services.

Nationally, about 100 specialty hospitals existed as of December 2003, mostly in states like Kansas that have no Certificate of Need regulations.

Between 1996 and 2003, New Jersey used CON regulations to “provide hospitals with progressively stronger incentives to reduce [racial disparities] in access to coronary angiography.”²⁵² “Under these reforms New Jersey doubled the number of angiography access points, mandated that the new facilities create outreach plans, and linked licensure for other profitable cardiac services to a successful record of improving access,” and there were “increases in service to African American patients following reform.”²⁵³ Even though “the newly licensed facilities contributed relatively little to reducing disparities,” researchers hypothesized that “added hospital competition contributed to the reduction in disparities.”²⁵⁴ While New Jersey’s experience may indicate that CON programs can be deployed to increase access to medical care for medically underserved groups, in this instance, the increased access emerged as a result of increased competition, not by protecting the market share of existing providers, which is the typical role of CON programs.

B. General Arguments Opposing CON Programs

1. **Medicare has Shifted from a Cost-Based to a Fixed Reimbursement Structure, Obviating the Initial Policy Justification for CON Programs**

When CON laws were originally enacted, “the federal government and private insurance reimbursed health care charges predominantly on a ‘cost-plus’ basis, which provided

²⁵² Joel C. Cantor, Derek DeLia, Amy Tidemann, Ava Stanley, & Karl Kronebusch, *Reducing Racial Disparities in Coronary Angiography*, 28 HEALTH AFFAIRS 5, 1522 (2009).

²⁵³ *Id.* at 1521-22.

²⁵⁴ *Id.* at 1521.

incentives for over-investment.”²⁵⁵ “There was concern that, because patients are usually not price-sensitive, providers engaged in a ‘medical arms race’ by unnecessarily expanding their services to offer the perceived highest quality services.”²⁵⁶ As the Antitrust Division of the DOJ observed in 2008, “the reimbursement methodologies that in theory may have justified the adoption of CON laws in the 1970s have changed significantly”:²⁵⁷

The federal government no longer reimburses on a cost-plus basis. In 1986, Congress repealed the National Health Planning and Resources Development Act of 1974. And, health plans and other purchasers routinely bargain with health care providers over prices. In sum, changed government regulation has eliminated the original justification for CON programs, leaving us with CON laws that now only serve to impede competition we rely on to spur innovation and contain costs.

2. There is a Lack of Empirical Evidence that CON Programs have Reduced Unnecessary Health Care Spending or Increased Access to Health Care for Medically Underserved Populations Despite Numerous Studies

The New York Public Health and Health Planning Council’s 2012 report on redesigning the state’s CON program evaluates the state of empirical evidence assessing the effectiveness of CON programs throughout the country:²⁵⁸

The evidence is inconclusive...regarding the effectiveness of CON as a mechanism for reducing the supply and associated health care spending or for consolidating value and improving quality. Given the significant variation among CON programs and health care markets, it has been difficult for researchers to control for the rigor of CON implementation and various market factors that impact

²⁵⁵ Joseph Miller, *Competition in Health care and Certificates of Need: Statement of the Antitrust Division, US Department of Justice Before the Florida Senate Committee on Health and Human Services Appropriations*, U.S. DEP’T JUSTICE ANTITRUST DIV. (Mar. 25, 2008), available at <http://www.justice.gov/atr/public/comments/233821.htm>.

²⁵⁶ *Id.*

²⁵⁷ *Id.*

²⁵⁸ *Report of the Public Health and Planning Council on Redesigning Certificate of Need and Health Planning*, PUB. HEALTH & PLANNING COUNCIL 31 (Dec. 6, 2012), available at https://www.health.ny.gov/facilities/public_health_and_health_planning_council/docs/con_redesign_report.pdf.

costs and quality. Studies evaluating the impact of CON on health care costs and spending are inconsistent.

The Antitrust Division of the DOJ has stated, “CON laws appear to have failed in their intended purpose of containing costs,” elaborating that “the empirical evidence on the economic effects of CON programs demonstrate near-universal agreement among health care economists that CON laws were unsuccessful in containing health care costs.”²⁵⁹ Further, the Antitrust Division is not persuaded by the cross-subsidization theory presented above and observes that current research reflects “competition does not undercut the ability of community hospitals to fulfill their charitable mission.”²⁶⁰

3. Directly Subsidizing Safety Net Providers for Uncompensated Care is More Effective and Less Costly than Trying to Accomplish this Goal through CON Programs

Since many CON supporters concede that the most compelling reason CON programs should continue is to protect safety net providers under the cross-subsidization theory, this argument begs the question: why not provide funding for uncompensated care directly instead of restricting competition for the entire health care market? The Antitrust Division of the DOJ articulates the point well: “To the extent that CON [programs] are used to further non-economic goals, those goals can be more efficiently achieved through other means that do not

²⁵⁹ Joseph Miller, *Competition in Health care and Certificates of Need: Statement of the Antitrust Division, US Department of Justice Before the Florida Senate Committee on Health and Human Services Appropriations*, U.S. DEP’T JUSTICE ANTITRUST DIV. (Mar. 25, 2008), available at <http://www.justice.gov/atr/public/comments/233821.htm>.

²⁶⁰ Joseph Miller, *Competition in Health care and Certificates of Need: Statement of the Antitrust Division, US Department of Justice Before the Florida Senate Committee on Health and Human Services Appropriations*, U.S. DEP’T JUSTICE ANTITRUST DIV. (Mar. 25, 2008), available at <http://www.justice.gov/atr/public/comments/233821.htm>.

impose the substantial (perhaps unintended) costs on consumers that restrictive CON laws impose.”²⁶¹

In support of this argument, CON programs may be too blunt of an instrument to effectively target unnecessary health care spending and even result in reduced access to necessary medical care. For instance, a 2012 study on prostate cancer imaging found that “regions with higher overall imaging rates tended to have not only higher rates of inappropriate imaging, but also higher rates of appropriate imaging,” and “regions with lower rates of inappropriate imaging also had lower rates of appropriate imaging,” what researchers called “the thermostat model.”²⁶² Researchers therefore warn, “simply limiting inappropriate health care use may have the unintended consequence of limiting appropriate care for patients who need it.”²⁶³

C. Themes for CON Reform in Response to the ACA

1. **Increased Consolidation of Health Care Organizations**

“The ACA has unleashed a merger frenzy, with hospitals scrambling to shore up their market positions, improve operational efficiency, and create organizations capable of managing population health.”²⁶⁴ For instance, “105 deals were reported in 2012 alone, up from

²⁶¹ Joseph Miller, *Competition in Health care and Certificates of Need: Statement of the Antitrust Division, US Department of Justice Before the Florida Senate Committee on Health and Human Services Appropriations*, U.S. DEP’T JUSTICE ANTITRUST DIV. (Mar. 25, 2008), available at <http://www.justice.gov/atr/public/comments/233821.htm>.

