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Certificate of Need in the Post-Affordable Care Act Era

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ABSTRACT

Certificate of need (“CON”) programs were conceived approximately fifty years ago as supply constraint mechanisms for healthcare services, in an environment that is essentially unrecognizable today. Every aspect of the healthcare landscape has changed dramatically, particularly in the years since the enactment of the Affordable Care Act. The historical rationales in support of CON programs have been vigorously questioned by scholars across disciplines, roundly criticized by the federal government, and largely disproven by research. Yet the status quo persists with thirty-five states retaining CON laws, due in large part to a combination of entrenched interests and political inertia that prevents either repeal or significant modification. Still, proponents of a more efficient healthcare model need not lose hope. Kentucky was widely recognized as among the most successful states in its implementation of the Affordable Care Act. As part of its implementation efforts, the Commonwealth reformed its CON program to reward healthcare providers who embrace rather than resist the changes occasioned by healthcare reform. While the eventual impact of Kentucky’s CON modernization cannot yet be known, these reforms may offer insights for additional states as they consider whether and how to reform their own CON programs. Indeed, rather than being a historic relic that

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must be tolerated in the absence of political will for change, it may be possible for a modernized CON program to serve as an additional regulatory tool for states seeking to nudge their healthcare providers into fuller engagement in the post-Affordable Care Act healthcare landscape.

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INTRODUCTION

CON programs are a powerful force in the majority of states, serving as a gatekeeper of the supply of healthcare facilities. In thirty-five states and the District of Columbia, providers of at least some healthcare services cannot simply enter a market and begin providing the services upon meeting the standards established by a state-licensing agency.¹ Rather, under state CON laws, providers of healthcare services must obtain a permit from the state before offering new services, constructing new buildings, or purchasing new medical equipment.² For example, if a hospital wishes to add additional beds to its facility, it must first convince state officials that the addition is “needed,” a determination that states make under varying theories and evaluation criteria.³ If the state is unpersuaded, the permit is denied.⁴ While these programs have been remarkably persistent,⁵ the dramatic changes in the U.S. healthcare environment following implementation of the Patient Protection and Affordable Care Act⁶ present an opportunity for a reconsideration of the role of CON in a modern regulatory system.

When CON programs were first conceived, they were largely envisioned as cost-containment mechanisms, slowing healthcare cost increases by preventing unfettered entry of new healthcare providers, particularly hospitals.⁷ Development of these programs was heavily influenced by the theory of Milton Roemer that “a built bed is a filled bed.”⁸ Thus, by preventing more beds from being built, and later by preventing proliferation of other services deemed “unnecessary,” states—and, for a time, the federal government—hoped to slow the alarming rise in healthcare expenditures.⁹ Later, and perhaps in response to criticisms that the programs were proving ineffective at achieving meaningful cost containment,¹⁰ additional

¹ See Richard Cauchi & Ashley Noble, *CON-Certificate of Need State Laws*, NAT'L CONF. OF ST. LEGISLATURES (Aug. 25, 2016), <http://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx> [<https://perma.cc/479B-MFEF>].

² *Id.*

³ See, e.g., 900 KY. ADMIN. REGS. 5:020E (2016); Maureen K. Ohlhausen, *Certificate of Need Laws: A Prescription for Higher Costs*, ANTI-TRUST, Fall 2015, at 50, 50.

⁴ Ohlhausen, *supra* note 3; see, e.g., KY. REV. STAT. ANN. § 216B.040 (West 2016).

⁵ See Lisa Schencker, *State Certificate-of-Need Laws Weather Persistent Attacks*, MOD. HEALTHCARE (Jan. 23, 2016), <http://www.modernhealthcare.com/article/20160123/MAGAZINE/301239964> [<https://perma.cc/26VY-EDAE>].

⁶ Patient Protection and Affordable Care Act, Pub. L. No. 111–148, 124 Stat. 119 (2010), amended by Healthcare and Education Reconciliation Act of 2010, Pub. L. No. 111–152, 124 Stat. 1029 (2010) (codified in scattered sections of Title 26 and 42 of the U.S.C.).

⁷ See Cauchi & Noble, *supra* note 1.

⁸ Nicholas Bagley, *Medicine as a Public Calling*, 114 MICH. L. REV. 57, 88 (2015); see also Sallyanne Payton & Rhoda M. Powsner, *Regulation Through the Looking Glass: Hospitals, Blue Cross, and Certificate-of-Need*, 79 MICH. L. REV. 203, 253 (1980).

⁹ Cauchi & Noble, *supra* note 1.

¹⁰ E.g., Bagley, *supra* note 8, at 89.

justifications for the programs became prevalent, such as ensuring an adequate distribution of healthcare services across geographic areas and socioeconomic groups, providing states a regulatory lever to require that healthcare providers deliver sufficient and quality care for the indigent.¹¹ Supporters of CON also correctly point to the fact that the market for healthcare services is not a normal market, which may justify different and more stringent regulatory interventions than in the case of an efficient market.¹² For example, consumption of healthcare services cannot be viewed as similar to consumption of a normal consumer product—most healthcare services are ordered for patients (e.g., surgery, imaging), and patients do not “shop” for these services like they do for other goods and services.¹³ Proponents also argue that CON laws do not block change entirely; rather, their primary value is to provide a formal role for evaluation by the state and participation in the evaluation process by other interested stakeholders.¹⁴

Those opposed to CON programs are vehement in their criticism, arguing that by limiting new entrants to the market, CON programs reduce price competition between facilities and may in fact promote a higher cost trajectory than would exist without the laws.¹⁵ Moreover, opponents argue that the virtual elimination of the “cost plus” pricing system in effect when CON laws were first enacted, in which hospitals were reimbursed under a formula that paid them, in essence, the cost of delivering a service plus a small percentage of profit, renders CON laws irrelevant in the modern healthcare delivery system.¹⁶ Opponents also point to inconsistencies in administration of CON programs by state officials, as well as the potential for applications to be granted on the basis of political influence, institutional prestige, or other factors apart from the “need” for a service or the interests of the community.¹⁷ Moreover, opponents question whether state policymakers are best situated to determine the best interests of a community and whether a particular provider should be permitted to offer healthcare services in a given area.¹⁸

¹¹ James B. Simpson, *Full Circle: The Return of Certificate of Need Regulation of Health Facilities to State Control*, 19 IND. L. REV. 1025, 1030—31, 1031 n.25 (1986).

¹² See, e.g., Cauchi & Noble, *supra* note 1.

¹³ *Id.* Although there is a considerable movement to create the tools to enable patients to shop and to compare health services among providers based on cost and quality, thus far, these new technologies have had only a small impact on consumer behavior. See, e.g., *Price Transparency Initiatives for Patients*, COUNTY HEALTH RANKINGS & ROADMAPS, <http://www.countyhealthrankings.org/policies/price-transparency-initiatives-patients> [<https://perma.cc/C3EW-RHZZ>] (last updated Nov. 18, 2015).

¹⁴ Cauchi & Noble, *supra* note 1.

¹⁵ *Id.*

¹⁶ Matthew D. Mitchell, *Do Certificate-of-Need Laws Limit Spending?* 10 (Mercatus Ctr., Working Paper, 2016), <https://www.mercatus.org/system/files/mercatus-mitchell-con-healthcare-spending-v1a.pdf> [<https://perma.cc/U479-8W3B>].

¹⁷ Cauchi & Noble, *supra* note 1.

¹⁸ *Id.*

The evidence for the effectiveness of CON programs at achieving any of their identified policy objectives is weak.¹⁹ Moreover, considerable evidence exists to raise a serious question as to whether CON programs do more harm than good in the healthcare markets in which they operate.²⁰ For example, some studies show that patients are at higher risk when undergoing certain procedures in CON states than in non-CON states.²¹ Legal and policy scholars have been fairly unrestrained in their criticism of CON programs, noting the potential for regulatory capture by entrenched incumbent providers and the increasing irrelevance of CON laws in a dramatically altered reimbursement environment for healthcare providers.²² And although the federal government actively supported—and in effect, required—states to enact CON laws for a brief period in the 1970s and 1980s, it has since changed its views. Now, the federal government routinely questions whether states should maintain CON laws, frequently offering comments from the Federal Trade Commission (“FTC”) and the Department of Justice (“DOJ”) Antitrust Division as states evaluate changes to or repeal their laws.²³ Despite the strong and persistent criticism leveled by scholars, researchers, and policymakers over the past decades, CON programs have endured, remaining in effect in varying strength and breadth in thirty-five states and the District of Columbia.²⁴ And the repeal movement has been stalled for at least the past fifteen years—no state has fully repealed its program since Indiana in 1999.²⁵

It is not for want of attempts to challenge that CON programs have endured.²⁶ Many frustrated healthcare providers, sometimes supported by organizations favoring more free market competition, have challenged CON laws under various constitutional theories, including the Commerce Clause, equal protection, and due process.²⁷ Those challenges have almost uniformly failed, except in the case of

¹⁹ See Bagley, *supra* note 8, at 89.

²⁰ Press Release, Federal Trade Commission & Department of Justice, to Illinois Task Force on Health Planning Reform, Agencies Say CON Laws Undercut Consumer Choice, Stifle Innovation and Weaken Markets Ability to Contain Healthcare Costs (Sept. 12, 2008), <https://www.ftc.gov/news-events/press-releases/2008/09/federal-trade-commission-department-justice-issue-joint-statement> [<https://perma.cc/W2RE-32YU>].

²¹ See *infra* Subsection III.C.i. (describing research regarding impact of CON laws on quality of care).

²² See *infra* Section II.B.

²³ See *infra* Section III.A. (discussing the federal government’s criticism of CON programs).

²⁴ See Cauchi & Noble, *supra* note 1.

²⁵ See Schencker, *supra* note 5. Note, however, that New Hampshire ended its Certificate of Need board in 2016, but it is questionable whether the end of the CON board should be considered a full repeal of CON in light of the ongoing CON-like oversight of new healthcare services by the New Hampshire Department of Health and Human Services. See Bob Sanders, *State Pulls Plug on New Hampshire Certificate of Need Board*, N.H. BUS. REV. (June 15, 2016), <http://www.nhbr.com/June-24-2016/State-pulls-plug-on-NH-Certificate-of-Need-board/> [<https://perma.cc/T9V4-YTHV>].

²⁶ *Id.*

²⁷ See *infra* Part IV. (discussing, among others, *Colon Health Ctrs. of Am., LLC v. Hazel*, 813 F.3d 145, 149 (4th Cir. 2016) and *Madarang v. Bermudes*, 889 F.2d 251, 253 (9th Cir. 1989)).

documented and significant discriminatory effect of the laws toward out-of-state healthcare providers,²⁸ or where CON laws infringed on a fundamental right like a woman's ability to access abortion services.²⁹

In view of the persistence of CON laws and the political inertia that prevents their repeal, legislators and policymakers must think creatively about strategies to evolve these programs to meet the challenges presented by the new healthcare environment. In particular, the Affordable Care Act has dramatically altered the delivery and payment landscapes for all healthcare providers, and these are changes that seem virtually certain to remain regardless of the different directions healthcare reform may proceed after the administration of President Barack Obama.³⁰ Kentucky was widely recognized as among the most successful states in the country for its implementation of the Affordable Care Act ("ACA") under former Governor Steven L. Beshear.³¹ Indeed, with over 570,000 additional individuals obtaining Medicaid and a drop in the Commonwealth's uninsured rate from 16% prior to the ACA to 8% at the end of 2014,³² some of the reasons for CON, such as ensuring that existing providers retain sufficient ability to deliver care to the uninsured, must be reexamined.³³ This paper uses the experience of Kentucky in modernizing its CON program following implementation of the ACA as a case study, drawing lessons that may have further application as other states consider reforms to their programs.³⁴ In particular, as part of its reform process, Kentucky appears to be the first state to have adopted explicit preferences in its CON program for providers who meet objective quality thresholds under federal government quality rankings, as well as preferences for providers who participate in so-called "value-based payment" programs, which seek to reward healthcare providers who deliver high-value care to patients.³⁵ In addition, Kentucky's reformed CON program requires new providers to adopt electronic medical records and participate in its health information exchange, with the goal of improving the ability of healthcare providers to coordinate patient care.³⁶ These elements of the revision process may be appropriate for duplication or adaptation in other state

²⁸ See *infra* Part IV. (discussing legal challenges to CON laws).

²⁹ *Planned Parenthood of Greater Iowa, Inc. v. Atchison*, 126 F.3d 1042, 1048–49 (8th Cir. 1997). Moreover, in view of the recent Supreme Court decision in *Whole Woman's Health v. Hellerstedt*, 136 S. Ct. 2292 (2016), CON laws impacting the right to abortion and other reproductive freedoms may be ripe for new challenge.

³⁰ See Bagley, *supra* note 8, at 62–68.

³¹ Samantha Artiga, et al., *Implementation of the ACA in Kentucky: Lessons Learned to Date and the Potential Effects of Future Changes*, KAISER FAM. FOUND. 1 (April 2016), <http://files.kff.org/attachment/issue-brief-implementation-of-the-aca-in-kentucky-lessons-learned-to-date-and-the-potential-effects-of-future-changes> [<https://perma.cc/3W97-R5N2>] ("Kentucky has had one of the most successful ACA implementation experiences among states.")

³² *Id.* at 1–2.

³³ *E.g.*, Simpson, *supra* note 11, at 1031–32.

³⁴ See *infra* Part V.

³⁵ 900 KY. ADMIN. REGS. 5:020E, §§ I.C., III.A., III.B., V.B. (2016).

³⁶ 900 KY. ADMIN. REGS. 5:020E (2016).

programs, as states consider which of their regulatory levers they can use to help shape a more effective, efficient healthcare delivery system.

Part II of this Article provides an overview of the evolution of CON programs, from the early experiments in health system planning following World War II through the CON programs in place today. Part III describes the longstanding federal government skepticism toward CON programs and the views of law and policy scholars as to the effectiveness of CON laws, and then considers the evidence of the impact of CON laws on cost, quality and access, as well as evidence regarding the political influence that permeates the programs. Part IV evaluates the nearly uniform failure of legal challenges to CON laws. Part V offers the experience of Kentucky in modernizing its CON program as a case study in the evolution of CON programs to meet the demands of a post-Affordable Care Act healthcare ecosystem. Part VI concludes this discussion.

I. THE EVOLUTION OF CERTIFICATE OF NEED PROGRAMS

A. *Early Iterations of Certificate of Need*

CON programs are a powerful force in the majority of states, serving as a gatekeeper to the supply of healthcare facilities.³⁷ Under CON laws, healthcare facilities are required to obtain a permit from state health planning entities before offering new services, constructing new buildings, or purchasing new medical equipment.³⁸ For example, if a hospital wishes to add additional beds to its facility, it must seek approval from the state, which will evaluate the request based on a determination of, at minimum, whether there exists sufficient public “need” for the new beds.³⁹ If the state determines that the need for the requested facility is not proven, the permit is denied.⁴⁰ Beyond need, which is usually determined either in whole or in part by reference to a numeric formula,⁴¹ additional review criteria may exist, including accessibility, costs, feasibility, available economic resources, quality, and others.⁴²

Others have written comprehensively about the history of the development of CON programs in the United States, and this Article will not duplicate that work.⁴³ However, an understanding of the underlying rationale for CON and changes in the programs over time is essential to understanding their place in the modern healthcare delivery system. In most instances, the government allows market forces to determine the appropriate supply of a product, and consumers to

³⁷ See Cauchi & Noble, *supra* note 1.

³⁸ *Id.*

³⁹ See *supra* note 3 and accompanying text.

⁴⁰ See *supra* note 3–4 and accompanying text.

⁴¹ See, e.g., KY. ADMIN. REGS. 5:020E (2016).

⁴² E.g., KY. REV. STAT. ANN. § 216B.040(2)(a)(2) (West 2016).

⁴³ See generally Simpson, *supra* note 11; Payton & Powsner, *supra* note 8.

purchase the amount of that product that meets their needs.⁴⁴ However, the market for healthcare services is not a normal market, and it is this recognition that led to the development of health planning authorities and ultimately to CON programs.⁴⁵

Following the end of World War II, “faced with the aging infrastructure of a healthcare system ill-equipped to accommodate the needs of returning soldiers and the inevitable baby boom that followed,”⁴⁶ Congress passed the Hospital Survey and Construction Act (the “Hill-Burton Act,” or the “Act”), which was designed to promote public and nonprofit hospital construction and modernization, primarily through the availability of federal funding for certain healthcare facility construction and modernization projects.⁴⁷ As described in its statement of purpose, the Hill-Burton Act included a health planning function, as the Act was intended to assist states:

[I]nventory their existing hospitals . . . to survey the need for construction of hospitals, and to develop programs for construction of such public and other nonprofit hospitals as will, in conjunction with existing facilities, afford the necessary physical facilities for furnishing adequate hospital, clinic, and similar services to all their people⁴⁸

As Nicholas Bagley recently observed, although the scope of the Hill-Burton Act increased rapidly throughout the 1960s, the health planning in this era “lacked regulatory bite,” as planning agencies could advocate for particular facilities and services to be provided, but could not compel the private sector to build facilities or provide the needed services.⁴⁹ At approximately the same time, increasing health sector costs led government officials to look to additional strategies to regulate costs, including by instituting CON programs to constrain facility supply as a cost control mechanism, an approach heavily influenced by theory of Milton Roemer that “[a] built bed is a filled bed.”⁵⁰ Under Roemer’s Law, there exists a direct correlation between capacity and utilization; when combined with the availability of third-party reimbursement, oversupply of resources will create its own demand for

⁴⁴ See Bagley, *supra* note 8, at 71–74.

⁴⁵ Cauchi & Noble, *supra* note 1.

⁴⁶ Carol Brayshaw Longwell & James T. Steele, Jr., *The Rise and Fall of Certificate of Need in Pennsylvania: An Experiment in Healthcare Planning and the Role of the Commonwealth Court*, 21 WIDENER L.J. 185, 186 (2011).

⁴⁷ Hospital Survey and Construction Act, Pub. L. No. 79-725, § 2, tit. VI, 60 Stat. 1040, 1041–49 (1946) (codified at 42 U.S.C. § 291 (2016)); see also *The Hill-Burton Act, 1946-1980: Asynchrony in the Delivery of Healthcare to the Poor*, 39 MD. L. REV. 316, 316 (1979).

⁴⁸ See Hospital Survey and Construction Act § 601(a); see also Bagley, *supra* note 8, at 85–90 (2015) (discussing the evolution of state health facility supply planning).

