FEDERAL TRADE COMMISSION
Washington, DC 20580

DEPARTMENT OF JUSTICE
Washington, DC 20530

The Honorable Kathy Byron
Virginia House of Delegates
523 Leesville Rd.
Lynchburg, VA 24502

Eva T. Hardy, Chair
COPN Work Group
c/o Secretary William Hazel
Patrick Henry Building
State Capitol
Richmond, VA 23219

October 26, 2015

Dear Delegate Byron and Ms. Hardy,

At the request of Delegate Byron, Vice Chair, Committee on Commerce and Labor, Virginia House of Delegates, we submit the enclosed joint statement by the Federal Trade Commission and the Antitrust Division of the U.S. Department of Justice (the "Agencies") to Virginia's Certificate of Public Need Work Group.

We hope that the statement is helpful to the Work Group as it reviews Virginia's Certificate of Public Need process. Thank you for your time and consideration.

Marina Lao

Marina Lao, Director
Office of Policy Planning
Federal Trade Commission

Robert Potter

Robert Potter, Chief
Legal Policy Section
Antitrust Division
U.S. Department of Justice

cc: Susan Puglisi (via email only)

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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

The Federal Trade Commission (the "FTC") and the Antitrust Division of the U.S. Department of Justice (the "Division") (together, the "Agencies") welcome the opportunity to share our views on certificate-of-need ("CON") laws.[1] We understand that Virginia's Certificate of Public Need ("COPN") Work Group has been charged with a review of "the current certificate of public need process and the impact of such process on health care services in the Commonwealth, and the need for changes to the current certificate of public need process."[2] It will "develop specific recommendations for changes to the certificate of public need process to address any problems or challenges identified during [its] review."[3]

CON laws, when enacted, had the laudable goals of reducing health care costs and improving access to care.[4] However, it is now apparent that CON laws can prevent the efficient functioning of health care markets in several ways that may undermine those goals. First, CON laws create barriers to entry and

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[1] Kathy Byron, Vice Chair, Committee on Commerce and Labor, Virginia House of Delegates, has requested that the FTC provide guidance to the Virginia COPN Work Group. Letter from Kathy Byron, Va. House of Delegates, to Marina Lao, Director, Office of Policy Planning, Fed. Trade Comm'n (Aug. 30, 2015).

[2] 2015 Va. Acts Chapter 665, Item 278.D.

[3] *Id.*

[4] CON programs originated under the 1974 National Health Planning and Resources Development Act. States were required to pass CON legislation to avoid losing certain federal funding. *See* CHRISTINE L. WHITE ET AL., ANTITRUST AND HEALTHCARE: A COMPREHENSIVE GUIDE 527 (2013).

expansion, limit consumer choice, and stifle innovation. Second, incumbent firms seeking to thwart or delay entry by new competitors may use CON laws to achieve that end. Third, as illustrated by the FTC's recent experience in the *Phoebe Putney* case, CON laws can deny consumers the benefit of an effective remedy following the consummation of an anticompetitive merger. Finally, the evidence to date does not suggest that CON laws have generally succeeded in controlling costs or improving quality. For these reasons, explained more fully below, the Agencies historically have suggested that states consider repeal or retrenchment of their CON laws and, in this case, respectfully suggest that the Work Group and the General Assembly consider whether repeal or retrenchment of Virginia's COPN laws would best serve its citizens.

I. The Agencies' Interest and Experience in Health Care Competition

Competition is the core organizing principle of America's economy,[5] and vigorous competition among sellers in an open marketplace gives consumers the benefits of lower prices, higher quality goods and services, greater access to goods and services, and innovation.[6] The Agencies work to promote competition through enforcement of the antitrust laws, which prohibit certain business practices that harm competition and consumers, and through competition advocacy, whereby the Agencies advance outcomes that benefit competition and consumers in comments on legislation, discussions with regulators, and court filings, among other fora.

Because of the importance of health care competition to the economy and consumer welfare, this sector has long been a priority of the Agencies.[7] The Agencies have extensive experience investigating anticompetitive mergers and

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[5] *See, e.g.*, N.C. State Bd. of Dental Exam'rs v. FTC, 135 S. Ct. 1101, 1109 (2014) ("Federal antitrust law is a central safeguard for the Nation's free market structures."); Standard Oil Co. v. FTC, 340 U.S. 231, 248 (1951) ("The heart of our national economic policy has long been faith in the value of competition.").