²⁶² Danil V. Makarov, Rani Desai, James B. Yu, Richa Sharma, Nitya Abraham, Peter C. Albertsen, Harlan M. Krumholz, David F. Penson, & Cary P. Gross, *Appropriate and Inappropriate Imaging Rates for Prostate Cancer Go Hand In Hand By Region, As If Set By Thermostat*, 31 HEALTH AFFAIRS 4, 730 (2012).

²⁶³ *Id.* at 737.

²⁶⁴ Leemore Dafny, *Hospital Industry Consolidation—Still More to Come?*, 370 NEW ENGLAND JOURNAL MED. 198 (2014), available at <http://www.nejm.org/doi/full/10.1056/NEJMp1313948>.

50 to 60 annually in the pre-ACA, pre-recession years of 2005-2007.”²⁶⁵ The organization of health care providers into ACOs, encouraged by federal health care reform, is “expected to accelerate provider consolidation in local markets.”²⁶⁶

The Delaware Health Resources Board has observed that the ACA will shift health care provider practices in a number of ways as providers work “to create linkages across the care continuum,” placing an “even greater emphasis on efficiency” with payment models that “incentivize provider consolidation and quality of care.”²⁶⁷ According to the Board, on a national scale, “CON programs will be an important piece of the puzzle” since they “have the potential to moderate the speed with which ACA incentives roll out across the U.S.”²⁶⁸ But the role a state’s CON program will have in shaping future health care reform will depend on the unique features of that state’s CON program. The Board provides the following example: “In instances where consolidation involves existing facilities, [the] CON process may not be involved. But, for states with CON regulations involving capital expenditures, this will not be the case.”²⁶⁹

In 2013, Alabama’s CON law was amended to “facilitate change of ownership transactions among health care providers,” clarifying that “transactions involving the sale, lease,

²⁶⁵ *Id.*

²⁶⁶ James C. Robinson, *More Evidence of the Association Between Hospital Market Concentration and Higher Prices and Profits*, NAT’L INST. FOR HEALTH CARE MGMT. (Nov. 2011), available at <http://www.nihcm.org/images/stories/NIHCM-EV-Robinson-Final.pdf>.

²⁶⁷ *Certificate of Need (CON) Programs: Stakeholder Views & Outcomes Research*, HEALTH RES. BD. (Oct. 24, 2013), available at <http://dhss.delaware.gov/dhss/dhcc/hrb/files/conprograms.pdf>.

²⁶⁸ *Id.*

²⁶⁹ *Id.*

or change of ownership of CON-owning entities are not subject to CON review.”²⁷⁰ Connecticut initially decided to exempt ACA-related consolidation efforts from its CON process through a less direct but arguably more comprehensive approach. Connecticut’s CON Reform Law of 2010 includes “the elimination of all capital expenditure thresholds,” the “removal of the ‘additional function or service’ requirement, and the elimination of CONs for termination of services,”²⁷¹ and these three reforms were projected to “reduce the number of applications by at least 50%.”²⁷² However, Connecticut ultimately stepped back from its laissez-faire approach with regard to ACA-related consolidations in 2014, when the state legislature adopted Act 14-168. Act 14-168 mandates that hospitals and hospital systems disclose “activities of group practices owned or affiliated with the hospital or hospital system” and requires physician groups with 30 or more physicians to provide annual written reports to OHCA that identify “the physicians, specialties, and service areas of the group practice” and “adds a requirement for [CON] approval for the transfer of ownership of a group practice to an entity other than a physician or group of physicians.”²⁷³ Section 7 of Act 14-168 “requires OHCA to consider whether a [CON] applicant has satisfactorily demonstrated that its proposal will not negatively impact the diversity of health care providers and patient choice in the geographic region of the

²⁷⁰ Quoted from Kristen Larremore, *CON Amendments Clarify Review Required for Change of Ownership Transactions*, BIRMINGHAM MED. NEWS, <http://www.birminghammedicalnews.com/news.php?viewStory=1855> (last visited Dec. 29, 2014); see ALA. CODE § 22-21-270 (2013).

²⁷¹ *Certificate of Need—A Policy Shift in Connecticut*, OFFICE HEALTH CARE ACCESS (May 2010), available at <http://cdm15019.contentdm.oclc.org/cdm/ref/collection/p128501coll2/id/148990>; but see Public Act 11-183 (effective in 2011), which reinstates the CON requirement for termination of services under certain circumstances, likely in response to concerns about needed services being cut off for vulnerable populations. Public Act 11-183 requires “a certificate of need for the termination of inpatient or outpatient services by a hospital, including, but not limited to, the termination of inpatient and outpatient mental health and substance abuse services.”

²⁷² *Id.*

²⁷³ *Public & Special Acts*, DEP’T PUB. HEALTH, <http://www.ct.gov/dph/cwp/view.asp?a=3902&q=277034&dphNav=|52607|> (last visited Dec. 30, 2014).

proposal and whether the applicant has satisfactorily demonstrated that any consolidation resulting from its proposal will not adversely affect health care costs or accessibility to care.”²⁷⁴

Increased consolidation in the health care industry could also diminish the long-run importance of CON regulation for the establishment of new health care providers. For instance, the Health Foundation of South Florida’s “limited speculation about a potential relationship between the ACA and the Florida CON program” predicts that “to the extent the ACA (by for example, incentivizing the creation of Accountable Care Organizations) encourages mergers, acquisitions, and other forms of consolidation within the health care industry in an effort to deliver care more efficiently, there are likely to be fewer CON applications for new hospitals, nursing homes, and hospices.”²⁷⁵

Some states have expressed concerns about the potential anticompetitive effects of increased consolidation and may want to deploy their CON programs to mitigate such risks. For instance, the New York Public Health and Health Planning Council’s 2012 report describes the potential effects of unconstrained consolidation.²⁷⁶

While the new models of care and payment show great promise, they also raise concerns. Large integrated systems and physician practices that accept risk-based or value-based payments have the potential to improve outcomes while reducing overall costs; but they may also exercise market power to drive out competition and drive up prices.