⁴⁹ Bagley, *supra* note 8, at 87–88.

⁵⁰ Milton I. Roemer, M.D., *Bed Supply and Hospital Utilization: A Natural Experiment*, J. AM. HOSP. ASS’N, Nov. 1, 1961, at 36, 36; see also Bagley, *supra* note 8, at 88.

excessive use.⁵¹ Thus, to prevent both overutilization of services and to control costs, supply constraints effected through CON programs were not only justifiable but actively supported by federal and state policymakers.⁵²

In 1966, New York became the first state to establish a CON program, requiring state approval for construction of hospital and nursing home construction, and was quickly followed by twenty states over the next six years.⁵³ The federal government soon followed suit and in recognition of the contribution of the “massive infusion of Federal funds into the existing healthcare system” to “inflationary increases in the cost of healthcare” and the “fail[ure] to produce an adequate supply or distribution of health resources,” Congress passed the National Health Planning and Resources Development Act of 1974 (“NHPRDA”).⁵⁴ NHPRDA provided significant funding for state health planning activities and “effectively required states to adopt certificate of need laws conforming to federal standards.”⁵⁵ By 1980, every state except Louisiana had a CON program.⁵⁶

Beyond their core supply constraint function, state CON programs often contain additional regulatory goals, including promotion and preservation of high quality healthcare services—which, as others have observed, is closely related to cost containment given the documented correlation between sufficient volume of services and quality of care.⁵⁷ Some CON programs also contain general goals or specific review criteria regarding adequate distribution of services among geographic areas as well as social and economic groups—for example, some CON programs require applicants to demonstrate a plan for the provision of charity care.⁵⁸ Additional policy goals may include reducing state expenditures on public programs, such as by limiting the number of nursing home beds (nursing home care is primarily funded through the Medicaid program), and ensuring the state

⁵¹ John Steen, *The Dartmouth Atlas on Roemer's Law*, DARTMOUTH ATLAS (2008) <http://www.ahpanet.org/files/TheDartmouthAtlasonRoemer'sLaw%20b.pdf> [<https://perma.cc/6R8N-CE6J>].

⁵² An alternative theory of the evolution of CON programs was posited by Sallyanne Payton and Rhoda M. Powsner, who wrote that Blue Cross and leading public and private health officials promoted CON in the late 1950s with goals to “(1) to restore public confidence [that had eroded with rising costs] in the voluntary hospitals and their financing arm, the Blue Cross . . . ; (2) to protect the dominance of the existing large voluntary teaching hospitals; and (3) to channel hospital growth in the developing suburbs into large, full-service, general hospitals.” Payton & Powsner, *supra* note 8, at 204.

⁵³ Simpson, *supra* note 11, at 1036.

⁵⁴ National Health Planning and Resources Development Act of 1974, Pub. L. No. 93–641, 88 Stat. 2225 (1975) (codified at 43 U.S.C. 300k).

⁵⁵ See Simpson, *supra* note 11, at 1026; see also National Health Planning and Resources Development Act of 1974.

⁵⁶ See Matthew Mitchell & Christopher Koopman, *40 Years of Certificate-of-Need Laws Across America*, MERCATUS CTR. (Sept. 27, 2016), <https://www.mercatus.org/publication/40-years-certificate-need-laws-across-america> [<https://perma.cc/6AS-DGMD>].

⁵⁷ See Simpson, *supra* note 11, at 1029–30.

⁵⁸ See *id.* at 1030–32, 1031 n.25.

maintains a role in large health policy decisions impacting state residents, such as the location of a new hospital.⁵⁹

While laudable in intent, CON programs were largely perceived as falling short of expectations by the early 1980s, particularly as a deregulatory political climate prevailed.⁶⁰ Costs continued to escalate, and a number of studies found that CON programs did not help contain healthcare expenditures.⁶¹ Moreover, as larger and more influential healthcare entities learned to navigate the often complicated and bureaucratic programs, perceptions of protectionism of incumbents further undermined support for CON.⁶² Congress, too, became skeptical of the benefits of CON and repealed NHPDA in 1987.⁶³ By 1990, eleven states repealed their programs, and by 2000 a total of fourteen states had repealed their CON laws.⁶⁴

B. The Stagnant Status Quo

Although many states repealed their programs following the repeal of the federal mandate, the trend toward full repeal has stalled. The last two states to repeal their programs were Indiana (1999) and Wisconsin (2000), although Wisconsin reinstated its program in 2011.⁶⁵ And in some sectors of healthcare, regulation via CON remains quite strong. For example, a 2004 study examined state policies for CON or moratoria for new building, renovation, and remodeling of long-term care providers, surveying state officials over a twelve year period from 1990–2002.⁶⁶ By 2002, the study found that the vast majority of states still regulated the supply of nursing homes, hospital-based nursing homes, and facilities for the developmentally disabled.⁶⁷ In addition, the study found that “18 percent of states regulate the supply of residential care facilities, 35 percent regulate home

⁵⁹ *See id.*

⁶⁰ *See id.* at 1026–27 (describing deregulatory goals of the administration of President Ronald Reagan).

⁶¹ *See, e.g.,* Christopher J. Conover & Frank A. Sloan, *Does Removing Certificate-of-Need Regulations Lead to a Surge in Healthcare Spending?*, 23 J. HEALTH POL., POLY & L. 455, 456 (1998).

⁶² *See* Bagley, *supra* note 8, at 86 (citing Sallyanne Payton & Rhoda M. Powsner, *Regulation Through the Looking Glass: Hospitals, Blue Cross, and Certificate-of-Need*, 79 MICH. L. REV. 203, 233 (1980)).

⁶³ *See* National Health Planning and Resources Development Act of 1974, Pub. L. No. 93-641, 88 Stat. 2225 (1975) (codified at 42 U.S.C. § 300k-300n-6 (1982)), *amended by* Health Planning and Resources Development Amendments of 1979, Pub. L. No. 96-79, §§ 1-129, 93 Stat. 592 (codified at 42 U.S.C. §§ 300k-300t (1976 & Supp. V 1981)), *repealed by* Drug Export Amendments Act of 1986, Pub. L. No. 99-660 § 701, 100 Stat. 3743, 3799 (1986).

⁶⁴ Mitchell & Koopman, *supra* note 56.

⁶⁵ *Id.* However, see *supra* note 26 for a description of New Hampshire's 2016 termination of its CON board.

⁶⁶ Charlene Harrington, et al., *Trends in State Certificate of Need and Moratoria Programs for Long-Term Care Providers* 19 J. HEALTH & SOC. POLY 31, 31 (2004).

⁶⁷ *Id.*

health agencies, and 37 percent regulate hospices.⁶⁸ In line with the traditional bases for CON programs, the authors found that the CON programs were based primarily based on strategies seeking cost containment and the appropriate distribution of services.⁶⁹ The authors cautioned, however, that CON programs that placed limits on home and community service providers could negatively impact access to care.⁷⁰

While CON remains prevalent, there continues to be vigorous debate over the wisdom of these programs in states at all points along the political spectrum. In recent years, several states have reexamined the efficacy of the CON system and proposed modifications to existing CON programs. In 2009, half of the thirty-six states with CON programs had bills to repeal or reform these programs introduced in their state legislatures.⁷¹ Illinois attempted significant reform that year, but those efforts resulted in fairly modest change.⁷² Fascinatingly, and relevant to the discussion of political influence in CON, manipulation of the CON process was one of the alleged corrupt activities that led to the removal of former Governor Rod Blagojevich from office and his ultimate indictment on charges of fraud, extortion and racketeering.⁷³ In a dramatic twist, Pamela Davis, a hospital CEO whose project had been stalled under the review process, wore a wire to assist the FBI in its investigation.⁷⁴

Around the same time in Alaska and Hawaii, Governors Sarah Palin and Linda Lingle attempted to repeal their states' CON laws, but neither succeeded.⁷⁵ And in 2008, Florida Governor Charlie Crist began an attempt to terminate the program but ultimately compromised on a reform bill in lieu of repeal.⁷⁶ Beyond full repeal, the National Conference of State Legislatures reported that CON-related bills were also introduced in 2009 in seventeen additional states.⁷⁷ In Alabama, a bill to

⁶⁸ *Id.*

⁶⁹ *Id.* at 31–32.

⁷⁰ *Id.* at 32.

⁷¹ See Andis Robeznieks, *Pros and CONs: Certificate-of-Need Reform Bills See Mixed Results*, MOD. HEALTHCARE (April 27, 2009), <http://www.modernhealthcare.com/article/20090427/MAGAZINE/904249983> [<https://perma.cc/2RJT-LYDH>].

⁷² See Legal Alert from McGuire Woods, *Illinois Certificate of Need: A New Majority of Five*, MCGUIREWOODS (June 2, 2010), <https://www.mcguirewoods.com/Client-Resources/Alerts/2010/6/Illinois-Certificate-of-Need-A-New-Majority-of-Five.aspx> [<https://perma.cc/RT6L-XQJX>].

⁷³ Robeznieks, *supra* note 71.

⁷⁴ *Id.*

⁷⁵ *Id.*

⁷⁶ *Id.*

⁷⁷ *Id.* Interestingly, although the repeal efforts were—and continue to be—mostly led by Republican governors, the reform efforts appear to be more bipartisan. In 2009, the seventeen states in which bills were introduced were: Alabama, Iowa, Maine, Maryland, Mississippi, Missouri, New Hampshire, New York, North Carolina, North Dakota, Oklahoma, Oregon, South Carolina, Vermont, Virginia and Washington. *Id.*

repeal CON was unsuccessful in the face of robust opposition from the state's hospital association.⁷⁸ In Oregon, the Association of Hospitals and Health Systems broke with most hospital associations and took the relative outlier position that "certificate of need is a failed experiment in regulating construction."⁷⁹ Nonetheless, the association opposed two bills introduced to slightly modify the CON process, preferring its own legislation, which it characterized as an approach that relied more on transparency through disclosure rather than regulation.⁸⁰ While no repeal efforts have succeeded since 1999, several states have undertaken smaller reform efforts, focusing on piecemeal changes to CON programs, such as exempting certain types of medical services from CON requirements.⁸¹ In 2009, several states passed small reforms to their CON systems, including New Jersey, Maryland, Washington, and West Virginia.⁸² Other states, including Connecticut, Illinois, and Georgia, have also reformed their CON programs in recent years.⁸³

These efforts at CON reform have continued in the post-Affordable Care Act era. For example, the North Carolina state legislature recently considered a bill that would have exempted certain ambulatory surgical centers from obtaining a CON.⁸⁴ Although the session expired without a vote on the CON legislation, several members of the legislature expressed support for continued reform efforts.⁸⁵ And in 2013, South Carolina Governor Nikki Haley vetoed the \$2 million allocated in the state budget for the CON program.⁸⁶ Although the state legislature sustained Haley's veto, several hospitals sued the state.⁸⁷ These hospitals argued that Haley was improperly using her veto to eliminate the CON program, and that her actions had exceeded her executive authority.⁸⁸ The legal battle eventually reached the state's Supreme Court, which ruled that the state had to continue to administer the CON program.⁸⁹

⁷⁸ *Id.*

⁷⁹ *Id.*

⁸⁰ *Id.*

⁸¹ Tracy Yee, et al., *Healthcare Certificate-of-Need Laws: Policy or Politics?*, NAT'L INST. FOR HEALTHCARE REFORM: RES. BRIEF, no. 4, May 2011, at 1, 7, http://nihcr.org/wp-content/uploads/2015/03/NIHCR_Research_Brief_No._4.pdf [<https://perma.cc/34VB-EPZ6>].

⁸² See Robeznieks, *supra* note 71.

⁸³ Yee, *supra* note 81, at 6.

⁸⁴ Rose Hoban, *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/>.

⁸⁵ *Id.*

⁸⁶ Meg Kinnard, *South Carolina Supreme Court Won't Review Certificate of Need Ruling*, POST AND COURIER (June 2, 2014, 11:49 AM), <http://www.postandcourier.com/article/20140602/PC1610/140609889/south-carolina-supreme-court-wont-review-certificate-of-need-ruling> [<https://perma.cc/L3L6-D7E3>].

⁸⁷ *Id.*

⁸⁸ *Id.*

⁸⁹ *Id.*

As of 2016, thirty-five states and the District of Columbia have CON programs of varying depth and scope.⁹⁰ Of the states that retain CON programs, the most heavily regulated services are long-term care and nursing home beds (35 plus D.C.), acute hospital beds (27), ambulatory surgical centers (26), cardiac catheterization (25), long-term acute care (25 plus D.C.), psychiatric services (25), open heart surgery (24), rehabilitation (24), and neo-natal intensive care (22).⁹¹

II. SKEPTICISM TOWARD CERTIFICATE OF NEED FROM ALL QUARTERS

A. Longstanding Federal Government Skepticism Toward Certificate of Need

Although the decision whether to maintain a CON program has been the prerogative of the states since the repeal of NHPDA in 1987, the federal government has not been neutral on the issue. Rather, for at least the past fifteen years, the FTC and the DOJ Antitrust Division have taken an active position against the continuance of CON programs.

For example, the FTC and DOJ issued statements to the Illinois Task Force on Health Planning Reform;⁹² the General Assembly and the Senate of the state of Georgia;⁹³ the Committee on Health, Education and Social Services of the Alaska House of Representatives;⁹⁴ and the Florida Senate Committee on Health and

⁹⁰ See *CON—Certificate of Need Laws*, NAT'L CONF. OF ST. LEGISLATURES (Aug. 25, 2016), <http://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx> [<https://perma.cc/T4UX-8ME3>].

⁹¹ See *infra* Table 1.

⁹² U.S. DEPT OF JUSTICE & FED. TRADE COMM'N, COMPETITION IN HEALTHCARE AND CERTIFICATES OF NEED: JOINT STATEMENT OF THE ANTITRUST DIVISION OF THE U.S. DEPARTMENT OF JUSTICE AND THE FEDERAL TRADE COMMISSION BEFORE THE ILLINOIS TASK FORCE ON HEALTH PLANNING REFORM (2008), https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-and-department-justice-written-testimony-illinois-task-force-health-planning-reform-concerning/v080018illconlaws.pdf [<https://perma.cc/6T3L-9WER>].

⁹³ *Competition in Healthcare and Certificates of Need, Before a Joint Session of the Health and Human Services Committee of the State Senate and the CON Special Committee of the State House of Representatives of the General Assembly of the State of Georgia* (Ga. 2007) (statement of Mark J. Botti, Litigation I Section Chief, U.S. Dep't of Justice), <http://www.justice.gov/atr/competition-healthcare-and-certificates-need> [<https://perma.cc/3UXY-ZBDN>].

⁹⁴ *Prepared Statement of the Federal Trade Commission Before the Standing Committee on Health, Education, and Social Services of the Alaska House of Representatives on House Bill 337, "An Act Establishing the Alaska Healthcare Information Office; Relating to Healthcare Planning and Information; Relating to the Certificate of Need Program for Certain Healthcare Facilities; and Providing for an Effective Date"* (Al. 2008) (statement of U.S. Fed. Trade Comm'n), https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-written-testimony-alaska-house-representatives-concerning-alaska-certificate-need-laws/v080007alaska.pdf [<https://perma.cc/89PZ-YEE5>].

Human Services Appropriations,⁹⁵ in each instance reiterating the government's position that CON laws undercut consumer choice, stifle innovation and weaken the market forces that could otherwise operate to help promote competition and potentially reduce the growth rate of healthcare expenditures. In the joint statements, the agencies opine that CON laws impede the efficient performance of healthcare markets by creating barriers to entry and expansion, to the detriment of healthcare competition and consumers.⁹⁶ The agencies cite economic research on the effects of CON laws, as well as some of the well-known risks that CON laws entail. For example, the agencies observe that in addition to limiting entry, CON laws create opportunities for existing competitors to exploit the CON process to thwart or delay new competition; they can facilitate anticompetitive agreements among providers; and, as noted by a number of researchers who interviewed former state CON officials, the CON process itself may be susceptible to corruption.⁹⁷

In the joint statements, the agencies also evaluate several arguments in support of CON laws, noting that the original cost-control reasons for CON laws no longer apply and that CON laws are an ineffective means by which to fund indigent care.⁹⁸ For these reasons, the agencies encourage states that continue to require certificates of need to consider whether such laws do more harm than good.⁹⁹ In addition to participating in individual state deliberations about the future of CON programs, in 2004 the agencies took the additional step of issuing a joint report entitled "Improving Healthcare: A Dose of Competition," in which they were unrestrained in their criticism of CON laws:

The Agencies believe that, on balance, CON programs are not successful in containing healthcare costs, and that they pose serious anticompetitive risks that usually outweigh their purported economic benefits. Market incumbents can too easily use CON procedures to forestall competitors from entering the incumbent's market. . . . Indeed, there is considerable evidence that CON programs can actually increase prices by fostering anticompetitive barriers to entry.¹⁰⁰

⁹⁵ *Competition in Healthcare and Certificates of Need, Statement of the Antitrust Division, U.S. Department of Justice Before the Florida Senate Committee on Health and Human Services Appropriations* (Fl. 2008) (statement of Joseph M. Miller, Litigation Section Assistant Chief, U.S. Dept. of Justice), <https://www.justice.gov/sites/default/files/atr/legacy/2008/06/09/233821.pdf> [<https://perma.cc/UZM3-3NV2>].

⁹⁶ See *supra* notes 92–95.

⁹⁷ See *supra* notes 92–95.

⁹⁸ See *supra* notes 92–95.

⁹⁹ See *supra* notes 92–95.

¹⁰⁰ DEP'T. OF JUSTICE & FED. TRADE COMM'N, IMPROVING HEALTHCARE: A DOSE OF COMPETITION 22 (2004), <https://www.ftc.gov/sites/default/files/documents/reports/improving-healthcare-dose-competition-report-federal-trade-commission-and-department-justice/040723healthcarerprt.pdf> [<https://perma.cc/V24T-6L9U>].