[6] *See, e.g.*, Nat'l Soc'y of Prof'l Eng'rs v. United States, 435 U.S. 679, 695 (1978) (The antitrust laws reflect "a legislative judgment that ultimately competition will produce not only lower prices, but also better goods and services. . . . The assumption that competition is the best method of allocating resources in a free market recognizes that all elements of a bargain—quality, service, safety, and durability—and not just the immediate cost, are favorably affected by the free opportunity to select among alternative offers.").

[7] A description of, and links to, the FTC's various health care-related activities can be found at https://www.ftc.gov/tips-advice/competition-guidance/industry-guidance/health-care. An overview of the Division's health care-related activities is available at http://www.justice.gov/atr/health-care.

business practices by hospitals, insurers, pharmaceutical companies, physicians, and other providers of health care goods and services. The Agencies also have provided guidance to the health care community on the antitrust laws, and have devoted significant resources to examining the health care industry by sponsoring various workshops and studies. Finally, through their competition advocacy programs, the Agencies have encouraged states to consider the competitive impact of various health care-related legislative and regulatory proposals, including CON laws.[8]

II. Virginia's COPN Laws

Virginia's COPN program requires providers to obtain a COPN from the State Health Commissioner (the "Commissioner") before initiating certain projects. The program covers facilities that include hospitals, nursing homes, psychiatric facilities, and rehabilitation hospitals and services that include general acute care services, cardiac services, obstetrics, and organ transplantation.[9] The Commissioner may not issue a COPN unless he or she has determined that there is a public need for the project,[10] and may condition a COPN on the provision of a certain amount of charity care, the provision of care

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[8] *See, e.g.*, Letter from Marina Lao, Dir., Office of Policy Planning, Fed. Trade Comm'n, et al., to The Honorable Marilyn W. Avila, N.C. House of Representatives (July 10, 2015), *available at* https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-concurring-comment-commissioner-wright-regarding-north-carolina-house-bill-200/150113ncconadv.pdf; Prepared Statement of the Federal Trade Commission Before the Florida State Senate (Apr. 2, 2008) [hereinafter FTC Florida Statement], *available at* https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-prepared-statement-florida-senate-concerning-florida-certificate-need-laws/v080009florida.pdf; Statement of the Antitrust Division, U.S. Department of Justice, Before the Florida Senate Committee on Health and Human Services (Mar. 25, 2008), *available at* http://www.justice.gov/atr/comments-competition-healthcare-and-certificates-need; Prepared Statement of the Federal Trade Commission Before the Standing Committee on Health, Education, & Social Services of the Alaska House of Representatives (Feb. 15, 2008) [hereinafter FTC Alaska Statement], *available at* https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-written-testimony-alaska-house-representatives-concerning-alaska-certificate-need-laws/v080007alaska.pdf; Statement of the Antitrust Division, U.S. Department of Justice, 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 (Feb. 23, 2007), *available at* http://www.justice.gov/atr/competition-healthcare-and-certificates-need.

[9] VA. CODE ANN. § 32.1-102.1 (2015); 12 VA. ADMIN. CODE § 5-220-100 (2011); *The Certificate of Public Need Program*, VA. DEP'T OF HEALTH, http://www.vdh.state.va.us/OLC/copn/ (last visited Oct. 22, 2015).

[10] VA. CODE ANN. § 32.1-102.3 (2015).

to persons with special needs, or the provision of health care services in a medically underserved area.[11] The program's goal is to "contain health care costs while ensuring financial viability and access to health care for all Virginia at a reasonable cost."[12]

The COPN process can be time-consuming and costly. Applications must be submitted to the Virginia Department of Health (the "Department") and, in certain cases, the appropriate regional health planning agency.[13] The Department reviews applications during 190-day review cycles designated for particular batch groups, which occur only twice a year for most batch groups.[14] Meetings, public hearings, and fact-finding conferences on applications may be convened.[15] According to the Department, the review process can take six to seven months to complete.[16] Once a decision is made, aggrieved parties, including, in at least some cases, incumbent providers, can appeal the decision to the circuit court.[17] Therefore, the CON process can delay entry by, at a minimum, many months, even when a COPN is ultimately granted. Further, some beneficial entry may be deterred since a potential entrant may decide that the process itself is too costly.