²⁷⁴ *Id.*

²⁷⁵ *Florida’s Health Care Certificate of Need*, HEALTH FOUNDATION S. FLA 11 (Jan. 2014), available at http://hfsf.org/certificate_of_need.pdf.

²⁷⁶ *Report of the Public Health and Planning Council on Redesigning Certificate of Need and Health Planning*, PUB. HEALTH & PLANNING COUNCIL 8 (Dec. 6, 2012), available at https://www.health.ny.gov/facilities/public_health_and_health_planning_council/docs/con_redesign_report.pdf (recommending increased CON regulation of private physician offices, discussed below).

After weighing the competitive risks against the opportunities created by new models of care, the New York Public Health and Health Planning Council ultimately recommended changes “to New York’s CON and licensing process to support successful integrated systems of care and new care and payment models,” including the use of ACO certification “in lieu of CON for certain facilities.”²⁷⁷ However, in 2013, Washington’s governor, Jay Inslee, “directed the Department of Health to update the [CON process] for hospital mergers and affiliations” to require CON review for a broader class of transactions, and the department expanded “the rules [to require] review [for] ‘change[s] in control’ in ‘any part’ of a hospital.”²⁷⁸ The governor explained, “considering the importance of health care reform, CON reforms are necessary because some affiliations, corporate restructuring, mergers, and other arrangements would result in outcomes similar to the traditional methods of sales, purchasing, and leasing of hospitals.”²⁷⁹ A superior court judge later invalidated the change, ruling that “the Department of Health had overstepped its authority in expanding the requirement to obtain a certificate of need from the state for such a broad range of business partnerships.”²⁸⁰

2. A Move Toward Outpatient Care

Under federal health care reform, “the goal will be to manage a population’s health across the care continuum, keeping patients healthy through preventative and primary care

²⁷⁷ *Id.*

²⁷⁸ Helen Adamopoulos, *Washington State Hospital Association Sues State over New Certificate of Need Policy*, BECKER’S HOSP. REVIEW (Feb. 14, 2014), <http://www.beckershospitalreview.com/hospital-transactions-and-valuation/washington-state-hospital-association-sues-state-over-new-certificate-of-need-policy.html> (last visited Jan. 3, 2015).

²⁷⁹ *Id.*

²⁸⁰ Lena Kauffman, *Court Finds Washington State Exceeded its Authority in Requiring a Certificate of Need for All Hospital Affiliations*, HEALTH CXO (Jun. 13, 2014), <http://www.healthcxo.com/topics/policy/court-finds-washington-state-exceeded-its-authority-requiring-certificate-need-all-hospital-affiliations> (last visited Jan. 3, 2015).

services, and out of acute care facilities whenever possible. By eliminating waste and redirecting patients to ambulatory centers, physician offices, clinics, and online and/or telephonic interactions, less work will be done in the hospital.”²⁸¹ “Inpatient stays are dropping while outpatient visits are rising, as the result of new technologies, reimbursement rules, and payment models. Total inpatient admissions for U.S. hospitals fell from 35.76 million in 2008 to 34.40 million in 2012. Meanwhile, total outpatient visits rose from 624 million to 675 million over the same period, according to the American Hospital Association.”²⁸² A national study showed a significant decline of “inpatient use rates” between 2006 and 2011, and this decline cannot be attributed to the national recession since it was true for all age groups, including elderly patients covered by Medicare.²⁸³

One of Kentucky’s “core principles” for modernization of its CON program is “supporting the evolution of care delivery” since “the trend is decisively away from a high-overhead acute/inpatient model to an outpatient centric model.”²⁸⁴ In its October 2014 special memorandum seeking stakeholder input, the Kentucky Cabinet for Health and Family Services states that to support this development, “the CON program will seek to give health care facilities

²⁸¹ Mark Grube, Kenneth Kaufman, & Robert York, *Decline in Utilization Rates Signals a Change in the Inpatient Business Model*, HEALTH AFFAIRS BLOG, <http://healthaffairs.org/blog/2013/03/08/decline-in-utilization-rates-signals-a-change-in-the-inpatient-business-model/> (last visited Jan. 19, 2015).

²⁸² Rebecca Vesely, *The Great Migration*, HOSPITALS & HEALTH NETWORKS (Mar. 11, 2014), http://www.hhnmag.com/display/HHN-news-article.dhtml?dcrPath=/templatedata/HF_Common/NewsArticle/data/HHN/Magazine/2014/Mar/cover-story-great-migration (last visited Jan. 19, 2015).

²⁸³ Mark Grube, Kenneth Kaufman, & Robert York, *Decline in Utilization Rates Signals a Change in the Inpatient Business Model*, HEALTH AFFAIRS BLOG, <http://healthaffairs.org/blog/2013/03/08/decline-in-utilization-rates-signals-a-change-in-the-inpatient-business-model/> (last visited Jan. 19, 2015).