In 2015 the agencies issued a joint statement in Virginia, in which they address several concerns about CON programs.¹⁰¹ First, the agencies observe that CON laws create barriers to entry, thereby suppressing competition, reducing the ability of markets to respond to demand for innovative and higher-quality and lower cost treatments, and shielding incumbent providers from competition from new entrants.¹⁰² Moreover, as the agencies observe, CON laws may further harm competition because competing healthcare providers may take advantage of the CON process to protect their businesses by using the CON process (e.g., filing comments, objecting to a competitor's application) to slow or thwart a competitor's attempt to enter the market.¹⁰³ Third, and perhaps most significantly from the agencies' perspective, CON laws can "entrench anticompetitive mergers by limiting the ability to implement effective structural remedies."¹⁰⁴ Drawing on the recent experience of the FTC in *FTC v. Phoebe Putney* which involved a challenge to the merger of two hospitals in Albany, Georgia,¹⁰⁵ the agencies note that the FTC was precluded by Georgia's CON laws from obtaining a remedy that would have restored competition to the marketplace following a merger that created a monopoly on certain services in Albany.¹⁰⁶ The FTC noted that the case "illustrates how state CON laws, despite their original and laudable goal of reducing healthcare facility costs, often act as a barrier to entry to the detriment of competition and healthcare consumers."¹⁰⁷ Thus, the agencies conclude that the Virginia working group studying the state's CON laws should carefully consider whether and under what circumstances the laws should be retained.¹⁰⁸

The agencies have also acted independently from one another in voicing concern over CON laws. For example, in 2008, the DOJ sent a letter to the Michigan Certificate of Need Commission warning against proposed standards for proton beam therapy because of the harm the CON program could have on competition and on consumers.¹⁰⁹ Similarly, the Federal Trade Commission has published staff statements before several states reiterating its position in favor of

¹⁰¹ FED. TRADE COMM'N & DEPT. OF JUSTICE: ANTITRUST DIV., JOINT STATEMENT OF THE FEDERAL TRADE COMMISSION AND THE ANTITRUST DIVISION OF THE U.S. DEPARTMENT OF JUSTICE TO THE VIRGINIA CERTIFICATE OF PUBLIC NEED WORK GROUP 1-2 (2015), https://www.ftc.gov/system/files/documents/advocacy_documents/joint-statement-federal-trade-commission-antitrust-division-u.s.department-justice-virginia-certificate-public-need-work-group/151026ftc-dojstmtva_copn-1.pdf [https://perma.cc/D8N8-87J4] [hereinafter FTC & DOJ Joint Statement to VA].

¹⁰² *Id.* at 5–6.

¹⁰³ *Id.* at 6–7.

¹⁰⁴ *Id.* at 7.

¹⁰⁵ *F.T.C. v. Phoebe Putney Health Sys., Inc.*, 133 S. Ct. 1003, 1008 (2013).

¹⁰⁶ FTC & DOJ Joint Statement to VA, *supra* note 101, at 7.

¹⁰⁷ *Id.* (citation omitted).

¹⁰⁸ *Id.* at 13.

¹⁰⁹ Letter from Joseph Miller, Assistant Chief, Litig. I Section, Antitrust Div., Dep't of Justice, to Senator Michael Bishop, Senate Majority Leader (June 6, 2008), <http://www.justice.gov/atr/comments-competition-healthcare-and-certificates-need> [https://perma.cc/Q98B-PANC].

full repeal of CON laws.¹¹⁰ And, as described in Section III.B., current FTC Commissioner Maureen Ohlhausen penned a 2015 article in which she vigorously questioned the ability of CON programs to deliver on any of their enumerated policy objectives.¹¹¹

B. Criticism of Certificate of Need From Scholars Across Disciplines

Among academic scholars, it is rare to find ardent, or even lukewarm defenders of CON programs. Although the arguments for the effectiveness of CON have not been conclusively disproven,¹¹² the prevailing view reflects considerable skepticism

¹¹⁰ *Certificate of Need Regulation of Healthcare Facilities: Prepared Statement of the Federal Trade Commission Before North Carolina State Goals and Policy Board*, FED. TRADE COMM'N 1, 2 (Mar. 6, 1989) ("To promote competition in healthcare markets, the Federal Trade Commission and its staff have been active both in antitrust law enforcement and in advocacy of regulatory reforms, including advocating the repeal of Certificate of Need regulation"), https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-comment-north-carolina-state-goals-and-policy-board-concerning-certificate-need-regulation/v890028.pdf [https://perma.cc/WM9J-696E]; Letter from Jeffrey I. Zuckerman, Dir., Bureau of Competition, Fed. Trade Comm'n, to Bernice Labeledz, Neb. State Senator, at 1 (Feb. 22, 1989) ("While we believe the outright repeal of CON regulation proposed in LB 745 would likely best serve the interests of healthcare consumers, we believe that passage of either of the other CON reform bills would likely also have significant positive effects on healthcare markets."), https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-comment-hon.bernice-labeledz-concerning-nebraska-l.b.429-439-and-745-liberalize-or-repeal-certificate-need-regulation/v890025.pdf [https://perma.cc/G4TX-L3VP]; Letter from John M. Mendenhall, Acting Dir., Cleveland Reg'l Office, Fed. Trade Comm'n, to John F. Pressman & Donald W. Snyder, Pa. State Representatives, at 14 (Mar. 30, 1988) ("We believe that the continued existence of CON regulation would be contrary to the interests of healthcare consumers in Pennsylvania."), https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-comment-hon.john.f.pressman-and-hon.donald-w.snyder-concerning-pennsylvania-h.b.1328-repeal-certificate-need-process/v880012.pdf [https://perma.cc/B4SM-6JB]; Letter from John M. Mendenhall, Acting Dir., Cleveland Reg'l Office, Fed. Trade Comm'n, to Gerald H. Law, Mich. State Representative, at 14 (Mar. 7, 1988) ("We believe that the continued existence of CON regulation would be contrary to the interests of healthcare consumers in Michigan."), https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-comment-hon.gerald-h.law-concerning-certificate-need-laws/v880007.pdf [https://perma.cc/F5NH-3YAU]; Letter from Jeffrey I. Zuckerman, Dir., Bureau of Competition, Fed. Trade Comm'n, to Maston T. Jacks, Esq., Chairman, Comm'n on Med. Facilities Certificate of Pub. Need, Commonwealth of Va., at 1 (Aug. 6, 1987) ("[W]e believe that CON regulation is unlikely to benefit healthcare consumers in Virginia, and we support the complete elimination of CON regulation."), https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-comment-virginia-commission-medical-facilities-concerning-reform-certificate-need/v870014.pdf [https://perma.cc/62XM-WZ24]; Letter from Janet M. Grady, Reg'l Dir., Fed. Trade Comm'n, to Mary George, Haw. State Senator, at 1 (Mar. 13, 1987) ("[W]e strongly encourage repeal of CON legislation."), https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-comment-governor-mary-george-concerning-hawaii-s.b.213-abolish-state-planning-and-health-agency-including-its-administration-certificates-need/p874645.pdf [https://perma.cc/MU3A-2CW6].

¹¹¹ Ohlhausen, *supra* note 3, at 51.

¹¹² See *infra* Section III.C.

about the ability of CON programs to achieve any of their intended aims. And even when the programs were at their most popular, many were questioning whether CON programs could truly deliver the benefits they promised.

In 1973, a time when CON programs were very much in vogue, Clark Havinghurst noted that it was “appropriate to inquire whether there is a realistic basis for expecting desirable results from introducing such regulatory controls in the market for health services.”¹¹³ While acknowledging the facially persuasive nature of the arguments in favor of CON programs,¹¹⁴ he nonetheless noted that at their core, CON programs are attempts to address symptoms rather than root causes of the underlying problems of escalating cost and utilization.¹¹⁵ Havinghurst correctly observed that the rationale for CON programs depended on the “continued predominance of financing mechanisms which encourage inefficiency both by guaranteeing recovery of costs, no matter how great, and by externalizing the costs of doctors’ and patients’ consumption decisions.”¹¹⁶ When compared to the potential for truly disruptive change in the healthcare delivery system, CON programs could be viewed as “conservative measures, designed to preserve the very institutions which create the problems to which they are addressed.”¹¹⁷ While he acknowledged similarities of the certificate of need process and its underlying theories supporting regulation to the “public utility” model of healthcare regulation espoused by some, Havinghurst suggested that CON programs were unlikely to be “appreciably effective” controlling costs due to the “practically unavoidable slippage involved in translating a persuasive rationale for regulation into a workable regulatory program.”¹¹⁸ Moreover, he noted that negative impacts associated with the interference with normal market forces, such as delays in innovation or reductions in efficiency, might outweigh the limited benefits CON programs could provide.¹¹⁹

Many others were equally skeptical of the benefits of CON programs, at least as they were administered in practice. By 1986, a number of states had repealed their CON programs, in part in response to the institution of the Medicare prospective payment system (providers were essentially paid a set fee for their services rather than a cost-based rate) and the increase in enrollment in health maintenance

¹¹³ Clark C. Havinghurst, *Regulation of Health Facilities and Services by “Certificate of Need”*, 59 VA. L. REV. 1143, 1147 (1973).

¹¹⁴ *Id.* at 1155 (“Indeed, they are considerably stronger in theory than the rationales offered to justify regulatory restrictions on entry and expansion in other industries. They originate in demonstrable market failures attributable to the manner in which healthcare is paid for, the control which providers exert over demand for healthcare, and the incentives affecting both consumption and investment decisions. As measures to correct the very real problems of overinvestment in, and overconsumption of, health services, certificate-of-need laws have earned many adherents.”) (internal footnotes omitted).

¹¹⁵ *Id.*

¹¹⁶ *Id.* at 1156.

¹¹⁷ *Id.*

¹¹⁸ *Id.* at 1147, 1148.

¹¹⁹ *Id.* at 1148.

organizations, whose business model contained independent incentives for cost containment.¹²⁰ Simpson noted that in making the decision to repeal their CON programs, states expressed “exasperation with the controversy that often surrounds certificate of need decisions.”¹²¹ Indeed, it appeared that Havinghurst’s caution about the distinction between CON programs as envisioned and as actually administered was leading to skepticism as to the value the programs added to the healthcare delivery system. The debate continued in subsequent decades, with no resolution.

In 1993, one of the few defenders of CON, Robert Hackey of the University of Massachusetts, acknowledged the rampant criticism of CON programs over the prior decade, but argued that more recent evidence suggested that CON programs “may be more effective than commonly believed.”¹²² While acknowledging that CON programs had not been shown to lower healthcare costs, Hackey argued that the expectations for meaningful cost control had always been unrealistic in relation to what the programs could actually deliver, placing a portion of the blame on the federal government’s overly heavy reliance on indirect cost containment strategies like CON (as a tool to reduce capital expenditures by hospitals) rather than more direct strategies like rate setting by regulation.¹²³ Moreover, Hackey was an early proponent of broadening the goals of CON programs beyond cost containment to include additional policy objectives, such as increasing access to care for the indigent and increasing lay participation in health policy planning.¹²⁴ Thus, rather than viewing CON as a failed experiment in cost containment, Hackey optimistically concluded that CON programs could assume a broader role in the 1990s as additional policy objectives were incorporated into the programs.¹²⁵ By 1998, writing with Peter Fuller, Hackey was more tempered in his views, acknowledging that in neighboring state Rhode Island, the ability of the CON program to achieve its goals had been hampered by a number of factors, including significant resource disparities between the state agency and the private entities that sought approval for new projects.¹²⁶ Nonetheless, he maintained that Rhode Island’s CON program, if appropriately funded and supported by leadership in the legislative and executive branches, could still offer the state a valuable mechanism by which to shape the organization and delivery of healthcare services.¹²⁷

¹²⁰ See Simpson, *supra* note 11 at 1080. Simpson also observed that the rate of utilization of institutional services was declining and that the annual rate of cost increases in healthcare expenditures was slowing. *Id.*

¹²¹ *Id.* at 1080.

¹²² Robert B. Hackey, *New Wine in Old Bottles: Certificate of Need Enters the 1990s*, 18 J. HEALTH POL. POL’Y & L. 927, 927 (1993).

¹²³ *Id.* at 929.

¹²⁴ *Id.* at 929–33.

¹²⁵ *Id.* at 933.

¹²⁶ Robert B. Hackey & Peter F. Fuller, *Institutional Design and Regulatory Performance: Rethinking State Certificate of Need Programs*, NEW ENG. J. PUB. POL’Y, Apr. 1998, at 53, 53 (1998).

¹²⁷ *Id.* at 68–69.

There do not appear to be many other researchers who shared Hackey's optimistic views. Rather, the prevailing view seems to have been steadily mounting criticism of CON laws. For example, in 1995, as Connecticut was considering abolishing its CON program, Quinnipiac Law Professor W. John Thomas urged the General Assembly to terminate the program on the grounds that during the two decades in which Connecticut had CON in place, there had been "a wealth of empirical studies indicating that such laws do not produce economic savings," studies which also "produced little evidence to suggest that CON laws have a positive effect on either the quality of or access to healthcare."¹²⁸

In addition, by the mid 1990s, as managed healthcare companies became increasingly prevalent in the insurance market, there were increasing questions as to the relevance of CON under this new payment system. After all, if the purpose of managed care was in fact to manage both care and cost by negotiating lower rates with providers and ensuring appropriate utilization, what additional value would CON bring? In a 1995 note, Patrick McGinley argued for the repeal of Florida's CON law on the grounds that its recently instituted managed competition system rendered the CON program moot, and indeed, that the continuance of the CON program risked the failure of Florida's managed competition strategy.¹²⁹ McGinley argued that if hospitals were protected from competition by CON laws, managed healthcare companies would be severely hamstrung in their ability to negotiate more favorable rates.¹³⁰

In 2001, as Illinois policymakers were engaged in debate about a controversial hospital expansion project, state government attorney Laretta Higgins Wolfson explicitly questioned whether the Illinois CON process had become so tainted by politics that it ought to be abolished.¹³¹ Wolfson observed that "[h]ospitals and market players have accused [the issuing entity] of being politically influenced . . . and . . . influenced by lobbyists rather than healthcare needs."¹³² Indeed, some contemporaneous critics in the national debate alleged that "the process of obtaining a CON has become an enterprise in itself '...becoming so lucrative that it attracts many politicians and former politicians who successfully use their influence to weight the process for those who employ their services."¹³³ Wolfson concluded that in Illinois, "[a]n analysis of CON theory and practices clearly shows that important public health decisions are being made by an entrenched group of men

¹²⁸ W. John Thomas, *Connecticut's Certificate of Need Statute: Time for Reevaluation*, 69 CONN. B.J. 405, 420 (1995). Unsurprisingly, the General Assembly did not terminate Connecticut's CON program, which remains in place today. See Mitchell & Koopman, *supra* note 56.

¹²⁹ Patrick McGinley, Comment, *Beyond Healthcare Reform: Reconsidering Certificate of Need Laws in a "Managed Competition" System*, 23 FLA. ST. U.L. REV. 141, 168 (1995).

¹³⁰ *Id.* at 186–87.

¹³¹ Laretta Higgins Wolfson, *State Regulation of Health Facility Planning: The Economic Theory and Political Realities of Certificates of Need*, 4 DEPAUL J. HEALTHCARE L. 261, 262 (2001).

¹³² *Id.* at 310.

¹³³ *Id.* (citation omitted).

and women, virtually unknown and accountable to no one,” and called for change in the form of research studies to evaluate the premises underlying CON programs.¹³⁴ Moreover, Wolfson argued that in the event the program remained, it would require considerable administrative simplification along with a removal of political influence and the resulting appearance of impropriety.¹³⁵

A 2007 study assessing the perception of Maryland’s CON program through a small-scale survey of hospital administrators found mixed results.¹³⁶ While acknowledging that the survey participants tended to report agreement with the position of their facilities as a CON facility, the authors found that respondents tended to agree there was a relationship between patient volumes and the quality of care.¹³⁷ More interestingly, the survey respondents agreed that CON decisions were influenced by politics, and that the public plays an insignificant role in decision making.¹³⁸ Even with those shortcomings in the program, respondents were concerned that terminating the CON program would lead to at least a short-term flooding of the market with unneeded services.¹³⁹

Although only Wisconsin has reinstated its program after repeal,¹⁴⁰ states that repealed their CON laws have periodically reconsidered the reasons for repeal. For example, a 2006 analysis of the history of California’s CON program and the reasons for its repeal concluded that the program suffered from inadequate staffing and lack of data, which resulted in the program being significantly less effective than if it had been adequately resourced.¹⁴¹ Although the program, initiated in 1969, had attempted to ensure access to quality healthcare and to contain costs by restricting excess hospital capacity, the report concluded that CON was ultimately viewed as a failure, an outcome that was heavily influenced not only by the lack of resources but also because of a number of exceptions that made the program difficult to administer, as well as relative lack of enforcement for noncompliance.¹⁴²

Even today, more than forty years after Congress first adopted national legislation on certificate of need, the debate remains unsettled, though there appears to be widespread acknowledgement that CON programs as administered are essentially unable to be insulated from political influence. Arguing in 2010 in favor of a more evolved model of state health planning rather than turning the healthcare

¹³⁴ *Id.* at 314–15.

¹³⁵ *Id.* at 315.

¹³⁶ Margaret Gillingham & Kathleen Galbraith, *The Role of Certificate of Need Legislation: A Survey*, 19 J. PUB. BUDGETING, ACCT’G & FIN. MGMT. 372 (2007).

¹³⁷ *Id.* at 375.

¹³⁸ *Id.* at 382.

¹³⁹ *Id.*

¹⁴⁰ Mitchell & Koopman, *supra* note 56.

¹⁴¹ CHARLENE WEAR SIMMONS, CAL. RESEARCH BUREAU, HOSPITAL PLANNING: WHAT HAPPENED TO CALIFORNIA’S CERTIFICATE OF NEED PROGRAM?, CRB 06-009, at 1 (2006), <https://www.library.ca.gov/crb/06/09/06-009.pdf> [https://perma.cc/9ALB-EAZ8].

¹⁴² *Id.* at 12.

delivery system over to market forces, John Blum acknowledged the marked distinction between the intent and reality of CON programs:

Somewhere along the journey of C.O.N. laws, these statutes became dominated by process review and evaluation, and the core function of creating state and regional health plans dropped from the agenda of these agencies, or planning was turned over to state bureaucrats whose best efforts were foiled by political realities.¹⁴³

Indeed, a 2010 retrospective article examining the forty-year history of Rhode Island's CON program, written by a former program director, observed that Rhode Island's recent passage of laws bringing physician-operated ambulatory surgery centers and freestanding magnetic resonance imaging ("MRI") and computed topography ("CT") scanning machines under the umbrella of CON was driven primarily by hospitals seeking to erect barriers to external competition for provision of those services rather than a need to restrict competition among providers of those services.¹⁴⁴ In Pennsylvania, a 2011 analysis revealed that even the sunset of the state's CON laws did not mean the end of the component parts of the program, which were quickly reconstituted in different state agencies in response to a desire among state policymakers to continue the program.¹⁴⁵ Following the sunset of the state's CON laws, the state Department of Health announced its intention to strictly construe the quality provisions in its licensing statutes (in addition to obtaining a certificate of need to provide the new services, applicants must also meet certain quality and other standards to be licensed to provide the services), and another state agency developed a new policy under which it would contract only with entities that met standards that were essentially the same as those that existed under the abolished CON program.¹⁴⁶

Most recently in 2015, current FTC Commissioner Maureen K. Ohlhausen characterized certificate of need programs as a "prescription for higher costs."¹⁴⁷ Ohlhausen observed that CON programs were particularly unhelpful to achieving the goals of healthcare market regulation in that they "stand out as an example of regulation that squelches the beneficial effects of competition in healthcare markets without delivering valuable public benefits in return."¹⁴⁸ Noting that the cost-plus

¹⁴³ John D. Blum, *Finding a New Regulatory Pathway for the Old Labyrinth of Health Planning*, 19 ANNALS OF HEALTH L. 213, 216 (2010).