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[11] VA. CODE ANN. § 32.1-102.2(C) (2015).

[12] *The Certificate of Public Need Program*, VA. DEP'T OF HEALTH, http://www.vdh.state.va.us/OLC/copn/ (last updated Aug.. 21, 2014).

[13] 12 VA. ADMIN. CODE § 5-220-180 (2011); Peter Boswell, Dir., Div. of Certificate of Public Need, Va. Dep't of Health Office of Licensure & Certification, Presentation at the July 1, 2015 COPN Work Group Meeting: The Certificate of Public Need Program in Virginia 9 (July 2015), http://www.vdh.state.va.us/Administration/documents/COPN/COPN%20Program%20in%20Virginia.ppt.

[14] 12 VA. ADMIN. CODE § 5-220-200 (2011). A party must file a notice of intent 70 days prior to the start of a review cycle and its application 40 days prior to the start of a cycle. 12 VA. ADMIN. CODE § 5-220-180 (2011); Boswell, *supra* note 13, at 9.

[15] 12 VA. ADMIN. CODE § 5-220-230 (2011).

[16] *The Certificate of Public Need Program*, VA. DEP'T OF HEALTH, http://www.vdh.state.va.us/OLC/copn/ (last updated Aug. 21, 2014).

[17] *See, e.g.*, Reston Hosp. Ctr., LLC v. Remely, 559 Va. App. 96, 111, 717 S.E.2d 417, 425 (Ct. App. 2011) (allegations by incumbent that its competing facility and service would suffer an appreciable reduction in utilization and efficiency sufficient to confer standing).

III. Analysis of the Likely Competitive Effects of Virginia's COPN Laws

Competition in health care markets can benefit consumers by containing costs, improving quality, and encouraging innovation.[18] Indeed, price competition generally results in lower prices for and, thus, broader access to, health care products and services, while non-price competition can promote higher quality and encourage innovation. CON laws may suppress these substantial benefits of competition by limiting the availability of new or expanded health care services. For these reasons, the Agencies historically have suggested that states with CON laws repeal or narrow those laws,[19] and now respectfully suggest that the Work Group and the General Assembly reconsider whether Virginia's COPN laws best serve its citizens.

A. CON Laws Create Barriers to Entry, Which May Suppress More Cost-Effective, Innovative, and Higher Quality Health Care Options

CON laws, such as Virginia's COPN laws, require new entrants to obtain a state-issued approval before offering certain health care services. By interfering with the market forces that normally determine supply of services, CON laws can suppress competition and shield incumbent health care providers from competition from new entrants.[20] As a result, they can:

- Delay, and raise the cost of, entry by firms that are potentially able to offer new, lower cost, more convenient, or higher quality services;
- Reduce the ability of the market to respond to consumer demand for different treatment options, settings, or prices; and

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[18] *See* FED. TRADE COMM'N & U.S. DEP'T OF JUSTICE, IMPROVING HEALTH CARE: A DOSE OF COMPETITION Executive Summary at 4 (2004) [hereinafter A DOSE OF COMPETITION], *available at* https://www.ftc.gov/sites/default/files/documents/reports/improving-health-care-dose-competition-report-federal-trade-commission-and-department-justice/040723healthcarerpt.pdf.

[19] *See* A DOSE OF COMPETITION, *supra* note 18, at ch. 8 at 6; 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 2 (Sept. 15, 2008) [hereinafter DOJ-FTC Illinois Testimony], *available at* 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.

[20] *See* A DOSE OF COMPETITION, *supra* note 18, ch. 8 at 4 (discussing examples of how CON programs limited access to new cancer treatments and shielded incumbents from competition from innovative newcomers).

- Remove or delay the competitive pressures that typically incentivize incumbent firms to innovate, improve existing services, or introduce new ones.[21]

We urge the Work Group and the General Assembly to consider that Virginia's COPN law may be causing these results in Virginia to the detriment of health care consumers and to consider the benefit to patients if new facilities and services would be able to enter the market more easily. This new entry – and the threat of entry – could restrain the price of health care, improve the quality of care, incentivize innovation in the delivery of care, and improve access to care.