²⁸⁴ *Special Memorandum: Certificate of Need Modernization: Core Principles: Request for Stakeholder Input*, CABINET FOR HEALTH & FAMILY SERV. OFFICE HEALTH POLICY (Oct. 8, 2014), available at <http://chfs.ky.gov/ohp/con/> (last visited Dec. 30, 2014).

the ability to respond to market trends in a timely fashion, enabling the continued service of local communities in a changing health care environment.”²⁸⁵

The New York Public Health and Health Planning Council’s 2012 report similarly recommends “reconsider[ing] the utility of CON for hospital beds in the next three to five years...given the growth of payment incentives that discourage admissions.”²⁸⁶

In its 2014 analysis of Florida’s CON program, the Health Foundation of South Florida posits that since “the ACA is likely to motivate or facilitate health provider behavior that encourages the delivery of more patient care on an outpatient basis, rather than within hospitals and nursing homes currently regulated by the Florida CON program,” CON regulation will likely become less of a central factor in constraining the supply of Florida’s health care services.²⁸⁷

3. Access to Care and Protection for Safety Net Providers

While federal health care reform presents opportunities that may benefit safety net providers, including “new funding for health centers; support for coordinated, patient-centered care; and expansion of the primary care workforce,” “declining payments to safety net hospitals, existing financial hardships, and shifts in the health care marketplace may intensify competition, thwart the ability to innovate, and endanger the financial viability of safety net providers.”²⁸⁸

²⁸⁵ *Id.*

²⁸⁶ *Report of the Public Health and Planning Council on Redesigning Certificate of Need and Health Planning*, PUB. HEALTH & PLANNING COUNCIL 9 (Dec. 6, 2012), available at https://www.health.ny.gov/facilities/public_health_and_health_planning_council/docs/con_redesign_report.pdf.

²⁸⁷ *Florida’s Health Care Certificate of Need*, HEALTH FOUNDATION S. FLA 11 (Jan. 2014), available at http://hfsf.org/certificate_of_need.pdf.

²⁸⁸ Dennis P. Andrulis & Nadia J. Siddiqui, *Health Reform Holds Both Risks and Rewards for Safety net Providers and Racially and Ethnically Diverse Patients*, 30 HEALTH AFFAIRS 10, 1830-1835 (2011).

For 2013, the annual cost of uncompensated care was estimated at \$84.9 billion, 65% of which was covered by federal government DSH, UPL, and IME payments.²⁸⁹ Combined, “Medicare and Medicaid payments accounted for an estimated 40.9% of uncompensated care funding in 2013.”²⁹⁰ The ACA substantially reduces Medicare and Medicaid DSH payments. For instance, by 2019, it is projected that Medicaid DSH payments will be cut about 50% over baseline projections, and Medicare DSH payments are projected to decline by 28%.²⁹¹ These DSH cuts were initiated under the assumption that increased federal funds through Medicaid coverage expansions would fill the gap, but under the 2012 Supreme Court decision, making Medicaid expansion voluntary, “hospitals [in states that do not expand their Medicaid programs] will likely have a higher level of uncompensated care than had been projected after enactment of health care reform.”²⁹²

In addition to facing cuts in DSH payments, a 2014 study comparing safety net to non-safety net hospitals in California showed that safety net hospitals were more likely to be penalized under the ACA’s value-based purchasing program, the Hospital Readmissions Reduction Program, and the electronic health record meaningful use program, even though the “safety net institutions had lower thirty-day risk-adjusted mortality rates” for acute myocardial

²⁸⁹ Teresa A. Coughlin, John Holahan, Kyle Caswell, & Megan McGrath, *An Estimated \$84.9 Billion in Uncompensated Care Was Provided in 2013; ACA Payment Cuts Could Challenge Providers*, 33 HEALTH AFFAIRS 5, 807-813 (2014).

²⁹⁰ *Id.*

²⁹¹ *Id.*

²⁹² *Id.*

infarction, heart failure, and pneumonia “and marginally lower adjusted Medicare costs” than non-safety net hospitals.²⁹³

According to the Director of Operations of the Connecticut Office of Health Care Access (OHCA), one of the primary goals of Connecticut’s CON Reform Law of 2010 was to “focus CON oversight to preserve access to ‘safety net’ services and potential areas of over-utilization.”²⁹⁴ In more recent years, the Connecticut legislature has imposed some additional requirements on potential CON applicants, many of which protect Medicaid recipients and medically underserved populations. For instance, Section 144 of Public Act 13-234 (effective October 1, 2013) “modifies the criteria to be considered by OHCA when reviewing [CON] applications” to include “a review of the provision of or any change in the access to services for Medicaid recipients and indigent persons and the impact upon the cost-effectiveness of providing access to services provided under the Medicaid program.”²⁹⁵ Section 144 also requires “OHCA to consider whether a [CON] applicant, who has failed to provide or reduced access to services by Medicaid recipients or indigent persons, has demonstrated good cause for doing so, which shall not be demonstrated solely on the basis of differences in reimbursement rates between Medicaid and other health care payers.”²⁹⁶ Even though Connecticut’s CON Reform Law of 2010 eliminated the CON requirement for termination of services, Public Act 11-183 (effective

²⁹³ Matlin Gilman, E. Kathleen Adams, Jason M. Hockenberry, Ira B. Wilson, Arnold S. Milstein, & Edmund R. Becker, *California Safety net Hospitals Likely to be Penalized by ACA Value, Readmission, and Meaningful-Use Programs*, 33 HEALTH AFFAIRS 8, 1314-1321 (2014).

²⁹⁴ Kimberly Martone, *Connecticut’s Certificate of Need Program*, OFFICE HEALTH CARE ACCESS, available at http://www.michigan.gov/documents/mdch/Sessions_F_R_-_Other_States_CON_Models_Connecticut_334499_7.pdf (last visited Dec. 30, 2014).

²⁹⁵ *Public & Special Acts*, DEP’T PUB. HEALTH, <http://www.ct.gov/dph/cwp/view.asp?a=3902&q=277034&dphNav=|52607|> (last visited Dec. 30, 2014).

²⁹⁶ *Id.*

in 2011) reinstated the CON requirement for termination of services under certain circumstances, likely in response to concerns about needed services being cut off for medically underserved populations, and requires “a [CON] for the termination of inpatient or outpatient services by a hospital, including, but not limited to, the termination of inpatient and outpatient mental health and substance abuse services.”²⁹⁷

Illinois’ Senate Bill 1905, enacted in 2009, “adds a ‘Safety Net Impact Statement’ to the general review criteria for substantive projects.”²⁹⁸ Under 20 Ill. Comp. Stat. § 3960, the Safety Net Impact Statement must describe: “the project’s material impact, if any, on essential safety net services...; the project’s impact on the ability of another provider or health care system to cross-subsidize safety net services...; [and] how the discontinuation of a facility or service might impact the remaining safety net providers in a given community.”