¹⁴⁴ Gerard R. Goulet, *Certificate of Need Over Hospitals in Rhode Island: A Forty-Year Retrospective*, 15 ROGER WILLIAMS U.L. REV. 127, 185–86 (2010).

¹⁴⁵ Carol Brayshaw Longwell & James T. Steele, Jr., *The Rise and Fall of Certificate of Need in Pennsylvania: An Experiment in Healthcare Planning and the Role of the Commonwealth Court*, 21 WIDENER L.J. 185, 193 (2011).

¹⁴⁶ *Id.* at 194–95.

¹⁴⁷ Ohlhausen, *supra* note 3, at 50.

¹⁴⁸ *Id.*

payment methodology that was in existence at the time programs began¹⁴⁹ has been largely abolished in favor of negotiated rates between insurers and providers, Ohlhausen argued that as the “purported market failure that CON laws were designed to fix no longer exists,” it should surprise no one that “it has proven difficult to demonstrate the benefits of a legislative scheme designed to fix an issue overtaken by subsequent events.”¹⁵⁰ She further explained that although the benefits of CON have been difficult to quantify, the negative results are readily apparent—CON laws operate to insulate healthcare providers from “socially beneficial” competition.¹⁵¹ She correctly raises the question as to why CON laws are still on the books in thirty-five states even in the absence of demonstrable success at achieving their original cost containment objectives.¹⁵² The answer, it seems, is a combination of legislative inertia and shifting policy rationales of CON proponents to justify the continued existence of the programs. Ohlhausen observes that CON laws “insulate politically powerful incumbents from market forces, and those providers naturally are loathe to give up the special government preferences that CON laws bestow.”¹⁵³ However, she writes, incumbents cannot directly espouse to legislators that they deserve special protection at the expense of the public interest—so instead, providers have adopted new rationales for the continued existence of CON, among them that the programs allow for improved care of the indigent.¹⁵⁴ This argument must be deconstructed to be understood, because it is not readily apparent how insulation from competition leads to better care for the poor. In essence, incumbents argue that the guarantee of restricted competition allows them to negotiate *higher* prices with private insurance companies, thereby conferring a larger profit margin, which allows for more resources to provide care to poorer patients without insurance.¹⁵⁵ So, there is a cross-subsidization whereby providers, usually hospitals, will charge higher rates to wealthier patients and retain profitable procedures that might otherwise migrate to lower-cost venues (e.g., imaging, outpatient surgical procedures) to subsidize unprofitable areas of the business, including indigent care.¹⁵⁶ The trouble, as Ohlhausen notes, is that this argument has not been proven to be correct—studies have not shown a marked

¹⁴⁹ Under a “cost-plus” methodology, providers of a healthcare service are paid their cost, plus an additional amount, usually calculated as a percentage of cost. See Leemore S. Dafny, *How Do Hospitals Respond to Price Changes?* 1 (Nat’l Bureau Econ. Research, Working Paper No. 9972, 2003), www.nber.org/papers/w9972.pdf [<https://perma.cc/FQS5-PC7T>] (describing evolution from Medicare cost-plus payments to Medicare prospective payment system).

¹⁵⁰ Ohlhausen, *supra* note 3, at 51.

¹⁵¹ *Id.*

¹⁵² *Id.* at 52.

¹⁵³ *Id.*

¹⁵⁴ *Id.*

¹⁵⁵ *Id.*

¹⁵⁶ *Id.*

difference in the provision of indigent care by hospitals in CON states as compared to those in states without the programs.¹⁵⁷

Ohlhausen is careful to distinguish among the circumstances in which CON laws offer the most benefit to incumbent healthcare providers. For example, in areas with stable or declining populations, CON laws would not normally provide much benefit to incumbent providers, as the incentive for new entrants to the market is low.¹⁵⁸ Conversely, in areas of rapid growth in population or demand for healthcare, CON laws restricting entry confer a valuable benefit on incumbents and are likely to increase prices, potentially giving providers a material windfall.¹⁵⁹ Moreover, Ohlhausen notes the unintended impact of CON laws on market efficiency: in a normal market, new entrants would be incentivized to provide services when incumbents either charged excessively high prices or operated at low levels of efficiency.¹⁶⁰ However, the protection of CON laws effectively benefits the weakest providers, who are insulated from the pressures of competition, while higher quality providers likely benefit less from CON due to the lower level of incentive for new provider entry.¹⁶¹ The degree of benefit is also influenced by a number of intertwined variables such as the scope of the CON law (e.g., the number of services regulated and the threshold for triggering a CON requirement), the degree of enforcement, and the probability of new entry or expansion in the absence of a CON law.¹⁶² Importantly, Ohlhausen points out, the degree of benefit to incumbents operates independently of the expected outcome—that is, how well healthcare providers execute their charge to provide indigent care.¹⁶³ Not only do providers reap uneven benefits from CON laws, the degree of benefit appears unrelated to both the level of expected indigent care and the quality of that care.¹⁶⁴ Thus, she surmises that the “poor fit” between CON laws and the goal of providing indigent care demonstrates that arguments by CON proponents that the programs support indigent care claims “appear to be little more than an argument of convenience by politically powerful special interests attempting to protect their historical government perquisites.”¹⁶⁵

A better approach to indigent care, in Ohlhausen’s view, would be for states to fund indigent care costs directly rather than through the hidden costs CON inflicts on the insured public and the market as a whole.¹⁶⁶ While urging that all states repeal their CON laws, she cautions that repeal alone is unlikely to create

¹⁵⁷ *Id.* at 52–53; *see also infra* Section III. C.

¹⁵⁸ Ohlhausen, *supra* note 3, at 52.

¹⁵⁹ *Id.* at 52–53.

¹⁶⁰ *Id.*

¹⁶¹ *Id.*

¹⁶² *Id.* at 53.

¹⁶³ *Id.*

¹⁶⁴ *Id.*

¹⁶⁵ *Id.*

¹⁶⁶ *Id.*

immediate, dramatic results due to what she believes is the “modest drag on the economy” that the laws exert.¹⁶⁷ Ultimately, Ohlhausen concludes that government regulations such as CON, which undermine the “socially beneficial competitive process without returning any offsetting benefits simply cannot be justified.”¹⁶⁸

*C. Research Casts Serious Doubt on the Effectiveness of
Certificate of Need Programs*

When assessing the evidence with regard to the effectiveness of CON programs, it is necessary to examine the research in light of the primary objectives of CON laws. The cost containment rationale is the oldest justification for CON laws, but it has been supplemented by additional policy objectives, such as increasing access to care, particularly for low-income populations, and improving quality among healthcare providers. In general, the evidence base for the ability of CON programs to achieve any of these objectives is weak, although studies vary in design and rigor.

i. CON Programs Do Not Appear to Lead to a
Reduced Healthcare Cost Trajectory

At first glance, it is not apparent how a supply constraint mechanism can result in lower costs for a product. Conventional economic theory suggests that restricting supply of a product does not result in reduced prices—rather, assuming constant demand, prices would increase in the face of decreased supply as more people competed to purchase a product in limited supply. However, healthcare is not a normal product and the market for health services has a number of factors that render it far from efficient. Thus, the theory for the ability of CON programs to contain costs, as noted above, is that by restricting the arms race among healthcare providers to build ever newer and more expensive facilities (e.g., new hospital buildings when an older one will suffice) and to offer newer and more expensive services even when those services are not demonstrably more effective than older treatments (e.g., MRI and CT scans instead of X-rays), CON programs prevent providers from raising prices to reflect the costs of these newer facilities and treatments.¹⁶⁹ This theory was reasonable at the time it was first conceived—when providers were often paid an amount equal to their cost plus a small percentage of that cost, there was no incentive for providers to keep costs low.¹⁷⁰ Thus, it stood to reason that restricting the ability of providers to increase their costs via capital

¹⁶⁷ *Id.*

¹⁶⁸ *Id.*

¹⁶⁹ See Simpson, *supra* note 11 at 1036–37.

¹⁷⁰ See McGinley, *supra* note 129 at 184–86.

expenditures would result in a more reasonable rate of increase in healthcare expenditures.

However, the evidence that CON programs result in lower costs is limited and dated, and there exists some research indicating that CON programs may in fact lead to higher costs. For example, a 2007 study of 1,957 acute care hospitals (based on 1991 data) showed that healthcare costs were, on average, higher in states with CON programs.¹⁷¹ Additional studies have come to similar conclusions. A more rigorous 2010 study, which controlled for more variables than in prior research (e.g., the stringency of a state's CON program), found no statistically significant correlation between the existence of a CON program and cost per hospital admission in a state, and a statistically significant positive correlation between the stringency of a state's CON program and the cost per admission.¹⁷² In essence the authors concluded that CON programs not only failed to correlate to lower costs, they might actually lead to *higher* costs per admission.¹⁷³ Similarly, evidence suggests that when services such as MRI machines and acute care beds are regulated, patients tend to pay more for these services.¹⁷⁴ While a 2014 study found lower hospital cost-inefficiency in CON states than non-CON states, as FTC Commissioner Ohlhausen observed, that particular study did not control for the possibility that the observed differences could be caused by many other differences between states without CON laws, such as market and environmental characteristics, factors which were addressed in the 2010 study.¹⁷⁵

In addition, studies appear to contradict fears about a flooding of the market with unnecessary services following a repeal of CON laws. For example, a 1998 study found no evidence of a surge in acquisition of facilities or in costs following removal of CON regulations.¹⁷⁶ The same study found that mature CON programs were not associated with a significant reduction in per capita costs.¹⁷⁷ And a 2003 study showed that states that repealed their CON laws did not experience significant growth in either nursing home or long-term care costs.¹⁷⁸ When viewed

¹⁷¹ Patrick A. Rivers, et al., *Does Certificate of Need Really Contain Hospital Costs in the United States?*, 66 HEALTH ED. J. 229, 229, 240–41 (2007).

¹⁷² Patrick A. Rivers, et al., *The Effects of Certificate of Need Regulation on Hospital Costs*, J. HEALTHCARE FIN., Summer 2010, at 1, 10–11.

¹⁷³ *Id.* at 11.

¹⁷⁴ Thomas Stratmann & Jake Russ, *Do Certificate-of-Need Laws Increase Indigent Care?* 11–12 (Mercatus Ctr., George Mason Univ., Working Paper No. 14-20, 2014), <http://mercatus.org/publication/do-certificate-need-laws-increase-indigent-care> [<https://perma.cc/SR7C-UEVS>].

¹⁷⁵ Michael D. Rosko & Ryan L. Mutter, *The Association of Hospital Cost-Inefficiency with Certificate-of-Need Regulation*, 71 MED. CARE RES. & REV. 280, 292–94 (2014); see also Ohlhausen, *supra* note 3, at 51.

¹⁷⁶ Christopher J. Conover & Frank A. Sloan, *Does Removing Certificate-of-Need Regulations Lead to a Surge in Healthcare Spending?*, 23 J. HEALTH POL., POL'Y & L. 455, 469 (1998).

¹⁷⁷ *Id.*

¹⁷⁸ David C. Grabowski, et al., *The Effects of CON Repeal on Medicaid Nursing Home and Long-Term Care Expenditures*, 40 INQUIRY 146, 154 (2003).

as a whole, this evidence casts considerable doubt on the proposition that CON programs lead to reduced healthcare expenditures or that their repeal leads to a surge in unnecessary services in the market.

ii. The Evidence That CON Programs Improve Access to Care is Weak

Although some argue that modernizing CON will decrease access to health services, evidence does not appear to support this conclusion, at least when using supply of services as a proxy for access. Admittedly, supply of services is an imprecise metric at best, because the fact that providers are located in a given geographic area does not mean that they are willing to provide services to all patients—the difficulty that the uninsured and patients with Medicaid have finding care, relative to those with private insurance, is well-documented.¹⁷⁹ Nonetheless, when using supply as a proxy for access, the evidence seems to support the conclusion that CON programs restrict access to care. For example, a 2014 study by George Mason University showed that while the average state has 362 hospital beds per 100,000 population, this number falls to 263 hospital beds per 100,000 population in states with CON programs.¹⁸⁰ In states that regulate acute care beds, this number falls to 131 beds per 100,000 population, and this number drops by an average of 4.7 beds for each additional service regulated.¹⁸¹ While limited in scope and rigor, this evidence suggests that the presence of CON programs reduces the capacity of health facilities, and that this effect permeates beyond the regulated services. Thus, restrictive CON programs may decrease access to health services. Similarly, CON proponents argue that the program's support increased access to care for the indigent, via the cross-subsidization principle described above.¹⁸² When repeal of CON laws is proposed, CON supporters warn of an influx of for-profit providers who will cherry-pick the more lucrative, privately insured patients, leaving the nonprofit hospitals with the lower-paying insured patients and the uninsured, ultimately leading to a decrease in the provision of care for the indigent.¹⁸³ A recent study, however, found no evidence that CON programs increase the amount of indigent care provided in a state.¹⁸⁴

¹⁷⁹ See, e.g., Austin Frakt, *Medicaid Patients Have Better Access to Primary Care than You Might Think*, INCIDENTAL ECONOMIST (November 12, 2014, 7:00 AM), <http://theincidentaleconomist.com/wordpress/medicaid-patients-have-better-access-to-primary-care-than-you-might-think/> [<https://perma.cc/8WXP-SZM3>] (describing studies on the relative ability of Medicaid and privately insurance to access care).

¹⁸⁰ See Stratmann and Russ, *supra* note 174, at 10–11.

¹⁸¹ *Id.* at 11.

¹⁸² *Id.* at 2–3.

¹⁸³ *Id.* at 17–18.

¹⁸⁴ *Id.* at 18.

iii. The Relationship Between CON and Quality of Care is Unclear

Proponents of CON programs argue that such programs improve quality by ensuring an adequate volume of patients. And indeed, this argument is based on reliable evidence showing that increased volume of patients does lead to improved outcomes in hospital settings.¹⁸⁵ This is easy to understand—especially when considering, for example, that surgeons who repeatedly perform highly complex, specialized procedures are likely to be better at those procedures than surgeons who perform the same procedure only intermittently.¹⁸⁶ Thus, evidence has shown that patients experience better outcomes in hospitals with expertise (usually measured as higher volume) in particular procedures.¹⁸⁷ Importantly, however, this demonstrated link between volume and quality appears to be independent of the existence of a CON program in a state. Moreover, some evidence suggests that stringent CON programs decrease the quality of care in many settings. For example, a 1988 study of 1,000 hospitals showed higher mortality rates in hospitals in states with stringent CON programs.¹⁸⁸ However, a 2002 study assessing risk-adjusted mortality rates and hospital volumes for Medicare patients undergoing a coronary artery bypass graft (“CABG”) in states with and without CON laws found higher mortality rates in states without certificate of need regulation.¹⁸⁹ In addition, the same study found that repeal of certificate of need regulations during the study period was associated with declines in hospital volume for CABG surgery.¹⁹⁰ A 2007 study examining whether rates of appropriate cardiac catheterization after admission for heart attack varied between states with and without CON regulation of cardiac catheterization found that “CON regulation was associated with modestly lower rates of equivocally and weakly indicated [(a scientific way of saying “potentially unnecessary”)] cardiac catheterization after admission for [heart attack], but [found] no significant differences in rates of strongly indicated catheterization.”¹⁹¹

¹⁸⁵ See, e.g., Himanshu J. Patel, et al., *Aortic Valve Replacement: Using a Statewide Cardiac Surgical Database Identifies a Procedural Volume Hinge Point*, 96 ANNALS THORACIC SURGERY 1560, 1560, 1565 (2013) (finding mortality for aortic valve replacement at high volume hospitals was 2.41% versus 4.34% at low volume hospitals).

¹⁸⁶ *Id.*

¹⁸⁷ *Id.*

¹⁸⁸ See Stephen M. Shortell & Edward F.X. Hughes, *The Effects of Regulation, Competition, and Ownership on Mortality Rates Among Hospital Inpatients*, 318 NEW ENG. J. MED. 1100, 1101, 1102 (1988).

¹⁸⁹ M. S. Vaughan-Sarrazin, et al., *Mortality in Medicare Beneficiaries Following Coronary Artery Bypass Graft Surgery in States With and Without Certificate of Need Regulation*, 288 J. AM. MED. ASS'N 1859, 1859 (2002).

¹⁹⁰ See *id.* at 1859, 1863–64.

¹⁹¹ Joseph S. Ross, et al., *Certificate of Need Regulation and Cardiac Catheterization Appropriateness After Acute Myocardial Infarction*, 115 CIRCULATION 1012, 1014–16 (2007).

More recently, a 2009 study found that states that had dropped CON regulations had lower mortality rates for CABG surgery than states that kept their CON programs.¹⁹² The study concluded that this effect may be the result of the increased fragmentation of care that results from CON programs.¹⁹³ Even a simple analysis conducted solely for illustrative purposes in this paper examining the likelihood of hospital penalization under the Medicare program¹⁹⁴ in states with and without CON programs shows that hospitals in CON states are approximately 50% more likely to be penalized than those in non-CON states.¹⁹⁵ As Figure 1 describes, the average percentage of hospitals that were penalized in states with a CON program was 57.6% , while the average percentage of hospitals penalized in states without a CON program was only 38%, a considerable difference.¹⁹⁶ Again, this simple analysis does not show that CON programs cause hospitals to be penalized; however, the higher rate of penalization in CON states does raise questions for further study in view of prior research on the relationship between quality of care and CON laws.