B. The CON Process May Be Exploited by Competitors Seeking to Protect Their Revenues

In addition to disrupting the market forces that typically determine the supply of services, CON laws may further harm competition because competitors may take advantage of the CON process to protect their revenues. For instance, an incumbent firm may file challenges or comments to a potential competitor's CON application merely to thwart or delay competition. As noted in an FTC-DOJ report, existing firms can use the CON process "to forestall competitors from entering an incumbent's market."[22] This use of the CON process by competitors can not only cause delay,[23] but can also divert scarce resources away from health care innovation as potential entrants incur legal, consulting, and lobbying expenses responding to competitor challenges.[24]

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[21] *See id.*; DOJ-FTC Illinois Testimony, *supra* note 19, at 6.

[22] A DOSE OF COMPETITION, *supra* note 18, Executive Summary at 22; *see also* Tracy Yee et al., Health Care Certificate-of-Need Laws: Policy or Politics? 2, 4 (Research Br. No. 4, Nat'l Institute for Health Care Reform May 2011) [hereinafter, Policy or Politics?] (interviewees stated that CON programs "tend to be influenced heavily by political relationships, such as a provider's clout, organizational size, or overall wealth and resources, rather than policy objectives," that, in Georgia, "large hospitals, which often have ample financial resources and political clout, have kept smaller hospitals out of a market by tying them up in CON litigation for years," that the CON process "often takes several years before a final decision," and that providers "use the process to protect existing market share – either geographic or by service line – and block competitors").

[23] *See, e.g.*, Policy or Politics?, *supra* note 22, at 5 ("CONs for new technology may take upward of 18 months, delaying facilities from offering the most-advanced equipment to patients and staff.").

[24] What makes this conduct more concerning is the fact that much of it, even if exclusionary and anticompetitive, may be shielded from federal antitrust scrutiny to the extent it involves protected petitioning of the state government. *See* DOJ-FTC Joint Illinois Testimony, *supra* note 19, at 6-7; FTC Florida Statement, *supra* note 8, at 8-9; FTC Alaska Statement, *supra* note 8, at 8-9.

Repeal or retrenchment of Virginia's COPN law would eliminate or mitigate the opportunity for this type of exploitation of the CON process.

C. CON Laws Can Impede Effective Antitrust Remedies and Can Facilitate Anticompetitive Agreements

As the FTC's recent experience in *FTC v. Phoebe Putney* demonstrates, CON laws can entrench anticompetitive mergers by limiting the ability to implement effective structural remedies. *Phoebe Putney* involved a challenge to the merger of two hospitals in Albany, Georgia.[25] The FTC alleged that the merger had created a monopoly in the provision of inpatient general acute care hospital services sold to commercial health plans in Albany and its surrounding areas. The FTC was ultimately precluded from obtaining a remedy that would have restored competition to the marketplace because of Georgia's CON laws and regulations.[26] As the Commission explained, "[w]hile [divestiture] would have been the most appropriate and effective remedy to restore the lost competition in Albany and the surrounding six-county area from this merger to monopoly, Georgia's [CON] laws and regulations unfortunately render a divestiture in this case virtually impossible."[27] The Commission further noted that the case "illustrates how state CON laws, despite their original and laudable goal of reducing health care facility costs, often act as a barrier to entry to the detriment of competition and healthcare consumers."[28] Thus, the Work Group and the General Assembly should consider whether Virginia's COPN laws could prevent divestiture as an effective tool to remedy anticompetitive mergers in appropriate cases.

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[25] *See generally* In re Phoebe Putney Health Sys., Inc., Dkt. No. 9348, *available at* https://www.ftc.gov/enforcement/cases-proceedings/111-0067/phoebe-putney-health-system-inc-phoebe-putney-memorial.

[26] The Eleventh Circuit affirmed the district court's dismissal of the case on state-action grounds and dissolved the stay that had prevented the parties from consummating the merger. The Supreme Court reversed, finding against state-action immunity. But, with the stay dissolved, the parties had consummated their merger before the state-action question was resolved by the federal courts. *See* FTC v. Phoebe Putney Health Sys. Inc., 133 S. Ct. 1003, 1011 (2013).

[27] Statement of the Federal Trade Commission at 1, In re Phoebe Putney Health Sys., Inc., Dkt. No. 9348, (Mar. 31, 2015), *available at* https://www.ftc.gov/system/files/documents/public_statements/634181/150331phoebeputneycommstmt.pdf.

[28] *Id.* at 3.