One of Kentucky’s CON modernization principles is “improving access to care.”²⁹⁹ To support this value, the Kentucky Cabinet for Health and Family Services emphasizes that “for a number of reasons, Medicaid members have, on average, a more challenging path toward access to care” and states that Kentucky’s “CON program will seek to incorporate strategies that will incentivize greater access to care for Medicaid members, the newly insured, and the remaining uninsured.”³⁰⁰

²⁹⁷ *Id.*

²⁹⁸ *Illinois CON Reform Bill Heading to Governor's Desk*, MCGUIREWOODS, (June 10, 2009), <http://www.mcguirewoods.com/Client-Resources/Alerts/2009/6/IllinoisCONReformBillHeadingtoGovernorsDesk.aspx>; 20 Ill. Comp. Stat. § 3960.

²⁹⁹ *Special Memorandum: Certificate of Need Modernization: Core Principles: Request for Stakeholder Input*, CABINET FOR HEALTH & FAMILY SERV. OFFICE HEALTH POLICY (Oct. 8, 2014), available at <http://chfs.ky.gov/ohp/con/> (last visited Dec. 30, 2014).

³⁰⁰ *Id.*

The New York Public Health and Health Planning Council’s 2012 report additionally expresses a concern that “essential and safety net providers may be destabilized by the growth of physician practices and integrated systems that attract lucrative patients, but decline to serve Medicaid beneficiaries and the uninsured” and further elaborates that especially for high risk populations, “payment arrangements that transfer risk to providers may contribute to instability and diminished access to necessary services [and may]....discourage the provision of medically necessary care.”³⁰¹

The North Carolina Hospital Association has stated similar concerns about CON reform since North Carolina has not adopted Medicaid expansion, and “North Carolina hospitals are slated for \$7.8 billion in federal Medicare cuts during the next decade, more than \$5.6 billion of which is directly related to the ACA.”³⁰²

4. The Shift from Volume-Driven to Value-Driven Care and Its Impact on Provider Incentives

“New payment models are replacing fee-for-service payments with value-based and risk-based payments that reward prevention and quality.”³⁰³ Under the ACA, this change is effectuated by a “shift in measurement and payment, moving from discrete fee-for-service transactions (payment for each task or service that is done at each moment) to payment for clinically and economically relevant episodes for patients and providers, referred to as bundled

³⁰¹ *Report of the Public Health and Planning Council on Redesigning Certificate of Need and Health Planning*, PUB. HEALTH & PLANNING COUNCIL 8 (Dec. 6, 2012), available at https://www.health.ny.gov/facilities/public_health_and_health_planning_council/docs/con_redesign_report.pdf (recommending increased CON regulation of private physician offices, discussed below).

³⁰² *State Priorities: 2014 North Carolina Hospitals’ Legislative Issues*, N.C. HOSP. ASSOC., <https://www.ncha.org/advocacy/state-issues/state-priorities> (last visited Jan. 2, 2015).

³⁰³ *Report of the Public Health and Planning Council on Redesigning Certificate of Need and Health Planning*, PUB. HEALTH & PLANNING COUNCIL 17 (Dec. 6, 2012), available at https://www.health.ny.gov/facilities/public_health_and_health_planning_council/docs/con_redesign_report.pdf (recommending increased CON regulation of private physician offices, discussed below).

payments.”³⁰⁴ Additionally, there are “Medicare and Medicaid penalties for health care-acquired conditions (not limited to hospital acquired), penalties for excessive preventable Medicare readmissions, as well as a focus on value-based purchasing (i.e., payment is based on performance as determined by quality measurements).”³⁰⁵ “Providers that embrace [the] migration to value-based care will need to work aggressively to eliminate unnecessary and/or ineffective activities in order to thrive under risk contracts. This requires a fundamental change in mindset, culture, and attitude about volume and activity. It also requires providers to rethink the organization and structure of their delivery networks to avoid supporting unnecessary capacity, and to drive patients into the lowest-possible cost setting in which quality care can be delivered.”³⁰⁶

In preparation for CON Reform, the Connecticut Office of Health Care Access published an overview in May 2010, entitled *Certificate of Need—A Policy Shift in Connecticut*.³⁰⁷ In the overview, the Office of Health Care Access explains the connection between CON Reform and federal health care reforms associated with the ACA.³⁰⁸

Federal health care reform contemplates moving from a “volume-driven” system to a patient-centered system. Under current [pre-reform] law, Connecticut’s CON process requires “need” to be demonstrated for nearly all new services, sites, and equipment. The key element of demonstrating “need” is to rely on theories of

³⁰⁴ Megan Reeve, Theresa Wizemann, Bradley Eckert, & Bruce Altevogt, *The Impacts of the Affordable Care Act on Preparedness Resources and Programs: Workshop Summary*, IOM 19 (2014), available at <http://www.ncbi.nlm.nih.gov/books/NBK241392/pdf/TOC.pdf>.

³⁰⁵ *Id.*

³⁰⁶ Mark Grube, Kenneth Kaufman, & Robert York, *Decline in Utilization Rates Signals a Change in the Inpatient Business Model*, HEALTH AFFAIRS BLOG, <http://healthaffairs.org/blog/2013/03/08/decline-in-utilization-rates-signals-a-change-in-the-inpatient-business-model/> (last visited Jan. 19, 2015).

³⁰⁷ *Certificate of Need—A Policy Shift in Connecticut*, OFFICE HEALTH CARE ACCESS (May 2010), available at <http://cdm15019.contentdm.oclc.org/cdm/ref/collection/p128501coll2/id/148990>.

³⁰⁸ Block quote from *id.* at 1.

supply and demand and present to the state projections of volumes that will result in a feasible project plan. As reimbursement and patients' insurance coverage begin to shift in response to health care reform efforts, the CON process becomes misaligned as it relies on volume-driven behavior and not value-driven outcomes.