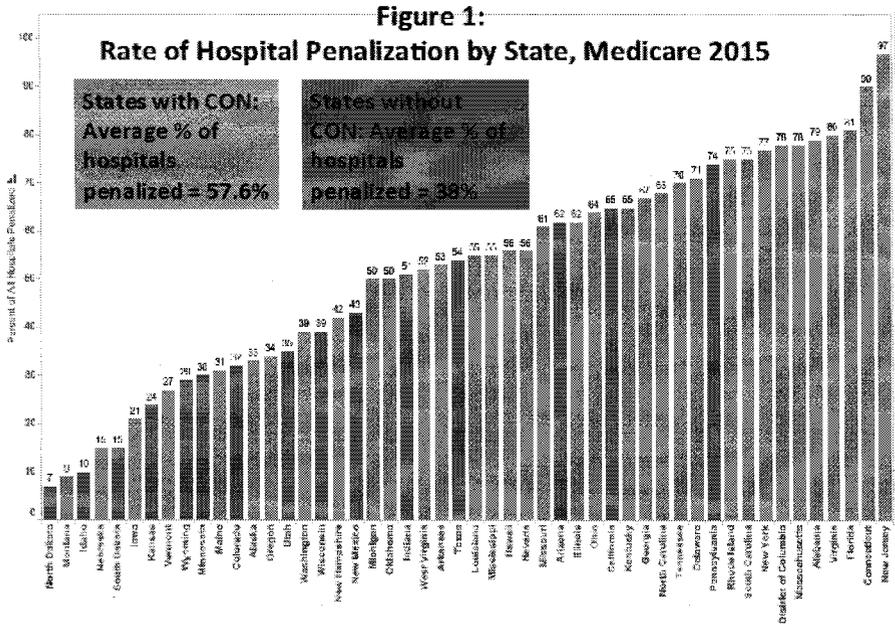
¹⁹² Vivian Ho, et al., *Certificate of Need (CON) for Cardiac Care: Controversy Over the Contributions of CON*, 44 HEALTH SERVS. RES. 483, 493–96 (2009).

¹⁹³ *See id.*

¹⁹⁴ *See Readmissions Reduction Program (HRRP)*, CTRS. FOR MEDICARE & MEDICAID SERVS., <https://www.cms.gov/medicare/medicare-fee-for-service-payment/acuteinpatientpps/readmissions-reduction-program.html> [<https://perma.cc/5RJ5-SS49>] (last modified Apr. 18, 2016, 5:08 PM) (explaining the Affordable Care Act established the “Hospital Readmissions Reduction Program,” which requires CMS to reduce payments to certain hospitals with excess readmissions).

¹⁹⁵ *Compare* Jordan Rau, *Half Of Nation’s Hospitals Fail Again to Escape Medicare’s Readmission Penalties*, KAISER HEALTH NEWS (Aug. 3, 2015), <http://khn.org/news/half-of-nations-hospitals-fail-again-to-escape-medicare-readmission-penalties/> [<https://perma.cc/7SSB-FYVZ>] (stating the percentage of hospitals in each state that are penalized), *with* Cauchi & Noble, *supra* note 1 (determining the likelihood of penalization in CON vs. non-CON states).

¹⁹⁶ *Compare* Rau, *supra* note 195 (stating the percentage of hospitals in each state that are penalized), *with* Cauchi & Noble, *supra* note 1 (determining the likelihood of penalization in CON vs. non-CON states).



Overall, the evidence does not support a conclusion that CON programs improve the quality of patient care, and there exist significant questions deserving of further research regarding the relationship between CON and quality of care.

iv. The Influence of Politics on Certificate of Need Programs

As noted above, stakeholders have consistently identified political influence as a barrier to effective administration of CON programs. Indeed, many stakeholders believe that the political process has prevented CON programs from achieving their objectives, rather than the regulation of the supply of healthcare facilities. For example, a 2009 qualitative study conducted by researchers at the Center for Studying Health System Change (“HSC”) seemed to confirm the influence of politics on the CON process.¹⁹⁷ The researchers characterized modern CON programs as “an arena where providers often battle for service-line dominance and market share,” rather than a neutral process designed to maximize health system efficiency.¹⁹⁸

The study included interviews with respondents from six states with CON laws (Connecticut, Georgia, Illinois, Michigan, South Carolina, and Washington), and

¹⁹⁷ See Yee, et al., *supra* note 81, at 1, 2–3.

¹⁹⁸ *Id.* at 1.

although stakeholder views varied widely about the effectiveness of CON regulations on access, quality and costs, there was consensus “[i]n five of the six states studied—all except Michigan—the CON approval process can be highly subjective and tends to be influenced heavily by political relationships rather than policy objectives.”¹⁹⁹ In particular, respondents believed factors such as a provider’s clout, organizational size, or overall wealth and resources, played more of a role in CON decisions than policy objectives.²⁰⁰ Moreover, state CON officials reported that although the basic function of their job was to process and review applications, they were often “caught in the competitive crossfire between providers during appeals, public hearings and legislative battles.”²⁰¹ Hospitals tended to view the process primarily through a competitive lens, using the process to protect existing market share, either geographic or by service line, and to block competitors from entering their markets.²⁰² However, the researchers noted that hospitals find the CON process onerous if they are attempting to enter a market.²⁰³ Confirming the anticompetitive nature of the process, one hospital respondent said, “[o]nce you have the franchise, you are happy to stop others from having it.”²⁰⁴

While the study respondents were fairly unequivocal about the shortcomings of CON programs, most still believed that they were better off with CON in place.²⁰⁵ One state hospital association respondent noted that while member hospitals initially had mixed views about the benefits of CON, they “banded together to support the process after realizing it was a valuable tool to block new physician-owned facilities.”²⁰⁶ Thus, rather than repeal, respondents concluded that CON programs should remain in place but would benefit from resource and process improvements, including “increased funding for evaluation, improved compliance monitoring and movement toward a process driven more by data and planning rather than political influence.”²⁰⁷ The authors found that respondents believed certain aspects of the Michigan process helped insulate decision making from politics, including a division of responsibility between setting CON review standards (done by an appointed commission that included many different stakeholders) and the actual review of CON applications (conducted by the state Department of Community Health).²⁰⁸

¹⁹⁹ *Id.*

²⁰⁰ *Id.* at 2.

²⁰¹ *Id.* at 3.

²⁰² *Id.* at 4.

²⁰³ *Id.*

²⁰⁴ *Id.*

²⁰⁵ *Id.*

²⁰⁶ *Id.*

²⁰⁷ *Id.* at 1.

²⁰⁸ *Id.* at 2–3.

III. THE ABILITY OF CON PROGRAMS TO SURVIVE CONSTITUTIONAL CHALLENGE

It is not for lack of legal challenge that CON programs remain in place. Opponents have attempted a number of constitutional and other challenges to the laws, but courts have refused to overturn them.

The most obvious and common line of challenge to CON laws is under the Commerce Clause. In *Colon Health Centers of America v. Hazel*, out-of-state providers of medical imaging services challenged Virginia's CON law under the dormant aspect of the Commerce Clause.²⁰⁹ The Fourth Circuit rejected the challenge and affirmed the district court, which found that the law neither discriminated nor placed an undue burden on interstate commerce.²¹⁰ The court first reiterated the well-known standard that a statute that is facially discriminatory or discriminatory in purpose or effect may survive strict scrutiny only if it "advances a legitimate local purpose that cannot be adequately served by reasonable nondiscriminatory alternatives."²¹¹ While the parties agreed the statute was not facially discriminatory, plaintiffs argued that it was discriminatory in purpose, with a primary goal to shelter existing providers (all of whom were, by definition, in-state) from competition at the expense of out-of-state businesses seeking entry into the market.²¹² Rejecting this argument, the court noted that Virginia's CON law served a number of "legitimate public purposes: improving healthcare quality by discouraging the proliferation of underutilized facilities, enabling underserved and indigent populations to access necessary medical services, and encouraging cost-effective consumer spending."²¹³ Accordingly, the court said it could not "discern a sinister protectionist purpose in this straightforward effort to bring medical care to all the citizens of the Commonwealth in the most efficient and professional manner."²¹⁴

Turning to the question of whether the law was discriminatory in effect, the court was equally unconvinced. Plaintiffs alleged that Virginia's law "systematically advantage[d] established in-state providers at the expense of new, primarily out-of-state firms," by impermissibly granting current providers "the authority to thwart the market entrance of out-of-state providers" through participation in the adversarial process as applications were evaluated (existing providers could oppose applications by new entrants at a hearing) and by allowing existing providers to file competing applications to block the approval of new entrants.²¹⁵ The court evaluated these claims with regard to whether the plaintiffs demonstrated that

²⁰⁹ *Colon Health Ctrs. of Am., LLC v. Hazel*, 813 F.3d 145, 149 (4th Cir. 2016).

²¹⁰ *Id.*

²¹¹ *Id.* at 152 (quoting *Or. Waste Sys. v. Dep't of Env'tl. Quality*, 511 U.S. 93, 101 (1994)).

²¹² *Id.* at 152–53.

²¹³ *Id.* at 153.

²¹⁴ *Id.*

²¹⁵ *Id.* (internal quotation marks omitted).

Virginia's CON law, "if enforced, would negatively impact interstate commerce to a greater degree than intrastate commerce," in considering whether the CON law "erects a special barrier to market entry by non-domestic entities,"²¹⁶ but concluded that plaintiffs had not shown that they faced a special hardship compared to in-state providers.²¹⁷ The court noted repeatedly that CON programs are generally policy decisions that are properly the purview of legislators, and although the plaintiffs were frustrated by legislative policy, the court declined to take the "potentially limitless step of striking down every state regulatory program that has some alleged adverse effect on market competition."²¹⁸ As the court observed, "[w]e live in such an interconnected economy that for any regulation some effects are almost bound to be felt out of state. To accept appellants' arguments 'would broaden the negative Commerce Clause beyond its existing scope.'"²¹⁹

Having rejected the plaintiffs' argument, the court determined that the law survived a rational basis review by balancing the putative local benefits against the incidental burdens on state commerce, as required by the Supreme Court in *Pike v. Bruce Church, Inc.*, 397 U.S. 137 (1970).²²⁰ Virginia had put forth a number of rational reasons in support of its CON program, among them the many justifications described above—improvement in healthcare quality, indigent care, ensuring appropriate distribution of services across geographic areas, and even healthcare cost reduction.²²¹ Fundamentally, the court believed that the decision over the merits of CON was a legislative one, observing that while "[t]he battle between laissez fairists and regulators is as old as the hills," these disputes are "more often over economics and politics than over law."²²² Moreover, the court noted, "[l]egislators, not jurists, are best able to compare competing economic theories and sets of data and then weigh the result against their own political valuations of the public interests at stake."²²³

Other circuits have ruled similarly. While there was brief excitement among those who oppose CON following the 2011 ruling in *Yakima Valley Mem'l Hosp. v. Wash. State Dep't of Health* ("*Yakima I*"), in which the Ninth Circuit upheld the dismissal of Sherman Act restraint of trade claims but remanded to the district court to consider a dormant Commerce Clause claim, the feeling was short-lived, as the district court granted summary judgment on the commerce clause claim and the Ninth Circuit affirmed in 2013.²²⁴ In *Yakima II* the plaintiff challenged

²¹⁶ *Id.* (citation omitted).

²¹⁷ *Id.* at 153–54.

²¹⁸ *Id.* at 155.

²¹⁹ *Id.* (quoting *United Haulers Ass'n, Inc. v. Oneida-Herkimer Solid Waste Mgmt. Auth.*, 550 U.S. 330, 348 (2007) (Scalia, J., concurring)).

²²⁰ *Id.* at 156–57.

²²¹ *Id.*

²²² *Id.* at 158.

²²³ *Id.*

²²⁴ *Yakima Valley Mem'l Hosp. v. Wash. State Dep't of Health* ("*Yakima II*"), 731 F.3d 843, 844 (9th Cir. 2013).

regulations related to scheduled, or “elective,” percutaneous coronary interventions (“PCIs”), which are nonsurgical procedures used to treat coronary heart disease.²²⁵ Under the Washington state CON law, elective PCIs could be performed only at hospitals with a minimum annual volume of 300 procedures.²²⁶ Yakima Valley Memorial Hospital claimed that the CON requirement lacked a reasonable basis and that its putative benefits were outweighed by the burden on interstate commerce, in violation of the dormant Commerce Clause.²²⁷ However, similarly to the court in *Colon Health Centers*, the Ninth Circuit had no difficulty finding that the regulation survived the *Pike* balancing test.²²⁸ “Accepting as true [Yakima Valley] Memorial’s arguments and evidence, the burden on interstate commerce is obviously too minor and remote to create a ‘substantial burden’ under *Pike*.”²²⁹ Moreover, the court found that Washington officials had made a reasonable determination in establishing the minimum threshold—acknowledging that courts normally would end the inquiry after determining that the burden on interstate commerce was insignificant, the *Yakima II* court nonetheless examined and decisively rejected the plaintiff’s claims that the safety benefits derived from the threshold established by Washington state were illusory or nonexistent.²³⁰

The only case in which a court has invalidated a CON law under a Commerce Clause theory appears to be a 2005 case addressing Puerto Rico’s CON program as applied to pharmacies. In *Walgreen Co. v. Rullan*, the First Circuit found that Puerto Rico’s CON program impermissibly discriminated against out-of-state pharmacies, based in large part on the fact that Puerto Rico had exempted all of its existing pharmacies from the certificate requirements when the law was enacted (over 92% of which were locally owned), along with significant disparities in treatment of in-state pharmacies and those from out of state.²³¹ The court explained:

While the Secretary has rejected virtually no unopposed applications, twenty-three percent of opposed applications have been denied. The negative effects on out-of-Commonwealth applicants have been particularly pronounced. Over fifty percent of out-of-Commonwealth entities have been forced to undergo the entire administrative process compared to less than twenty-

²²⁵ *Id.*

²²⁶ *Id.* at 847.

²²⁷ *Id.* at 844.

²²⁸ *Id.* at 847–48.

²²⁹ *Id.* at 847.

²³⁰ *Id.* at 848–49. Equal protection claims have fared similarly poorly in court. See *Madarang v. Bermudes*, 889 F.2d 251, 253 (9th Cir. 1989) (“Enforcement of the CON regulations does not violate the equal protection clause of the fourteenth amendment.”). The *Madarang* court also rejected a substantive and procedural due process challenge. *Id.*

²³¹ *Walgreen Co. v. Rullan*, 405 F.3d 50, 55 (1st Cir. 2005).

five percent of local applicants. Moreover, of those applicants forced to endure the hearing process, the Secretary has granted certificates to ninety percent of the local applicants but only to fifty-eight percent of out-of-Commonwealth applicants.²³²

Moreover, the court observed that since the law was enacted in 1979, the percentage of locally owned pharmacies had actually increased, from 92% to 94%, which the court believed was a strong indicator that the CON law as applied had “limited competition in favor of the predominantly local group of existing pharmacies.”²³³

Several factors caution against extrapolation of the court’s ruling in *Rullan* to other CON laws. First, the court found that the primary—and perhaps only—justification the state official gave for denying a certificate was that permitting a new entrant would “cause undue competition for existing facilities.”²³⁴ This is distinct from the justifications offered in the *Yakima II* and *Colon Health*, where states carefully described and documented a litany of policy objectives their CON programs were designed to achieve. Indeed, the *Yakima II* court distinguished *Rullan* on the ground that the Puerto Rico statute in effect protected local pharmacies from out-of-state competition, which was unlike the situation in *Yakima II*, where the in-state hospital was seeking to offer the same service that was already offered by a provider owned by an out-of-state parent.²³⁵ Second, as described above, in *Rullan* there were considerable disparities in the treatment of and outcomes for out-of-state applicants.²³⁶ The court in *Colon Health* believed this to be a meaningful distinction between the two cases.²³⁷ Indeed, it does not appear that any CON laws have been invalidated in whole or in part since *Rullan*.

A final case worth mentioning involves the 1997 invalidation of Iowa’s CON law as applied to abortion facilities. In *Planned Parenthood of Greater Iowa, Inc. v. Atchison*, the Eighth Circuit upheld the district court’s determination that requiring the plaintiff to undergo the CON review process amounted to a substantial and unconstitutional burden on the right of access to abortion.²³⁸ Applying *Planned Parenthood of So. Pa. v. Casey*,²³⁹ the court recognized that CON laws serve legitimate purposes and are constitutional if they impose only the “incidental effect of making it more difficult or more expensive to procure an abortion” and do not “otherwise impose an undue burden on one’s ability to obtain

²³² *Id.* at 56 (internal footnotes omitted).

²³³ *Id.*

²³⁴ *Id.*

²³⁵ *Yakima II*, 731 F.3d at 848.

²³⁶ *Rullan*, 405 F.3d 50 at 55.

²³⁷ *Colon Health Ctrs. of Am., LLC v. Hazel*, 813 F.3d 145, 153–54 (4th Cir. 2016).

²³⁸ *Planned Parenthood of Greater Iowa, Inc. v. Atchison*, 126 F.3d 1042, 1048 (8th Cir. 1997).

²³⁹ *Planned Parenthood of So. Pa. v. Casey*, 505 U.S. 833 (1992).

an abortion.²⁴⁰ However, the court found that state officials subjected plaintiffs to the CON requirement solely because they intended to provide abortion services, and that similarly situated facilities that did not provide abortion services had consistently been exempted from the CON requirement.²⁴¹ As with *Rullan*, the highly specific circumstances of this case caution against attempts to generalize to other challenges to CON laws.

Thus, it appears that CON programs are firmly established in the thirty-five states where they have not been repealed, and will be upheld by courts in the absence of blatantly protectionist measures. Those inclined to reform CON will have to undertake these efforts via the legislative and regulatory process, as courts have steadfastly refused to interject themselves into policy decisions with regard to the structure of state healthcare delivery systems.

IV. CERTIFICATE OF NEED IN THE POST-AFFORDABLE CARE ERA: A CASE STUDY FROM KENTUCKY

A. The Changing Healthcare Landscape: The Affordable Care Act and Value-Based Payment

The United States' healthcare system has changed tremendously in the past decade, driven by a number of factors, the most significant of which are the ACA and the related move toward so-called "value-based payment."²⁴² On March 23, 2010, President Obama signed the ACA into law.²⁴³ The ACA was intended to provide all persons in the *United States* with guaranteed access to affordable healthcare by fixing the "patchwork" United States system, filling in gaps in the existing framework by: eliminating the ability of insurance companies to discriminate based on pre-existing conditions and strictly limiting pricing based on age; requiring individuals who lack access to an affordable employer-based insurance option to purchase private insurance (with subsidies for individuals from 100 to 400% of the Federal Poverty Level ("FPL")); and expanding eligibility for Medicaid to include all adults with income less than 138% of the FPL.²⁴⁴

²⁴⁰ *Archison*, 126 F.3d at 1048, 1049.