Additionally, CON programs have facilitated anticompetitive agreements among competitors. For example, in 2006, a hospital in Charleston, West Virginia, used the threat of objection during the CON process to induce another hospital to refrain from seeking a CON for a location where it would have competed to a greater extent with the existing hospital's program.[29] In a separate but similar case, the informal urging of state CON officials led a pair of closely competing West Virginia hospitals to agree that one hospital would seek a CON for open heart surgery, while the other would seek a CON for cancer treatment.[30] While the Division secured consent decrees prohibiting these agreements between competitors to allocate services and territories,[31] such conduct indicates that CON laws can provide the opportunity for anticompetitive agreements.

IV. Evidence on the Impact of CON Laws

States originally adopted CON programs over forty years ago as a way to control health care costs and mitigate the incentives created by a cost-based health care reimbursement system.[32] Although that reimbursement system has changed significantly, CON laws remain in force in many states, and CON proponents continue to raise cost control as a justification for CON programs. CON proponents also argue that CON laws positively affect the quality of health care services and that CON programs have enabled states to assure access to health care services. As described below, however, the empirical evidence on balance suggests that these laws have failed to produce cost savings or higher quality health care.

A. CON Laws Appear to Have Failed to Control Costs

Proponents of CON programs contend that CON laws contain health care costs by preventing "overinvestment" in capital-intensive facilities, services, and equipment. They claim that normal market forces do not discipline investment in the health care sector given, in many cases, the disconnect between the party

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[29] United States v. Charleston Area Med. Ctr., Inc., No. 2:06-0091 (S.D. W.Va. 2006).

[30] United States v. Bluefield Reg'l Med. Ctr., Inc., No. 1:05-0234 (S.D. W.Va. 2005).

[31] *See also* Press Release, U.S. Dep't of Justice, Department of Justice Statement on the Closing of the Vermont Home Health Investigation (Nov. 23, 2005), *available at* http://www.justice.gov/archive/opa/pr/2005/November/05_at_629.html (home health agencies entered into territorial market allocations, which were facilitated by the state regulatory program, to give each other exclusive geographic markets; without the state's CON laws, competitive entry might have disciplined this cartel behavior).

[32] *See* A DOSE OF COMPETITION, *supra* note 18, ch. 8 at 2; WHITE, *supra* note 4, at 527.

selecting a provider (the patient) and the party paying all or most of the bill (the insurer), and the information asymmetries among provider, patient, and insurer. They therefore call for a regulatory regime requiring preapproval for health care investments.[33]

However, CON laws are likely to increase, rather than constrain, health care costs. By potentially shielding incumbents from competition, CON laws can permit providers with market power to charge higher prices. When health plans and other purchasers can choose among alternative providers, they can bargain more effectively. Empirical evidence examining competition in health care markets generally has demonstrated that more competitive health care markets bring price and quality benefits to consumers and, in particular, that prices are higher in concentrated provider markets.[34] Furthermore, both the FTC and the Division have engaged in significant enforcement efforts to prevent anticompetitive behavior in health care provider markets because the evidence suggests that consumers benefit from competition.[35] It is simply not the case that competition cannot work in health care markets.[36]

Also, CON laws may restrict investments that would benefit consumers and lower costs in the long run. Because CON laws raise the cost of investment for everyone, they make it less likely that beneficial investment will occur. The CON application process directly adds to the cost of investment for both incumbents and potential entrants. CON laws shield incumbents from

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[33] *See CON Background*, AM. HEALTH PLANNING ASS'N, http://www.ahpanet.org/copnahpa.html ("The rationale for imposing market entry controls is that regulations, grounded in community-based planning, will result in more appropriate allocation and distribution of health care resources and, thereby, help assure access to care, maintain or improve quality, and help control health care capital spending.").

[34] *See, e.g.*, Martin Gaynor & Robert Town, *The Impact of Hospital Consolidation – Update*, ROBERT WOOD JOHNSON FOUNDATION: THE SYNTHESIS PROJECT (2012) (synthesizing research on the impact of hospital mergers on prices, cost, and quality and finding that hospital consolidation generally results in higher prices, hospital competition improves quality of care, and physician-hospital consolidation has not led to either improved quality or reduced costs).

[35] *Supra* note 7.