In support of its CON modernization principle of “improving value of care” the Kentucky Cabinet for Health and Family Services explains that “as health care transitions from a fee-for-service model to a value-based purchasing framework, payers will continue to seek evidence of value in health services.”³⁰⁹ Therefore, Kentucky’s CON program “will seek to incentivize both price transparency and demonstrable value from health professionals and facilities.”³¹⁰ However, the Cabinet acknowledges that accomplishing this goal may require “exempting services for which CON [regulation] is no longer necessary,” as an additional CON modernization principle, elaborating that the “Office of Health Policy will seek to focus on strategies to modernize Kentucky’s CON program to be more reflective of modern health care trends.”³¹¹

The New York Department of Public Health and Health Planning Council’s 2012 report recommends streamlining “the CON process by eliminating administrative steps that no longer serve their intended purpose, impede achievement of policy goals, or are not cost-effective,” and the Council offers the following explanation of how the shift to value-driven care shaped its recommendations:³¹²

³⁰⁹ *Special Memorandum: Certificate of Need Modernization: Core Principles: Request for Stakeholder Input*, CABINET FOR HEALTH & FAMILY SERV. OFFICE HEALTH POLICY (Oct. 8, 2014), available at <http://chfs.ky.gov/ohp/con/> (last visited Dec. 30, 2014).

³¹⁰ *Id.*

³¹¹ *Id.*

³¹² *Report of the Public Health and Planning Council on Redesigning Certificate of Need and Health Planning*, PUB. HEALTH & PLANNING COUNCIL 7-8 , 33 (Dec. 6, 2012), available at

CON's role in controlling costs through curbs on supply is predicated in large part on the existence of a payment system that rewards the delivery of greater quantities of care and more complex, capital-intensive care. In the context of payment mechanisms that incentivize health and discourage preventable utilization, the utility of CON as a mechanism to reduce health care spending is questionable. However, value-based and risk-based payments are just beginning to take hold. Even the Medicare ACOs are receiving fee-for-service payments, albeit together with shared savings. Hospitals, in particular are struggling to manage through this transition period. Many are still trying to maximize their inpatient costs while minimizing readmission penalties. Hospital-sponsored ACOs are still vying for high-end services like cardiac surgery. Thus, in the near term, New York's health care markets remain flawed in ways that justify some controls on supply.

In the longer term, several factors are expected to improve efficiencies in health care markets and arguably lessen the need for CON. The transition away from fee-for-service to value-based and risk-based payments should discourage unnecessary capital investment and supply-driven utilization.

5. **Comprehensive Care**

Federal health care reform places a great emphasis on comprehensive care, and strengthening primary care is thought to improve “care coordination, making it easier for clinicians to work together, and helping clinicians spend more time with their patients.”³¹³ In 2011, CMS “launched the Comprehensive Primary Care Initiative (CPCI), a cooperative, multi-payer effort designed to help primary care practices deliver higher quality, better coordinated, and more patient-centered care.”³¹⁴ To incentivize comprehensive care, the ACA additionally

https://www.health.ny.gov/facilities/public_health_and_health_planning_council/docs/con_redesign_report.pdf (recommending increased CON regulation of private physician offices, discussed below).

³¹³ *Fact Sheet: Comprehensive Primary Care Initiative*, CTR. FOR MEDICARE & MEDICAID INNOVATION (Aug. 22, 2012), available at <http://innovation.cms.gov/Files/fact-sheet/Comprehensive-Primary-Care-Initiative-Fact-Sheet.pdf>.

³¹⁴ *Comprehensive Primary Care Initiative (CPCI) Overview*, AM. ACAD. FAMILY PHYSICIANS, <http://www.aafp.org/advocacy/informed/payment/pcincentive.html> (last visited Jan. 19, 2015).

provides funding for patient centered medical homes, which are “designed to improve quality of care through team-based coordination of care, treating the many needs of the patient at once, increasing access to care, and empowering the patient to be partner in their own care.”³¹⁵ The ACA also incentivizes the creation of Medicare-certified ACOs through a shared-savings program. ACOs are “groups of doctors, hospitals, and other health care providers, who come together voluntarily to give coordinated high quality care to Medicare patients they serve.”³¹⁶

One of Kentucky’s CON modernization principles is “incentivizing development of a full continuum of care,” elaborating that “better care, increased value, and improved population health depend on an integrated continuum of care in which providers communicate with each other and ensure that patients receive timely, coordinated care in an appropriate setting.”³¹⁷ In acknowledgment that “payment structures are evolving to reflect these goals,” the Cabinet states that Kentucky’s CON program should “work to promote and support providers and facilities that seek to develop a robust continuum of care alone or in partnership with others.”³¹⁸

³¹⁵ *The Affordable Care Act Supports Patient-Centered Medical Homes in Health Centers*, U.S. DEP’T HEALTH & HUMAN SERV. (Aug. 26, 2014), <http://www.hhs.gov/news/press/2014pres/08/20140826a.html> (last visited Jan. 19, 2015).

³¹⁶ *Accountable Care Organizations (ACOs): General Information*, CTR. FOR MEDICARE & MEDICAID SERV., <http://innovation.cms.gov/initiatives/aco/> (last visited Jan. 19, 2015).

³¹⁷ *Special Memorandum: Certificate of Need Modernization: Core Principles: Request for Stakeholder Input*, CABINET FOR HEALTH & FAMILY SERV. OFFICE HEALTH POLICY (Oct. 8, 2014), available at <http://chfs.ky.gov/ohp/con/> (last visited Dec. 30, 2014).

³¹⁸ *Id.*

The Health Foundation of South Florida's 2014 report highlights that some states' CON programs may lack the flexibility to accommodate the establishment of new and innovative comprehensive care programs.³¹⁹

The ACA may motivate hospitals to attempt to build new comprehensive rehabilitation beds in an effort to control the costs of whole episodes of care. These beds would serve many of the same patients who otherwise would be discharged from hospitals to nursing homes. It is unlikely that CON applications for new comprehensive rehabilitation beds would be granted if AHCA determines that sufficient nursing home beds already exist.

To support the move toward comprehensive care, in its 2012 report, the New York Public Health and Health Planning Council recommends facilitating increased care coordination and expanded access to primary care and hospice services. The Council recommends eliminating CON for certain primary care facilities since "primary care is not supply-sensitive or volume-sensitive or capital-intensive."³²⁰

6. Electronic Medical Records and Information Sharing

Under the reforms initiated by HITECH Act and the ACA, "the collection, analysis, use, and sharing of health data" have become "a driving force in the transformation of U.S. health care."³²¹ "About 80% of hospitals and more than half of the physician practices in the country are now using health IT and EHRs."³²² For instance, the ACA funds Health Center

³¹⁹ *Florida's Health Care Certificate of Need*, HEALTH FOUNDATION S. FLA 11 (Jan. 2014), available at http://hfsf.org/certificate_of_need.pdf.