²⁴¹ *Id.* at 1046.

²⁴² See Patient Protection and Affordable Care Act, Pub. L. No. 111–148, 124 Stat. 119 (2010), amended by Healthcare and Education Reconciliation Act of 2010, Pub. L. No. 111–152, 124 Stat. 1029 (2010) (codified in scattered sections of Title 26 and 42 of the U.S.C.); see also MELINDA ABRAMS, ET AL., *THE AFFORDABLE CARE ACT'S PAYMENT AND DELIVERY SYSTEM REFORMS: A PROGRESS REPORT AT FIVE YEARS*, COMMONWEALTH FUND 10 (May 2015), http://www.commonwealthfund.org/~media/files/publications/issue-brief/2015/may/1816_abrams_aca_reforms_delivery_payment_rb.pdf [<https://perma.cc/LP4H-UFTH>].

²⁴³ Patient Protection and Affordable Care Act, Pub. L. No. 111–148, 124 Stat. 119 (2010), amended by Healthcare and Education Reconciliation Act of 2010, Pub. L. No. 111–152, 124 Stat. 1029 (2010) (codified in scattered sections of Title 26 and 42 of the U.S.C.).

²⁴⁴ *Id.*

If the ACA was fully implemented, the overwhelming majority of United States residents²⁴⁵ would be able to access affordable healthcare, with thirty-two million people projected to acquire insurance after implementation at the time the law was passed.²⁴⁶ The ACA has been tremendously controversial and the subject of multiple lawsuits, including *National Federation of Independent Business v. Sebelius*, in which the Supreme Court upheld the constitutionality of the law's individual mandate provision but ruled that states had the option whether to expand their Medicaid programs to cover individuals below 138% of the FPL.²⁴⁷ Although states have varied significantly in their implementation of the ACA,²⁴⁸ the United States has seen a material expansion of insurance coverage since the law's primary coverage provisions came into effect in 2014, with an estimated 20 million individuals obtaining insurance coverage.²⁴⁹

Thus, the healthcare landscape has altered significantly—for example, in Kentucky, the rate of uncompensated care provided by hospitals has dropped sharply since the ACA, reflecting that many individuals who were formerly uninsured are now covered by Medicaid or private insurance plans.²⁵⁰ These changes have implications for CON programs. In particular, one of the historic justifications for continuation of CON programs has been, in essence, that providers, especially safety-net hospitals, require protection from competition in order to maintain sufficiently profitable services (from privately insured patients) to subsidize the uncompensated care that they provide to the indigent.²⁵¹ This rationale is materially less persuasive when the poor are now insured via Medicaid,

²⁴⁵ Under the Affordable Care Act, undocumented residents are neither eligible for the Medicaid expansion nor federal subsidies to purchase insurance via the exchanges established under the Affordable Care Act. 26 U.S.C. § 5000A(d)(3) (2016) (stating that the mandate does not apply to undocumented immigrants); Affordable Care Act § 1312(f)(3) (banning undocumented immigrants from purchasing insurance via exchanges). In addition, the law bans undocumented residents from purchasing insurance on the exchanges solely at their own expense. *Id.*

²⁴⁶ Letter from Douglas Elmendorf, Dir., Cong. Budget Office, to Nancy Pelosi, Speaker, U.S. House of Representatives (Mar. 20, 2010), <http://www.cbo.gov/ftpdocs/113xx/doc11379/AmendReconProp.pdf> [<https://perma.cc/TN4J-PEF2>].

²⁴⁷ *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 132 S. Ct. 2566, 2580, 2608 (2012).

²⁴⁸ The drop in uninsured rates has varied significantly across the states. See Barack Obama, *United States Healthcare Reform: Progress to Date and Next Steps*, 316 J. AM. MED. ASS'N 525, 527, 530 (2016), <http://jama.jamanetwork.com/article.aspx?articleid=2533698> [<https://perma.cc/7GVS-ES37>]. For example, thirty two states and the District of Columbia have chosen to expand their Medicaid programs; the remaining states have not. *Current Status of State Medicaid Expansion Decisions*, KAISER FAM. FOUND. (Oct. 14, 2016), <http://kff.org/health-reform/slide/current-status-of-the-medicaid-expansion-decision/> [<https://perma.cc/YJH3-5J46>].

²⁴⁹ Obama, *supra* note 248, at 527.

²⁵⁰ See *Study of the Impact of the ACA Implementation in Kentucky, Quarterly Snapshot: January - March 2015*, FOUND. FOR A HEALTHY KY., https://www.healthky.org/res/images/resources/SHADAC_ACA-Impact-Study_Quarterly-Snapshot-Q12015_0-1-.pdf [<https://perma.cc/2MJ6-P33A>] (last visited Nov. 11, 2016).

²⁵¹ See Ohlhausen, *supra* note 3, at 50, 52.

which allows hospitals and other providers to be reimbursed for the services they provide.

Similarly, the federal government has led a movement away from “fee for service” (“FFS”) reimbursement, in which healthcare providers are reimbursed for specific services they provide without reference to the quality of those services, whether the service was truly necessary, or the patient outcome as a result of the service. Recognizing that the FFS system created economically undesirable incentives for healthcare providers and failed to reward higher quality providers for delivering efficient care, the Centers for Medicare and Medicaid Services (“CMS”) has undertaken a robust effort to reform the way in which the Medicare program pays for healthcare services. CMS has several value-based payment programs, some optional and others mandatory, and this Article will not describe them in detail.²⁵² For purposes of this Article, it is sufficient to observe that under these value-based payment programs, healthcare providers who treat Medicare patients (which is most healthcare providers in the United States)²⁵³ either currently or will soon receive at least a portion of their payment under a payment system that incorporates measures of the value of the care delivered. Before the ACA, almost no Medicare payments were made under value-based payment models. However, the payment landscape has changed dramatically in the past several years. For example, since 2012, CMS has penalized hospitals a portion of their Medicare reimbursements if they fail to meet quality standards with regard to the rate of readmission following certain procedures.²⁵⁴

The Obama Administration has established aggressive goals to increase the percentage of Medicare payments that are made under value-based structures; the Department of Health and Human Services (“HHS”), which oversees CMS, has set a goal of tying 30% of FFS Medicare payments to quality or value through alternative payment models by the end of 2016,²⁵⁵ and tying 50% of payments to

²⁵² Interested readers should visit the CMS website to learn more about value-based payment. See *What Are Value-Based Programs?*, CTRS. FOR MEDICARE & MEDICAID SERVS., <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/Value-Based-Programs.html> [<https://perma.cc/E4NE-4FZX>] (last visited Nov. 11, 2016).

²⁵³ See Cristina Boccuti, et. al., *Medicare Patients' Access to Physicians: A Synthesis of Evidence*, KAISER FAM. FOUND. (Dec. 10, 2013), <http://kff.org/medicare/issue-brief/medicare-patients-access-to-physicians-a-synthesis-of-the-evidence/> [<https://perma.cc/7V4R-GY99>] (finding that 91% of non-pediatric physicians reported accepting new Medicare patients).

²⁵⁴ See *CMS Final Rule to Improve Quality of Care During Hospital Inpatient Stays*, CTRS. FOR MEDICARE AND MEDICAID SERVS. (Aug. 2, 2013), <https://www.cms.gov/newsroom/mediareleasedatabase/fact-sheets/2013-fact-sheets-items/2013-08-02-3.html> [<https://perma.cc/FYK5-LJS3>].

²⁵⁵ Press Release, Dep't of Health and Human Servs., HHS Reaches Goal of Tying 30 Percent of Medicare Payments to Quality Ahead of Schedule (Mar. 3, 2016), <http://www.hhs.gov/about/news/2016/03/03/hhs-reaches-goal-tying-30-percent-medicare-payments-quality-ahead-schedule.html> [<https://perma.cc/UM34-YMAE>].

these models by the end of 2018.²⁵⁶ In addition, HHS also established a “goal of tying 85 percent of all traditional Medicare payments to quality or value by 2016 and 90 percent by 2018 through programs such as the Hospital Value Based Purchasing and the Hospital Readmissions Reduction Programs.”²⁵⁷ Given that Medicare comprises a large share of the healthcare expenditures in the United States (approximately 20% in 2014),²⁵⁸ the flow-through effects on the business models of healthcare providers can be expected to be significant as private insurers and eventually state Medicaid plans follow suit.²⁵⁹

In short, the post-ACA healthcare market looks very different. This is true whether a state has embraced healthcare reform or resisted it. Accordingly, the historic rationale for CON programs, much of which rested on a foundation of (1) a large uninsured population requiring significant uncompensated care from providers and (2) a market in which providers were reimbursed under a FFS payment structure, must now be reexamined in view of the shifted coverage and payment landscape. Policy objectives such as cost containment via supply restrictions (on the theory that a bed built is a bed filled) and preventing overutilization of high-cost services are significantly less relevant when payment is based on the value of the service delivered rather than the quantity of services provided. Similarly, enabling cross-subsidization of profitable services to support the provision of indigent care becomes less necessary when the uninsured population is significantly reduced.

B. Case Study: Modernization of the CON Program in Kentucky

In Kentucky, as in the thirty-five other states that retain CON programs, there

²⁵⁶ Press Release, Dep’t of Health and Human Servs., Better, Smarter, Healthier: In Historic Announcement, HHS Sets Clear Goals and Timeline for Shifting Medicare Reimbursements from Volume to Value (Jan. 26, 2015), <http://www.hhs.gov/about/news/2015/01/26/better-smarter-healthier-in-historic-announcement-hhs-sets-clear-goals-and-timeline-for-shifting-medicare-reimbursements-from-volume-to-value.html> [https://perma.cc/SQ87-9EHC].

²⁵⁷ *Id.* For more detail on these programs, see generally *Readmissions Reduction Program (HRRP)*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Apr. 18, 2016, 5:08 PM), <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Readmissions-Reduction-Program.html> [https://perma.cc/92HN-3F2V]; *Hospital Value-Based Purchasing*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Oct. 30, 2015, 2:33 PM), <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/hospital-value-based-purchasing/index.html> [https://perma.cc/P6LF-F86S].

²⁵⁸ *NHE Fact Sheet*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Aug. 10, 2016, 4:51 PM), <https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/nationalhealthexpenddata/nhe-fact-sheet.html> [https://perma.cc/DT44-G5ZH].

²⁵⁹ Indeed, some state Medicaid plans are already adopting value-based payment models in their programs. See *The State Innovation Models (SIM) Program: A Look at Round 2 Grantees*, KAISER FAM. FOUND. (Sept. 25, 2015), <http://kff.org/medicaid/fact-sheet/the-state-innovation-models-sim-program-a-look-at-round-2-grantees/> [https://perma.cc/QH37-FURQ].

has been no political will for repeal of the CON laws among either party.²⁶⁰ There was widespread acknowledgement among policymakers and stakeholders, however, that the CON program was ripe for modernization in view of the changing coverage and payment landscapes.²⁶¹ Accordingly, the administration of Governor Steven L. Beshear undertook a thorough examination of Kentucky's CON program to identify ways to evolve the program to meet the needs of the post-ACA environment.²⁶²

i. Kentucky's Certificate of Need Program Prior to the Affordable Care Act

Kentucky first enacted CON laws in 1972.²⁶³ Since that time, the program has undergone minor revisions, such as a 2012 amendment that exempted certain long-term care facilities from the certificate of need process.²⁶⁴ Today, Kentucky requires most types of healthcare providers to obtain a certificate of need before providing health services. These services include the following:²⁶⁵

- Acute hospital beds
- Comprehensive rehabilitation
- Inpatient psychiatric facilities
- Residential psychiatric facilities
- Nursing facilities
- Home health agencies
- Hospice services
- Residential hospice services
- Cardiac catheterization services
- Ambulatory surgical centers
- Chemical dependency centers
- Private duty nursing
- Neonatal care centers
- Open heart programs
- Transplant programs
- Magnetic resonance imaging
- Positron emission tomography
- Megavoltage radiation equipment

²⁶⁰ See DELOITTE, THE COMMONWEALTH OF KENTUCKY HEALTHCARE FACILITY CAPACITY REPORT 52 (2013), http://healthbenefitexchange.ky.gov/Documents/KY_Health_Care_Facility_Capacity_Report_2013_%5B2%5D.pdf [<https://perma.cc/R9CH-THW9>] [hereinafter KENTUCKY HEALTHCARE FACILITY CAPACITY REPORT].

²⁶¹ Special Memorandum from the Ky. Cabinet for Health & Family Servs. Office of Health Policy, Certificate of Need Modernization: Core Principles Request for Stakeholder Input (Oct. 8, 2014), <http://chfs.ky.gov/NR/rdonlyres/A8B19E4D-2B97-44C1-A461-9E8D3BEACD94/0/SpecialMemorandumCONModernization.doc> [<https://perma.cc/6BVT-HEJN>] [hereinafter Special Memorandum from Ky. Cabinet].

²⁶² See, e.g., KENTUCKY HEALTHCARE FACILITY CAPACITY REPORT, *supra* note 260, at 7–10.

²⁶³ Christopher Koopman, et al., *Certificate-of-Need Laws: Implications for Kentucky*, MERCATUS CTR. (May 26, 2015), <https://www.mercatus.org/publication/certificate-need-laws-implications-kentucky> [<https://perma.cc/P7W2-XX4Z>].

²⁶⁴ See H.B. 388, Reg. Sess. (Ky. 2012).

²⁶⁵ DELOITTE, *supra* note 260, at 7.

The process by which a potential provider can obtain a CON in Kentucky is governed by both statute²⁶⁶ and regulation.²⁶⁷ The Cabinet for Health and Family Services is empowered, under KRS § 216B.040(3)(e) and the pursuant regulations, to create a procedure to review CON applications.²⁶⁸ The Cabinet must review applications that require formal review within ninety days of issuing a public notice regarding a hearing.²⁶⁹ The ninety-day review period follows the date of public notice, which gives interested parties notice that an application is being reviewed.²⁷⁰ Applications are reviewed in batches, with applications for similar services being reviewed together.²⁷¹ Hearings are conducted by administrative law judges, who enter a final decision on behalf of the Cabinet.²⁷² Decisions of the administrative law judges may be reviewed by state circuit courts.²⁷³ A hearing may or may not be requested by affected parties after the public notice.²⁷⁴ At a hearing, affected parties—including, but not limited to, the original applicant—may participate.²⁷⁵ Whether a party is “affected” has been the subject of litigation. For example, a Kentucky court found that a hospital lacked standing to challenge the application of a birthing center, because the services provided for childbearing at the hospital were materially different than those at a birthing center.²⁷⁶ But, affected parties often include other health service providers in the area.²⁷⁷

When formally reviewing CON applications, the Cabinet looks to ensure that applications meet criteria described in section 216B.040(2)(a) of the Kentucky Revised Statutes and title 900, section 6:065 of the Kentucky Administrative Regulations. These criteria place the burden on an applicant to produce evidence of five criteria,²⁷⁸ described in Figure 2, on the following page:

²⁶⁶ See KY. REV. STAT. ANN. § 216B.010-990 (West 2016).

²⁶⁷ See 900 KY. ADMIN. REGS. 5:020, 6:020-6:130 (2016).

²⁶⁸ See KY. REV. STAT. ANN. § 216B.040(3)(e) (West 2016).

²⁶⁹ 900 KY. ADMIN. REGS. 6:065, 6:090 (2016).

²⁷⁰ 900 KY. ADMIN. REGS. 6:065 (2016).

²⁷¹ KY. REV. STAT. ANN. § 216B.062 (West 2016).

²⁷² 900 KY. ADMIN. REGS. 6:090 (2016).

²⁷³ KY. REV. STAT. ANN. § 216B.115(1) (West 2016).

²⁷⁴ KY. REV. STAT. ANN. § 216B.085 (West 2016).

²⁷⁵ *Id.*

²⁷⁶ *Visitation Birth & Family Wellness Ctr., Inc. v. Cabinet for Health & Family Servs.*, No. 13-CI-01013 (Ky. Cir. Feb. 23, 2015), <http://birthmonopoly.com/bmp/wp-content/uploads/2015/02/Circuit-Court-Decision.pdf> [<https://perma.cc/RC5S-9GL4>].

²⁷⁷ *Id.*

²⁷⁸ KY. REV. STAT. ANN. § 216B.040(2)(a) (West 2016).

Figure 2. Summary of Certificate of Need Requirements in Kentucky²⁷⁹

Consistency with the State Health Plan	Need and accessibility	Interrelationships and linkages	Costs, economic feasibility, and resource availability	Quality of care
The state health plan establishes annual CON review standards. The applicant must show the proposed facility is consistent with the state’s assessment of need for various health services.	The proposal must meet an identified need in a defined geographic area and be accessible to all residents of the area.	The proposal must serve to accomplish appropriate and effective linkages with other services, facilities, and elements of the healthcare system in the region and state, accompanied by assurance of effort to achieve comprehensive care, proper utilization of services, and efficient functioning of the healthcare system.	The proposal, when measured against the cost of alternatives for meeting needs, must be an effective and economical use of resources, not only of capital investment, but also ongoing requirements for health manpower and operational financing.	The applicant must be prepared to and capable of undertaking and carrying out the responsibilities involved in the proposal in a manner consistent with appropriate standards and requirements assuring the provision of quality healthcare services, as established by the Cabinet.

ii. The Need for Modernization of the CON Program

As described in Section IV.A. above, the healthcare environment in the United States has undergone enormous changes in the past decade, particularly since enactment of the ACA.²⁸⁰ In Kentucky, it was apparent that one of the most important changes likely to result from the implementation of the ACA was an

²⁷⁹ This figure was constructed with data from KY. REV. STAT. ANN. § 216B.040(2)(a) (West 2016).