[36] Indeed, similar arguments made by engineers and lawyers in defense of anticompetitive agreements on price – that competition fundamentally does not work in certain markets, and in fact is harmful to public policy goals – have been rejected by the courts, and private restraints on competition have been condemned. *See, e.g.*, FTC v. Superior Court Trial Lawyers Ass'n, 493 U.S. 411, 424 (1990); Nat'l Soc'y of Prof'l Eng'rs v. United States, 435 U.S. 679, 695 (1978).

competitive incentives to invest. The Agencies have found no empirical evidence that CON laws have successfully restricted "over-investment."[37]

Finally, the best empirical evidence suggests that greater competition incentivizes providers to become more efficient.[38] Recent work shows that hospitals faced with a more competitive environment have better management practices.[39] Consistent with this, there is evidence suggesting that repealing or narrowing CON laws can reduce the per-patient cost of health care.[40]

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[37] Some papers find that CON laws are associated with lower utilization of hospital beds. These studies, however, do not address the critical question of whether the lower bed utilization in states with CON laws is a result of preventing over-investment or restricting beneficial investment. *See, e.g.*, Paul L. Delamater et al., *Do More Hospital Beds Lead to Higher Hospitalization Rates? A Spatial Examination of Roemer's Law*, 8 PLOS ONE e54900, 13-14 (2013) (finding "a positive, significant association between hospital bed availability and hospital utilization rates"); Fred J. Hellinger, *The Effect of Certificate-of-Need Laws on Hospitals Beds and Healthcare Expenditures: An Empirical Analysis*, 15 AM. J. MANG. CARE 737 (2009) (finding that CON laws "have reduced the number of hospital beds by about 10%").

[38] Furthermore, recent marketplace developments may undermine further the case for CON laws. Proponents of CON programs generally assume that providers are incentivized to provide a higher volume of services. But this assumption may be undermined as policy reforms and market developments encourage a move toward value-based payments and away from volume-based payment structures.

[39] *See, e.g.*, Nicholas Bloom et al., *The Impact of Competition on Management Quality: Evidence from Public Hospitals*, 82 REV. ECON. STUDIES 457, 457 (2015) ("We find that higher competition results in higher management quality.").

[40] *See, e.g.*, Vivian Ho & Meei-Hsiang Ku-Goto, *State Deregulation and Medicare Costs for Acute Cardiac Care*, 70 MED. CARE RES. & REV. 185, 202 (2012) (finding an association between the lifting of CON laws and a reduction in mean patient costs for coronary artery bypass graft surgery, and finding that these cost savings slightly exceed the fixed costs of new entrants); Patrick A. Rivers et al., *The Effects of Certificate of Need Regulation on Hospital Costs*, 36 J. HEALTH CARE FIN. 1, 11 (2010) (finding a positive relationship between the stringency of CON laws and health care costs per adjusted admission and concluding that the "results, as well as those of several previous studies, indicate that [CON] programs do not only fail to contain [hospital costs], but may actually *increase* costs as well" (emphasis in original)). While other studies evaluate the impact of repealing CON laws (with varying results), many of these studies are less persuasive because they do not account for preexisting cost differences between the states. *Compare* Michael D. Rosko & Ryan L. Mutter, *The Association of Hospital Cost-Inefficiency with Certificate-of-Need Regulation*, 71 MED. CARE RES. & REV. 1, 15 (2014) (finding "a plausible association between CON regulation and greater hospital cost-efficiency"), *with* Gerald Granderson, *The Impacts of Hospital Alliance Membership, Alliance Size, and Repealing Certificate of Need Regulation on Cost Efficiency of Non-profit Hospitals*, 32 MANAGE. DECIS. ECON. 159, 167-68 (2011) ("[R]epealing state CON programs contributed to an improvement in hospital cost efficiency.").

B. Quality of Care Arguments Should Not Preclude COPN Reform

Proponents also have argued that CON laws improve the quality of health care services. Specifically, they contend that providers performing higher volumes of procedures have better patient outcomes, particularly for more complex procedures.[41] Hence, by concentrating services at a limited number of locations, CON laws could increase the number of procedures performed by particular providers and reduce the frequency of adverse outcomes.