³²⁰ *Report of the Public Health and Planning Council on Redesigning Certificate of Need and Health Planning*, PUB. HEALTH & PLANNING COUNCIL 9-10, 34 (Dec. 6, 2012), available at https://www.health.ny.gov/facilities/public_health_and_health_planning_council/docs/con_redesign_report.pdf (recommending increased CON regulation of private physician offices, discussed below).

³²¹ Megan Reeve, Theresa Wizemann, Bradley Eckert, & Bruce Altevogt, *The Impacts of the Affordable Care Act on Preparedness Resources and Programs: Workshop Summary*, IOM 51 (2014), available at <http://www.ncbi.nlm.nih.gov/books/NBK241392/pdf/TOC.pdf>.

³²² *Id.* at 51-53.

Network grants that “support the adoption and meaningful use of certified electronic health record technology and technology-enabled quality improvement strategies in health centers. The networks, comprised of at least 10 collaborating health center organizations, are designed to promote enhanced sharing of information and expertise, to address key operational and clinical needs through greater program integration.”³²³

Investing in electronic medical records and other information-sharing infrastructure could potentially trigger CON requirements in states that regulate capital expenditures as a covered activity. However, according to the fifty-state survey above, many states either exempt or exclude electronic medical records from CON coverage. Even where activities related to electronic medical records require a CON under a literal reading of statutory provisions and regulations, research did not disclose any attempts to enforce such provisions.

One of Kentucky’s CON modernization core principles is “promoting adoption of efficient technology,” and in support of this principle, the Kentucky Cabinet for Health and Family Services explains that “increased adoption of technologies such as electronic medical records, participation in information sharing platforms such as the Kentucky Health Information Exchange, and participation in large-scale data projects such as an All Payer Claims Database are critical elements of a modernized, higher quality and more efficient health system.”³²⁴

7. Quality and Population Health

Under the ACA and related health care reform efforts, there has been an increased focus on considerations of quality and population health. For instance, under the Hospital Value-

³²³ *Affordable Care Act Helps Expand the Use of Health Information Technology*, HEALTH RES. & SERV. ADMIN. (Dec. 20, 2012), <http://www.hrsa.gov/about/news/pressreleases/121220healthcenternetworks.html> (last visited Feb. 2, 2015).

³²⁴ *Special Memorandum: Certificate of Need Modernization: Core Principles: Request for Stakeholder Input*, CABINET FOR HEALTH & FAMILY SERV. OFFICE HEALTH POLICY (Oct. 8, 2014), available at <http://chfs.ky.gov/ohp/con/> (last visited Dec. 30, 2014).

Based Purchasing Program, “Medicare will reward hospitals that provide higher quality or better patient outcomes” through making “value-based incentive payments to acute care hospitals, based either on how well the hospitals perform on certain quality measures or how much the hospitals’ performance improves on certain quality measures from their performance during a baseline period.”³²⁵ Additionally, the “health care infrastructure is shifting to focus more and more on population health management and the nonmedical determinants of health that happen outside hospital walls,” and “through altering payment mechanisms, care systems are now being held accountable for the overall health of their patient population, not just [for] services rendered while inside their institution[s].”³²⁶

CON programs are not designed to fulfill the role of licensing standards, and empirical studies on whether CON programs have the capacity to accomplish health care quality goals remain inconclusive. A 2012 study found that for states with large a metropolitan area, states with CON programs regulating neonatal intensive care units (NICUs) had lower all-infant mortality rates than states lacking such programs.³²⁷ However a 2009 study, comparing Medicare inpatient claims in states with CON programs covering cardiac procedures to those in states that dropped their cardiac CON programs during the study period (Delaware, North Dakota, Nebraska, Nevada, Ohio, Oregon, and Pennsylvania), found no evidence that cardiac CON regulation improved patient mortality rates or otherwise influenced the overall number of

³²⁵ *Hospital Reimbursements and the ACA*, HEALTH PRF'L & ALLIED EMP., <http://www.hpae.org/political/ACAcampaign/reimbursements> (last visited Jan. 19, 2015).

³²⁶ *Id.*

³²⁷ S.A. Lorch, P. Maheshwari, & O. Even-Shoshan, *The Impact of Certificate of Need Programs on Neonatal Intensive Care Units*, 32 JOURNAL OF PERINATOLOGY 39-44 (2012).

procedures performed for coronary artery bypass graft surgery and percutaneous coronary interventions.³²⁸

To support quality and population health goals, the New York Department of Public Health and Health Planning Council's 2012 report recommends incorporating "quality and population health factors into CON reviews" and developing "a regulatory and health planning framework that, together with payment incentives and other policy tools, drives health system improvement and population health."³²⁹

Similarly, one of Kentucky's CON modernization core principles is "incentivizing quality."³³⁰ In support of this goal, the Kentucky Cabinet for Health and Family Services explains that since "health care is rapidly moving toward adoption of objective quality metrics," Kentucky's CON program "will seek to support those providers who demonstrate attainment of robust quality indicators."³³¹

Michigan's CON regulation of open-heart surgery programs previously relied on volume requirements of 200-300 surgeries per year, as a proxy for quality, supported by medical literature indicating that cardiac surgery "programs with higher volumes and surgeons with

³²⁸ Vivian Ho, Meei-Hsiang Ku-Goto, & James G. Jollis, *Certificate of Need (CON) for Cardiac Care: Controversy over the Contributions of CON*, 44:2 HEALTH RESEARCH & EDUC. TRUST 483- 500 (April 2009); see Verdi J. DiSesa, Sean M. O'Brien, Karl F. Welke, Sarah M. Beland, Constance K. Haan, Mary S. Vaughan-Sarrazin, & Eric D. Peterson, *Contemporary Impact of State Certificate-of-Need Regulations for Cardiac Surgery: An Analysis Using the Society of Thoracic Surgeons' National Cardiac Surgery Database*, AM. HEART ASSOC. (2006), available at <http://circ.ahajournals.org/content/114/20/2122.full> (consistently finding "CON states have significantly higher [hospital cardiac surgery volumes] but similar mortality compared with non-CON states").