²⁸⁰ See *supra* Section IV.A.

increase in the number of individuals accessing health services over ensuing years, particularly immediately following the expansion of insurance coverage to more Kentucky residents.²⁸¹ As part of its ACA implementation effort, Kentucky contracted with an independent consulting firm to conduct a thorough review of Kentucky's healthcare facility capacity to determine whether Kentucky had in place the healthcare infrastructure to meet the current and anticipated future need for services for its residents (the "Facility Capacity Study").²⁸²

The Facility Capacity Study had several important findings. Among them, projections of changes in healthcare utilization rates as a majority of the 640,000 uninsured Kentuckians (prior to January 1, 2014, when the ACA's insurance coverage provisions became effective), gained coverage either through Medicaid expansion or private health insurance in the years following ACA implementation.²⁸³ The study concluded that the shift in coverage would result in a shift in utilization, with the use of inpatient services increasing by 6% and the use of outpatient services increasing by 3% by 2017.²⁸⁴ The study identified several shortcomings in Kentucky's existing delivery system. In particular, the study documented excess capacity in acute care settings (inpatient hospital beds), projecting a decline of as much as 5% in the demand for inpatient acute care by 2017, even after accounting for impacts of population growth and coverage expansion due to the ACA.²⁸⁵ The study also observed that the national use rate for outpatient surgery was 56% higher than the Kentucky rate; similarly, ambulatory surgical facilities in the Commonwealth were experiencing high utilization.²⁸⁶ The study also projected a need for additional home health capacity in order to meet a projected 14% increase in demand for home health services.²⁸⁷ Finally, the study found a need for more home and community based services to support the transition of patient care from facilities to the community.²⁸⁸

Unsurprisingly, the study concluded that the Commonwealth's CON program has slowed health facility expansion, and identified ambulatory surgical centers as a particular example of this artificially slowed growth.²⁸⁹ Of the forty-three applications for ambulatory surgical center CONs since 2003, two were approved, eighteen were denied, revoked, deferred or withdrawn, and twenty-three were approved under a nonsubstantive review process, an expedited process that applies only in limited circumstances.²⁹⁰ The ASC applicants approved under the

²⁸¹ DELOITTE, *supra* note 260, at 11.

²⁸² *Id.* at 7.

²⁸³ *Id.*

²⁸⁴ *Id.* at 18–19.

²⁸⁵ *Id.* at 27.

²⁸⁶ *Id.* at 45–46.

²⁸⁷ *Id.* at 71.

²⁸⁸ *Id.* at 77–78.

²⁸⁹ *Id.* at 58.

²⁹⁰ *Id.* at 109; *see also* 900 KY. ADMIN. REGS. 6:075 (2016) (providing for nonsubstantive review); KY. REV. STAT. ANN. § 216B.015(18) (West 2016) (defining "nonsubstantive review").

nonsubstantive review process consisted largely of applications from facilities with existing CONs who sought to make minor changes to their facilities, such as location and cost escalations on existing projects.²⁹¹ Thus, the evidence in the report suggested that of the twenty new providers seeking to enter the health market, 90% were denied entry.²⁹²

The Facility Capacity Study contained a number of recommendations, several of which related to the Kentucky CON program. Given a documented need for additional home health services, the study recommended that the Commonwealth consider the discontinuation of the requirement that home health agencies obtain a CON.²⁹³ The study documented excess capacity and market distortion resulting from partial regulation of MRIs (only certain MRI providers were required to obtain CON approval; others who already possessed a CON for MRIs could add another MRI machine without obtaining a CON); accordingly, the study recommended that the Commonwealth consider discontinuing the CON program for certain types of imaging, including MRIs.²⁹⁴ In view of the shortage of ambulatory surgery capacity described above, the study also recommended possible suspension, discontinuation, or relaxation of the CON program in relation to ambulatory surgery centers.²⁹⁵

iii. The Modernization Process in Kentucky

Rather than simply accepting the recommendations of the Facility Capacity Study, the Cabinet for Health and Family Services undertook a year-long process of stakeholder input and revision to the existing State Health Plan, which outlines

²⁹¹ DELOITTE, *supra* note 260, at 109.

²⁹² *See id.*

²⁹³ *Id.* at 86.

²⁹⁴ *Id.* at 98–105.

²⁹⁵ *Id.* at 110.

the numerical need criteria by which applications are assessed.²⁹⁶ On October 8, 2014, the Cabinet announced its intention to critically review Kentucky's CON program.²⁹⁷ As a first step, the Cabinet identified seven guiding principles for the modernization process, described in Figure 3 below, with an overarching vision of identifying reforms that would enable Kentucky to develop a health system that could achieve the so-called "Triple Aim: better value, better care, and population health improvement."²⁹⁸ Stakeholders were invited to submit comments in writing or at either of two listening sessions held by Cabinet officials, and the Cabinet requested that proposals specifically identify how they would further one or more of the goals outlined in the guiding principles.²⁹⁹

Figure 3. Summary of Guiding Principles of Kentucky CON Modernization³⁰⁰

- *Supporting the Evolution of Care Delivery.* The trend is decisively away from a high-overhead acute/inpatient model to an outpatient-centric model. Thus, the CON program will seek to give healthcare facilities the ability to respond to market trends in a timely fashion, enabling the continued service

²⁹⁶ In a particularly unusual twist, Kentucky's CON program is currently structured to consider the question of the need for a particular service twice. Section 216B.040(2)(a) of the Kentucky Revised Statutes requires the Cabinet for Health and Family Services to establish criteria for the issuance and denial of certificates of need and limits review to certain considerations. KY. REV. STAT. ANN. § 216B.040(2)(a) (West 2016). The first consideration is "Consistency with plans" which requires that "[e]ach proposal approved by the Cabinet shall be consistent with the State Health Plan, and shall be subject to biennial budget authorizations and limitations, and with consideration given to the proposal's impact on healthcare costs in the Commonwealth." *Id.* Thus, all applications are first evaluated for consistency with the State Health Plan, which contains formulas and other criteria to determine whether there is a documented need for a particular service. *Id.* However, there is also a separate and additional review criterion called "need and accessibility," which requires proposals to "meet an identified need in a defined geographic area and be accessible to all residents of the area." *Id.* Critics of the CON program documented many instances in which the State Health Plan formula showed that a service was needed, yet existing providers opposed an application on the ground that they could meet the existing need without introduction of a new provider into the market. *See, e.g., Public Hearing on 900 KAR 5:020 and 900 KAR 1:055 Before the Commonwealth of Kentucky Cabinet for Health and Family Servs.* 20 (June 22, 2015, 9:00 AM) (statement of Brian Lebanion, Professional Home Healthcare Agency, Inc. & Friends and Companions Adult Day Care Health). Applications were routinely denied on this ground (failure to prove need and accessibility), yet there exists no enforcement mechanism to ensure that the additional need will in fact be met by existing providers. *Id.* For that reason, the state considered issuing a new regulation pursuant to which providers who demonstrated consistency with the State Health Plan would receive a rebuttable presumption of compliance with the "need and accessibility" criteria; however, this regulation was withdrawn prior to the end of the Beshear administration. *See* 900 KY. ADMIN REGS. 6:070 (filed Aug. 14, 2014, 1:00 PM) (amended after comments), <http://chfs.ky.gov/NR/rdonlyres/8ED9C4F8-5241-41F2-AE93-918BE794C934/0/900KAR6070A.mendedafterCommentsCONconsiderationsforformalreview.pdf> [<https://perma.cc/6VKJ-ZC6T>].

²⁹⁷ Special Memorandum from Ky. Cabinet, *supra* note 261.

²⁹⁸ *Id.*

²⁹⁹ *Id.*

³⁰⁰ *Id.*

of local communities in a changing healthcare environment.

- *Incentivizing Development of a Full Continuum of Care.* 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. Payment structures are evolving to reflect these goals; therefore, the CON program will work to promote and support providers and facilities that seek to develop a robust continuum of care alone or in partnership with others.
- *Incentivizing Quality.* Healthcare is rapidly moving toward adoption of objective quality metrics. Thus, the CON program will seek to support those providers that demonstrate attainment of robust quality indicators.
- *Improving Access to Care.* For a number of reasons, Medicaid members have, on average, a more challenging path toward access to care. Thus, the CON program will seek to incorporate strategies that will incentivize greater access to care for Medicaid members, the newly insured and the remaining uninsured.
- *Improving Value of Care.* As healthcare transitions from a fee-for-service model to a value-based purchasing framework, payers will continue to seek evidence of value in health services. Thus, the CON program will seek to incentivize both price transparency and demonstrable value from health professionals and facilities.
- *Promoting Adoption of Efficient Technology.* 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. Thus, the CON program will seek to incentivize adoption of technologies deemed to further improve value in Kentucky's health system.
- *Exempting Services for which CON is no longer necessary.* Kentucky regulates via CON many services that even CON states exempt. Thus, Office of Health Policy will seek to focus on strategies to modernize Kentucky's CON program to be more reflective of modern healthcare trends.

iv. Stakeholder Input on CON Modernization

More than fifty individuals and organizations attended the listening sessions, and written comments were submitted by nearly sixty discrete entities representing hundreds of stakeholders, including large statewide organizations such as the

Kentucky Hospital Association, the Kentucky Primary Care Association, the Kentucky Association of Healthcare Facilities, and many others.³⁰¹ Key themes from the comments are consistent with those that have been identified in other states: allowing for provision of indigent care, supporting higher quality services via the prevention of excess market dilution, promotion of market stability, and helping to contain costs. Key themes from select stakeholder groups are summarized below.³⁰²

- *Comments from Hospitals:* Comments from hospitals and hospital associations tended to be supportive of the current CON program and opposed to significant changes. These comments focused on the stability provided by the CON program and questioned whether CON modernization was necessary to achieve healthcare innovation. Yet several comments suggested piecemeal policy changes to improve the CON program, such as exempting diagnostic modalities like MRIs from CON requirements. Other suggested policy changes included providing preferential treatment for CON applicants who will serve a designated number of Medicaid patients and requiring health facilities to disclose information about proposed prices in the CON application process in an effort to promote price transparency and competition.
- *Comments from Community-Based Service Providers:* Home and community-based health providers were split on the necessity of continuing the CON program for these services. While some commented on the importance of maintaining the program, others noted that CON should be limited to high-risk projects with a large capital investment, a category that does not include services such as home health. Many long-term care providers expressed the belief that it is important to continue to regulate long-term care via CON. These providers made several suggestions about how to modify the CON program to achieve the Cabinet's goals, including exemptions to allow providers to shift beds from low-utilization service areas to high-utilization service areas without submitting an additional application.
- *Comments from Other Stakeholders:* Other stakeholders—including professional organizations, industry groups, and charitable foundations—offered a variety of comments regarding the CON modernization process. Many of these comments suggested exempting certain services, such as birth centers and home health services, from the CON application

³⁰¹ See generally *CON Modernization*, KY. CABINET FOR HEALTH & FAM. SERVS., <http://www.chfs.ky.gov/ohp/con/conmod.htm> [<https://perma.cc/5V6B-DNVN>] (last updated July 14, 2015) (containing links to the written comments received and links to videos of the listening sessions).

³⁰² For full stakeholder online comments, see *CON Modernizations Comments*, KY. CABINET FOR HEALTH & FAM. SERVS., <http://www.chfs.ky.gov/ohp/con/conres.htm> [<https://perma.cc/6K8L-XZA4>] (last updated Mar. 30, 2015).

process. These comments also emphasized the importance that the Cabinet proceed cautiously with CON modernization so as to ensure that all changes reflect existing evidence and current patient need.

v. The Reforms to the CON Program

In May 2015, the Cabinet proposed several reforms to the CON process via a revised State Health Plan, which became effective in October 2016. These reforms can broadly be lumped into three categories: use of uniform review criteria to promote increased use of electronic medical records and health information exchanges; exemption of certain services from the State Health Plan; and preferential treatment for providers who meet certain objective quality metrics or participate in value-based payment programs.³⁰³

a. Uniform Review: Criteria for All Applications

The revised State Health Plan includes a requirement for all applicants for a certificate of need to meet several criteria:

- All new applicants are required to demonstrate a plan for indigent and medically underserved patients in the proposed service area;
- All applicants who propose to expand existing services (or add beds) are required to document not only the existence of a signed participation agreement with the Kentucky Health Information Exchange (KHIE),³⁰⁴ but also active participation in the exchange via submission of summary of care records and accessing of data and information from KHIE for care coordination if the existing service has an electronic health record; and
- All new providers must document the existence of a signed participation agreement with KHIE and submit summary of care records as well as access data and information from KHIE for care coordination within twelve (12) months of licensure.³⁰⁵

³⁰³ 900 KY. ADMIN. REGS. 5:020 (2015), *amended by* 900 KY. ADMIN. REG. 5:020E (2016).

³⁰⁴ The Kentucky Health Information Exchange is a “common, secure electronic information infrastructure,” which “meets national standards to ensure interoperability across various health systems and connectivity to the National Health Information Network,” thereby affording healthcare providers “the functionality to support preventive health and disease management through alerts, messaging and other tools.” *About KHIE*, KY. HEALTH INFO. EXCHANGE, <http://khie.ky.gov/Pages/aboutkhie.aspx> [<https://perma.cc/K3WQ-42AH>] (last visited Nov. 12, 2016).

³⁰⁵ 900 KY. ADMIN. REGS. 5:020 §§ I.C., III.A., III.B., V.B. (2015), *amended by* 900 KY. ADMIN. REGS. 5:020E (2016).

Together, these provisions require providers to undertake meaningful participation in KHIE, with the ultimate objective of increasing care coordination of patients.³⁰⁶ For example, if a patient arrives at a hospital, the hospital should be able to access the patient's medical records from other providers via KHIE, which should in theory prevent medical errors and improve the ability of providers to provide seamless, coordinated care.³⁰⁷ Moreover, these new criteria require all new providers to use electronic medical records, as participation in KHIE is not possible without them.³⁰⁸ Admittedly, healthcare providers already had considerable incentives to increase their use of electronic medical records through the federal government's "Meaningful Use" initiative;³⁰⁹ however, the requirement under the revised State Health Plan to use KHIE to both share and obtain patient records builds upon the existing federal incentive by adding a more prescriptive element to the regulatory landscape.³¹⁰ In addition, the uniform review criteria maintain the preexisting requirement for applicants to document a plan of care for the uninsured and medically underserved.³¹¹

b. Removal of Certain Services from the State Health Plan

The revised State Health Plan removes two service categories from review: adult day health programs and outpatient healthcare centers.³¹² The original proposal by the Cabinet contemplated removing several other components from the State Health Plan (ambulance services, chemical dependency treatment beds, and MRI); however, in response to feedback from stakeholders, those proposals were retracted (ambulance services and chemical dependency treatment beds) or modified (MRI; *see below*).³¹³ It is important to note, however, that the

³⁰⁶ *See id.*

³⁰⁷ *See id.*

³⁰⁸ *See id.*

³⁰⁹ *See generally Meaningful Use Definition & Objectives*, HEALTHIT.GOV, <https://www.healthit.gov/providers-professionals/meaningful-use-definition-objectives> [<https://perma.cc/G7XE-APMX>] (last updated Feb. 6, 2015); *EHR Incentive Programs*, HEALTHIT.GOV, <https://www.healthit.gov/providers-professionals/ehr-incentive-programs> [<https://perma.cc/NCV8-X6BL>] (last updated Jan. 15, 2013).

³¹⁰ *See* 900 KY. ADMIN. REG. 5:020 at iv (2016).

³¹¹ *See id.*

³¹² *See generally id.* Under the prior State Health Plan, an "Outpatient Healthcare Center" was defined as "a public or private provider-based institution with permanent facilities on a single campus, that is under the supervision of an organized medical staff and that is comprised of components for the provision of primary care, ambulatory surgery, twenty-four (24) hour emergency care, and radiologic and magnetic resonance imaging." KY. ADMIN. REGS. 5:020 at 57 (2013). At the time of the most recent revision to the State Health Plan, there was only one "Outpatient Healthcare Center" in the Commonwealth. KY. CABINET FOR HEALTH & FAMILY SERVS., HEALTHCARE FACILITY DIRECTORIES, MISCELLANEOUS DIRECTORIES at 22 (Sept. 2016), chfs.ky.gov/NR/rdonlyres/B18B4766-D692-4054-AF53-D149D028868B/0/MiscellaneousDirectoryOctober2016.pdf [<https://perma.cc/VWL4-RBXK>].

³¹³ *See* 900 KY. ADMIN. REGS. 5:020 at 49–51, 57, 61.

consequence of removal from the State Health Plan is *not* full exemption from the CON process.³¹⁴ Under Kentucky law, full exemption can be accomplished only by legislation.³¹⁵ Rather, removal moves the service category into a different, more streamlined form of CON review called “nonsubstantive review,” pursuant to which applications are reviewed monthly rather than batched semi-annually, and where approval is more likely.³¹⁶

c. Consistency With the State Health Plan for Providers Who Meet Objective Quality Metrics or Participate in Value-Based Payment Programs

Most significantly, the revised State Health Plan creates new review criteria that effectively preference providers who meet objective quality metrics or participate in value-based payment programs.³¹⁷ Under prior State Health Plans, providers normally had to demonstrate consistency with the plan by showing need for a particular service under a numeric formula contained in the plan for most health services.³¹⁸ For example, under the prior plan, consistency with the State Health Plan for home health services had been determined pursuant to a numeric formula that required applicants who wished to open a new home health agency to demonstrate a need for at least 250 additional patients as shown in calculations conducted by the Cabinet for Health and Family Services, or 125 additional patients in the case of existing agencies who wished to expand operations into a new service area.³¹⁹ In essence, if the Cabinet’s numerical calculations did not show a need for a sufficient number of new patients, applications could not be approved because it would not be possible to show consistency with the State Health Plan.

Under the new State Health Plan, existing home health agencies who achieve specific quality ratings under rating systems established by CMS need not meet the numeric formula for need describe above; rather, those agencies are deemed consistent with the state health plan solely by virtue of attaining quality standards.³²⁰ Similarly, a hospital that meets certain CMS quality thresholds can be deemed consistent with the plan in recognition of input from hospitals that establishing hospital-owned home health agencies would better allow them to follow patients after discharge, ultimately improving quality and continuity of care.³²¹ In addition, the updated State Health Plan adds a provision deeming

³¹⁴ KY. REV. STAT. ANN. § 216B.061 (West 2016) (requiring a certificate of need for most new health services and many expansions of existing services).

³¹⁵ *Id.*

³¹⁶ KY. REV. STAT. ANN. § 216B.095 (West 2016).

³¹⁷ See 900 KY. ADMIN. REGS. 5:020 (2016).

³¹⁸ See 900 KY. ADMIN. REGS. 5:020 (2013).

³¹⁹ *Id.* at 32–33.

³²⁰ 900 KY. ADMIN. REGS. 5:020E at 36–37 (2016).