³²⁹ *Report of the Public Health and Planning Council on Redesigning Certificate of Need and Health Planning*, PUB. HEALTH & PLANNING COUNCIL 7-8 (Dec. 6, 2012), available at https://www.health.ny.gov/facilities/public_health_and_health_planning_council/docs/con_redesign_report.pdf (recommending increased CON regulation of private physician offices, discussed below).

³³⁰ *Special Memorandum: Certificate of Need Modernization: Core Principles: Request for Stakeholder Input*, CABINET FOR HEALTH & FAMILY SERV. OFFICE HEALTH POLICY (Oct. 8, 2014), available at <http://chfs.ky.gov/ohp/con/> (last visited Dec. 30, 2014).

³³¹ *Id.*

higher volumes” tend to have better patient outcomes.³³² However, in 2013, the Michigan CON Commission “approved new standards that dropped the minimum number of procedures to 150 for new programs or existing programs seeking new licenses,” in addition to introducing “new quality standards.”³³³ The chairman of the Michigan CON commission predicted “public reporting of quality standards [would] increase competition among programs to improve outcomes and patient safety.”³³⁴ The Commission published the new CON review standards for open-heart surgery services, including “quality assurance standards” as a requirement of approval for all applicants, on March 18, 2014.³³⁵ The state of Washington has required CON applicants for open-heart surgery to meet enumerated quality standards, in addition to a volume requirement, since 1992. To obtain a CON for open-heart surgery, the state of Washington requires applicants to demonstrate that they can perform a minimum of 250 open-heart procedures per year in addition to meeting quality standards, which include “having at least two board certified cardiac surgeons [working exclusively in a single institution], one of whom shall be available for emergency surgery twenty-four hours a day.”³³⁶

³³² Jay Greene, *New CON Rules De-Emphasize Open Heart Surgery Numbers as Quality Measurement*, CRAIN’S DETROIT BUS. (Mar. 16, 2014), <http://www.craindetroit.com/article/20140316/NEWS/303169996/new-con-rules-de-emphasize-open-heart-surgery-numbers-as-quality> (last visited Feb. 2, 2015).

³³³ *Id.*

³³⁴ *Id.*

³³⁵ *Certificate of Need (CON) Review Standards for Open Heart Surgery (OHS) Services*, MICH. DEP’T CMTY. HEALTH (March 18, 2014), available at http://www.michigan.gov/documents/mdch/Open_Heart_Standards_204892_7.pdf.

³³⁶ Wash. Admin. Code § 246-310-261 (effective Jun. 6, 1992), available at <http://app.leg.wa.gov/wac/default.aspx?cite=246-310-261>.

IV. Discussion: Should CON Programs Continue, and How Does the ACA Change the Equation?

In its 2012 report, the New York Public Health and Health Planning Council offered the following assessment of the strengths and limitations of CON programs:³³⁷

CON is not an all purpose, regulatory tool that can be deployed to maximize all of the opportunities created by health care reform or address all of the risks. CON impacts the supply and distribution of health care resources. It is best suited to curbing excess health care capacity that drives unnecessary utilization and spending. It can also promote access to services by channeling development to underserved areas and may help to protect the viability of essential providers. CON does not, however, provide funding for struggling providers, nor does it monitor payment arrangements, affect the health status of populations, or prevent the delivery system failures that may generate preventable utilization and excess spending. Other policies and regulatory approaches, such as licensure and surveillance, insurance oversight, grants, public health interventions, and regional planning, may provide more effective responses to these issues.

Whether CON programs should continue, change, or be abandoned entirely remains open for debate. Unfortunately there remains a stunning scarcity of empirical evidence confirming or seriously challenging the effectiveness of CON regulation. Given the nature and limitations of policy research, the empirical studies and other statistics that have been published are unequipped to isolate the role of CON programs.

Since the most compelling argument in support of maintaining CON programs relates to their capacity to protect safety net providers, the reduction of DSH payments under the ACA strengthens this justification in states that refuse to adopt Medicaid expansion. Even in states that expand their Medicaid programs, the research above indicates safety net providers may be more likely to be penalized than their competitors under the ACA's value-based

³³⁷ *Report of the Public Health and Planning Council on Redesigning Certificate of Need and Health Planning*, PUB. HEALTH & PLANNING COUNCIL 9-10, 35 (Dec. 6, 2012), available at https://www.health.ny.gov/facilities/public_health_and_health_planning_council/docs/con_redesign_report.pdf.

purchasing program, the Hospital Readmissions Reduction Program, and the electronic health record meaningful use program.³³⁸

The policy analysis above and the fifty-state survey reveal there are a number of ways states can adjust their CON programs to respond to the ACA and related trends. States can customize their CON programs to facilitate the innovations they seek to embrace and prevent, or at least mitigate, anticipated negative repercussions. For instance, the ACA incentivizes the increased consolidation of health care organizations, so states seeking to encourage this trend, as well as states with a more reluctant and cautious attitude towards increased consolidation, can adjust their CON programs accordingly.

The ACA and related trends may diminish the justification for continuing certain kinds of CON regulation, for instance of inpatient beds. There are also many ACA-related goals that CON programs were not designed, and are not currently equipped, to accomplish, like quality of care, which are better addressed by other regulatory tools, like licensure programs.

V. **Conclusion**

CON programs are mechanisms intended to reduce unnecessary health care spending and protect access to safety net providers for medically underserved populations. Whether or not they effectively accomplish these goals remains open to debate. The ACA and related health care reform efforts shift provider incentives in many ways. While some of these changes may undermine the continued utility of certain kinds of CON regulation, the ACA and related developments may leave safety net providers even more vulnerable to unconstrained competition, especially in states that choose not to expand their Medicaid programs.

³³⁸ See Matlin Gilman, E. Kathleen Adams, Jason M. Hockenberry, Ira B. Wilson, Arnold S. Milstein, & Edmund R. Becker, *California Safety net Hospitals Likely to be Penalized by ACA Value, Readmission, and Meaningful-Use Programs*, 33 HEALTH AFFAIRS 8, 1314-1321 (2014).