³²¹ *Id.* at 36; see also KY. HOSP. ASS’N, STATE HEALTH PLAN COMMENTS (June 24, 2015), [chfs.ky.gov/NR/rdonlyres/C78FBA9E-7DC3-4185-9EAD-D4CF9D2579A3/0/CommentsfromHospitals.pdf](https://perma.cc/443K-TCQR) [https://perma.cc/443K-TCQR].

certain providers consistent with the plan if they participate in federal value-based payment programs.³²²

In the case of ambulatory surgery centers, the most hotly contested area in the CON program,³²³ the updated State Health Plan added a provision allowing hospitals that meet certain quality thresholds under CMS rankings to be deemed consistent with the plan.³²⁴ In so doing, the plan attempts to provide a mechanism for an increase in outpatient facilities, as recommended by the Facility Capacity Study, while still being responsive to concerns of stakeholders about possible market destabilization in the event of a flood in outpatient providers. Similarly, nursing home providers have more flexibility under the revised plan. Under the prior plan, it was exceptionally difficult for new beds to be approved, and there was no ready mechanism for transfer of beds among providers. The revised plan attempts to address that concern through the addition of a specific provision enabling the transfer of nursing home beds, but only among providers who meet specific CMS quality thresholds.³²⁵

Significantly, the revised plan attempts to facilitate the provision of high quality cancer treatment in additional geographic areas of the Commonwealth, an issue of particular importance given Kentucky's historically high cancer rates.³²⁶ Under the prior plan, applicants for megavoltage radiation services had to satisfy a formula

³²² 900 KY. ADMIN. REGS. 5:020 at 37 (2015), *amended by* 900 KY. ADMIN. REGS. 5:020E (2016) (“[A]n application to home health services shall be consistent with this Plan if the application is submitted by: (a) An entity or entities that comprise a Kentucky-based federally qualified Accountable Care Organization (“ACO”) under the Medicare Shared Savings Program or the Next Generation ACO Model . . . or (b) A licensed Kentucky home health agency which shares common management and control with an entity that provides substantial health management services to a physician-led Kentucky-based federally qualified Accountable Care Organization (“ACO”) under the Medicare Shared Savings Program or the Next Generation ACO Model, to provide home health services within counties in which attributed patients of such physician-led ACO reside . . .”).

³²³ In an attempt to ensure that the Cabinet for Health and Family Services did not remove the Ambulatory Surgical Center criteria from the State Health Plan, the Kentucky General Assembly enacted the following as part of the 2014–2016 Biennium Budget legislation:

Health Facility Licensing: Notwithstanding any statute to the contrary, the document required under KRS 216B.015(28) [the State Health Plan] shall contain a utilization-based need methodology which accounts for all sites of service in the review of applications proposing the establishment of a facility to be licensed under 902 KAR 20:106 [ASCs].

H.B. 235, Reg. Sess. (Ky. 2014), <http://www.lrc.ky.gov/Statrev/ACTS2014rs/0117.pdf> [<https://perma.cc/3XXM-NC24>].

³²⁴ 900 KY. ADMIN. REGS. 5:020 at 59 (2015).

³²⁵ 900 KY. ADMIN. REGS. 5:020 at 33 (2015).

³²⁶ See *2015 Annual Report: Cancer Deaths*, AMERICA'S HEALTH RANKINGS, <http://www.americashealthrankings.org/explore/2015-annual-report/measure/cancerdeaths/state/KY> [<https://perma.cc/AME2-V7JK>] (last visited Nov. 13, 2016) (ranking Kentucky 50th among states in cancer deaths based on three-year average, age-adjusted number of deaths attributed to cancer per 100,000 population).

demonstrating a projected need for a certain number of services.³²⁷ While the revised plan maintains that numerical formula, it also adds a specific provision deeming applications from entities certified as Academic Comprehensive Cancer Centers consistent with the plan.³²⁸ For example, under this new provision the University of Kentucky Markey Cancer Center, a National Cancer Institute designated entity,³²⁹ has a smoother pathway to offer its services in additional areas of the state.³³⁰ In this way, Kentuckians may be able to stay closer to home to receive cancer therapy. And finally, while MRI was not removed from the State Health Plan following objections from stakeholders, a new provision was added to the plan allowing for addition of new MRI services if the applicant demonstrates that the new service is consistent with accreditation requirements of the American College of Radiology.³³¹

vi. Lessons Learned on the Relevance of Certificate of Need Programs in the Post-ACA Environment: Promoting Modernization of State Healthcare Delivery Systems

The question of the role of CON programs in the new healthcare world is not new. As described in Part III above, others have questioned the value of CON programs in view of shifting payment models and changing delivery landscapes. And in the post-ACA era, these questions are magnified to a considerable degree, as some have noted. For example, Pamela Smith considered whether the Community Health Needs Assessment required of hospitals under ACA (in which hospitals must document their community impact as part of retaining their tax-exempt status)³³² should be combined with need assessments conducted pursuant to state CON programs, thereby saving money, time, and personnel resources.³³³ And if HHS retains its commitment to value-based payment following the Obama

³²⁷ 900 KY. ADMIN. REGS. 5:020 at 48 (2013).

³²⁸ 900 KY. ADMIN. REGS. 5:020 at 52 (2015).

³²⁹ See *National Cancer Institute Designation*, UK HEALTHCARE: MARKEY CANCER CTR., <http://ukhealthcare.uky.edu/Markey/NCI/> [<https://perma.cc/3LQX-3TBS>] (last visited Nov. 13, 2016).

³³⁰ See generally *Find a Cancer Center*, NAT'L CANCER INST., <https://www.cancer.gov/research/nci-role/cancer-centers/find#Kentucky> [<https://perma.cc/WVN9-JC3W>] (last visited Nov. 13, 2016) (showing that the Markey Cancer Center is the only NCI designated center in Kentucky).

³³¹ 900 KY. ADMIN. REGS. 5:020 at 49–51 (2015).

³³² 26 U.S.C. § 501(r) (2016).

³³³ Pamela C. Smith & Kelly Noe, *Is the Community Health Needs Assessment Replacing the Certificate of Need?*, J. HEALTHCARE FIN., June/July 2014, at 1, 3–6.

administration, which seems likely,³³⁴ the need for modernization of CON laws to enable providers to adapt to the new environment will only increase.

The call for full-scale repeal of CON programs has largely been unsuccessful and seems likely to continue to fall on deaf ears among legislators in the states that retain CON laws. A more successful strategy for health-oriented policymakers and stakeholders is to embrace CON programs as an additional regulatory tool to drive systematic change in healthcare delivery systems. The ability of healthcare providers to respond to economic incentives is well documented,³³⁵ and although response varies depending on the design and strength of the incentive, the introduction of a new, high-quality competitor into a market is undoubtedly a powerful incentive for existing providers.³³⁶ And while admittedly, healthcare is not a normal market,³³⁷ there is no reason to believe that healthcare providers will be unresponsive to incentives to expand their businesses into new geographic areas or service lines.

To be clear, the requirement that healthcare providers demonstrate the quality of the services they intended to provide as part of the CON application process is not novel. Indeed, many states have quality requirements as part of their programs.³³⁸ However, Kentucky appears to be the first state to include explicit preferences for those providers who meet objective quality metrics or participate in value-based payment models.³³⁹ And although these reforms have been in effect only since late 2015 and are subject to change by a new gubernatorial

³³⁴ In a rare bipartisan move in 2015, Congress passed the Medicare Access & CHIP Reauthorization Act of 2015 (“MACRA”) to significantly reform Medicare payment, shifting incentives to reward providers who participate in value-based payment programs. Medicare Access & CHIP Reauthorization Act of 2015, Pub. L. No. 114-10, 129 Stat. 87, 91–98, 105–07, 145 (2015).

³³⁵ See, e.g., Kevin Quinn, *The 8 Basic Payment Methods in Healthcare*, 163 ANNALS INTERNAL MED. 300, 300 (2015).

³³⁶ See, e.g., Anne Saker, *St. Elizabeth Wages Battle over Christ Surgicenter*, CINCINNATI POST ENQUIRER, June 2, 2016, at A1 (describing fight between existing provider in Northern Kentucky and Ohio hospital seeking to enter the market).

³³⁷ See Cauchi & Noble, *supra* note 1.

³³⁸ See, e.g., *Certificate of Need (CON) Program Summary*, ALASKA DEPT HEALTH & SOC. SERVS., <http://dhss.alaska.gov/dhcs/pages/certificateofneed/default.aspx> [https://perma.cc/783H-M6HM] (last visited Nov. 13, 2016); see also *CON-Certificate of Need State Laws*, NAT’L CONF. ST. LEGIS. (Aug. 25, 2016), <http://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx> [https://perma.cc/6NJA-QDAZ] (referencing specific state CON statutes).

³³⁹ However, as part of its State Innovation Model Awards, the Centers for Medicare and Medicaid Services is providing additional incentive for states to consider how they can align their regulatory authorities, such as certificate of need to reinforce accountable care and delivery system transformation. See CTRS. FOR MEDICARE & MEDICAID INNOVATION, C.F.D.A. NO. 93.624, STATE INNOVATION MODELS: FUNDING FOR MODEL DESIGN AND TESTING ASSISTANCE (2012), https://innovation.cms.gov/files/x/stateinnovation_foa.pdf [https://perma.cc/86UE-2WTF]. Indeed, as a State Innovation Model Design Award grantee, Kentucky included in its final Model Design an intent to leverage its regulatory authority, including the certificate of need program, to promote a move toward delivery system transformation. *Kentucky State Innovation Model (SIM)*, KY. CABINET FOR HEALTH & FAM. SERVS., <http://www.chfs.ky.gov/ohp/sim> [https://perma.cc/3F9W-EQ3B] (last updated Nov. 1, 2016).

administration, this novel approach to CON appears to be leading to expansion of higher-quality services into new areas and service lines. Indeed, since Kentucky's new State Health Plan has become effective, many new providers have applied and received approval to deliver services, and others are still navigating the process.³⁴⁰ Over time, it is reasonable to expect that patients will gravitate to higher quality providers and that existing providers will at least attempt to improve the quality of the services they deliver in order to retain their existing market share. In this way, a rising tide may lift all boats in the healthcare delivery system. Similarly, the possibility of the expansion of service lines and into new geographic areas for participation in value-based payment models, particularly when layered on top of existing (and ever-increasing) federal pressure to participate in those models, should incentivize at least some providers to embrace the changing landscape rather than resist it. If that occurs, CON may regain a valuable role in shaping the healthcare delivery system rather than serving primarily as an anti-competitive relic whose repeal is prevented by political inertia and entrenched incumbents.

CONCLUSION

Certificate of need programs were conceived in a healthcare environment that is essentially unrecognizable today. Every aspect of the healthcare landscape has changed dramatically, from healthcare delivery systems to payment structures to the insurance coverage models. These changes have been particularly magnified in the past five years as a result of the enactment and implementation of the ACA. The historical rationales in support of CON programs seem particularly anachronistic in today's rapidly changing healthcare landscape, and critics rightly observe that the persistence of CON laws has the potential to slow necessary change in healthcare delivery systems. Already, healthcare consumes approximately 17.5% of the U.S. GDP,³⁴¹ and there is almost no evidence that CON laws have slowed that rise, and considerable evidence that CON programs may contribute to increased cost, lower quality, and foregone opportunities for market forces to incentivize the provision of more efficient services. Nonetheless, CON laws persist for various reasons, not least among them the power of entrenched healthcare interests in states with CON programs and the resulting political inertia that prevents repeal or significant modification of the programs.

³⁴⁰ See, e.g., *Certificate of Need Newsletter*, OFF. OF HEALTH POL'Y (Ky. Cabinet for Health & Fam. Servs., Frankfort, Ky.), Dec. 17, 2015, at 1, 4–15, chfs.ky.gov/NR/rdonlyres/FA3880A8-8E43-4D8D-ABD3-F7EB0478B061/0/DEC2015.doc [<https://perma.cc/PDS4-SYQD>].

³⁴¹ *National Health Expenditures 2014 Highlights*, CTRS. FOR MEDICARE & MEDICAID SERVS., <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/highlights.pdf> [<https://perma.cc/4TBQ-B6VD>] (last visited Nov 3, 2016).

Kentucky was widely recognized as among the most successful states in its implementation of ACA.³⁴² As part of its implementation efforts, the Commonwealth undertook a thorough review of its CON program and identified opportunities to modify the program to create opportunities for providers who embrace rather than resist efficient changes in care delivery systems and value-based payment models, including use of electronic medical records, participation in the Commonwealth's health information exchange, attainment of objective quality standards under federal provider rating systems such as Medicare Hospital Compare, and participation in federally supported value-based payment programs. While it remains to be seen how a new gubernatorial administration will implement these reforms, and whether there will remain sufficient political will to retain them, these reforms may offer insight to additional states as they consider whether and how to reform their own CON programs. Indeed, rather than being a persistent nuisance that must be tolerated and worked around because there is no political will to change the status quo, it may be possible for a modernized CON program to serve as an additional regulatory tool for states seeking to nudge their healthcare providers into fuller engagement in the post-Affordable Care Act healthcare landscape.

Table 1: Regulated CON Service by State³⁴³

Regulated Services	Number of States	States, Districts & Commonwealth
Acute Hospital Beds	28	AL, AK, CT, DE, FL, GA, HI, IL, IA, KY, ME, MD, MI, MS, MO, NV, NJ, NY, NC, RI, SC, TN, VT, VA, WA, WV, DC
Air Ambulance	5 +DC	AL, ME, MA, MI, VT, DC
Ambulance Services, Ground <i>(generally not counted)</i>	1	AZ

³⁴² See, e.g., Samantha Artiga, et al., *Implementation of the ACA in Kentucky: Lessons Learned to Date and the Potential Effects of Future Changes*, KAISER FAM. FOUND. (Apr. 2016), <http://files.kff.org/attachment/issue-brief-implementation-of-the-aca-in-kentucky-lessons-learned-to-date-and-the-potential-effects-of-future-changes> [https://perma.cc/HEC6-UQJR].

³⁴³ *Certificate of Need State Laws*, NAT'L CONF. ST. LEGISLATURES (Aug. 25, 2016), <http://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx> [https://perma.cc/T4UX-8ME3].

<i>as a CON state)</i>		
Ambulatory Surgical Centers (ASC)	27	AL, AK, CT, DE, GA, HI, IL, IA, KY, ME, MD, MA, MI, MS, MT, NV, NY, NC, RI, SC, TN, VT, VA, WA, WV, DC
Burn Care	11	AL, HI, ME, MD, NJ, NY, NC, TN, VT, WA, DC
Cardiac Catheterization	26	AL, AK, CT, DE, GA, HI, IL, IA, KY, ME, MD, MI, MS, MO, NJ, NY, NC, RI, SC, TN, VT, VA, WA, WV, DC
Computed Tomography (CT) Scanners	13	AK, CT, HI, ME, MI, MO, NY, NC, RI, VT, VA, WV, DC
Gamma Knives	15	AL, AK, GA, HI, ME, MA, MI, MS, MO, NC, RI, SC, VT, VA, DC
Home Health	18	AL, AR, GA, HI, KY, MD, MS, MT, NJ, NY, NC, SC, TN, VT, WA, WV, DC
Hospice	18	AL, AR, CT, FL, HI, KY, MD, MS, NY, NC, OR, RI, SC, TN, VT, WA, WV, DC
Intermediate Care Facilities/Mental Retardation (ICF/MR)	22	AR, FL, GA, HI, IL, IA, KY, LA, MD, MS, MO, MT, NV, NJ, NC, OK, SC, TN, VT, VA, WV, WI
Long Term Acute Care (LTAC)	26 +DC	AL, AK, CT, DE, FL, GA, HI, IL, IA, KY, ME, MD, MI, MS, MO, NJ, NC, OR, RI, SC, TN, VT, VA, WA, WV, DC
Lithotripsy	14 +DC	AK, DE, GA, HI, ME, MA, MI,

		MO, NY, NC, SC, TN, VT, VA, DC
Nursing Home Beds/Long Term Care Beds	36 +DC	AL, AK, AR, CT, DE, FL, GA, HI, IL, IA, KY, LA, ME, MD, MA, MI, MS, MO, MT, NE, NV, NJ, NY, NC, OH, OK, OR, RI, SC, TN, VT, VA, WA, WV, WI, DC
Medical Office Buildings	1 +DC	VT, DC
Mobile Hi Technology (CT / MRI / PET, etc.)	15 +DC	AK, CT, HI, KY, ME, MI, MO, NY, NC, RI, SC, VT, VA, WV, DC
Magnetic Resonance Imaging (MRI) Scanners	18 +DC	AK, CT, HI, KY, ME, MA, MI, MS, MO, NY, NC, RI, SC, TN, VT, VA, WV, DC
Neo-Natal Intensive Care	23	AL, AK, CT, FL, GA, HI, IL, KY, ME, MD, MA, MI, NJ, NY, NC, RI, SC, TN, VT, VA, WA, WV, DC
Obstetrics Services	15	AL, AK, CT, GA, HI, IL, ME, MD, NY, RI, VT, VA, WA, WV, DC
Open Heart Surgery	25	AL, AK, CT, GA, HI, IL, IA, KY, ME, MD, MA, MI, MS, NJ, NY, NC, RI, SC, TN, VT, VA, WA, WV, DC
Organ Transplants	21	AL, AK, CT, FL, HI, IL, IA, KY, ME, MD, MA, MI, NJ, NY, NC, RI, VT, VA, WA, WV, DC
Positron Emission Tomography (PET) Scanners	20	AK, CT, DE, GA, HI, KY, ME, MA, MI, MS, MO, NC, RI, SC, TN, VT, VA, WV, DC

Psychiatric Services	26	AL, AK, AR, CT, FL, GA, HI, IL, KY, ME, MD, MA, MI, MS, NJ, NC, OK, RI, SC, TN, VT, VA, WA, WV, DC
Radiation Therapy	23	AL, AK, CT, DE, GA, HI, IA, KY, ME, MA, MI, MS, MO, NY, NC, RI, SC, TN, VT, VA, WV, DC
Rehabilitation	25	AL, FL, GA, HI, IL, KY, ME, MD, MA, MS, MO, MT, NE, NJ, NY, NC, RI, SC, TN, VT, VA, WA, WV, DC
Renal Failure/Dialysis	12	AL, AK, HI, IL, ME, MS, NY, NC, VT, WA, WV, DC
Assisted Living & Residential Care Facilities	5	AR, LA, MO, NC, VT
Subacute Services	13	AK, FL, HI, IL, NC, OK, RI, SC, TN, WA, WI, VT, DC
Substance/Drug Abuse	19	AL, CT, FL, GA, HI, KY, ME, MD, MA, MS, MT, NC, RI, SC, TN, VT, WV, DC
Swing Beds	12	AL, HI, IL, ME, MI, MS, MT, OR, TN, VT, WA, DC
Ultra-Sound	4	HI, ME, VT, DC