Such arguments do not fully consider the literature or the effect of competition on clinical quality. First, the most pronounced effect of volume on quality outcomes may be limited to certain relatively complicated procedures.[42] Second, even for services where certain studies have shown a volume/outcome relationship, such as coronary artery bypass graft surgery,[43] evidence suggests that these volume effects may not offset the other effects of CON programs on quality.[44] The volume/outcome relationship is just one mechanism by which quality of health care can be affected by CON laws, so this literature only provides a partial picture of the impact of CON. A more complete picture is obtained by studies that directly analyze the impact of changes in CON laws on health outcomes. The weight of this research has found, contrary to the volume/outcome justification for CON laws, that repealing or narrowing CON

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[41] This relationship between the volume of surgical procedures and quality has been studied in numerous settings, and is often supported by the evidence. *See, e.g.*, Martin Gaynor et al., *The Volume-Outcome Effect, Scale Economies, and Learning-by-Doing*, 95:2 AM. ECON. REV. 243, 245 (2005) ("Like the prior literature, we find a large volume-outcome effect.").

[42] *See* Ethan A. Halm et al., *Is Volume Related to Outcome in Health Care? A Systematic Review and Methodological Critique of the Literature*, 137.6 ANNALS INTERNAL MED. 511, 514 (2002) ("We found the most consistent and striking differences in mortality rates between high- and low-volume providers for several high-risk procedures and conditions, including pancreatic cancer, esophageal cancer, abdominal aortic aneurysms, pediatric cardiac problems, and treatment of AIDS. The magnitude of volume-outcome relationships for more common procedures, such as [coronary artery bypass graft surgery], coronary angioplasty, and carotid endarterectomy, for which selective referral and regionalization policies have been proposed, was much more modest.").

[43] *See* Gaynor et al., *supra*, note 41, at 244.

[44] *See, e.g.*, Vivian Ho et al., *Certificate of Need (CON) for Cardiac Care: Controversy over the Contributions of CON*, 44:2 HEALTH SERVS. RES. 483, 483 (2009) ("States that dropped CON experienced lower [coronary artery bypass graft surgery] mortality rates relative to states that kept CON, although the differential is not permanent.").

laws is generally unlikely to lower quality, and may, in fact, improve the quality of certain types of care.[45]

C. More Targeted Policies May Be More Effective at Ensuring Access to Care and Would Not Inflict Anticompetitive Costs

Another argument advanced by proponents of CON programs is that the programs enable states to increase access to care for their indigent residents and in medically underserved areas. The general argument is that, by limiting competition, CON laws allow incumbent health care providers to earn greater profits – through the charging of higher prices and the preservation of their volume of lucrative procedures – than they would earn in a competitive environment. These incumbents can then use those extra profits to cross-subsidize their provision of care to the indigent. Additionally, proponents maintain that regulators can use CON laws to restrict entry into well-served areas and encourage it in underserved areas. Virginia COPN laws go further, explicitly providing that a COPN may be conditioned on the applicant's agreement to provide a certain amount of indigent care, care to patients requiring specialized services, or care in medically underserved areas.[46]

Though the Agencies appreciate the importance of ensuring access to health care for the indigent and in medically underserved areas, we urge the Work Group and the General Assembly to consider whether there are more effective or narrowly tailored ways in which to accomplish this public policy goal. As described in Section III.A., above, CON programs may restrict competition from potentially lower priced, higher quality, and more innovative providers. They also may reduce the ability of providers to respond to consumer demand. As a result, CON programs may impede providers from providing

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[45] *See* Suhui Li & Avi Dor, *How Do Hospitals Respond to Market Entry? Evidence from a Deregulated Market for Cardiac Revascularization*, 24 HEALTH ECON. 990, 1006 (2015) (finding that repeal of Pennsylvania's CON program improved "the match between underlying medical risk and treatment intensity"); Ho & Ku-Goto, *supra*, note 40, at 199 (finding association between lifting of CON laws and shorter lengths of stay and fewer strokes during admission for coronary artery bypass patients, finding no significant association between lifting CON laws and three other complications during admission for coronary artery bypass graft patients, and finding no significant associations between lifting of CON laws and length of stay or need for coronary artery bypass graft surgery for percutaneous coronary intervention patients); David M. Cutler et al., *Input Constraints and the Efficiency of Entry: Lesson from Cardiac Surgery* 2:1 AM. ECON. J.: ECON. POLICY 51, 52 (2010) (finding that new entry after repeal of Pennsylvania's CON program "had a salutary effect on the market for cardiac surgery by directing more volume to better doctors and increasing access to treatment").

[46] VA. CODE ANN. § 32.1-102.4(F) (2015).

access to all patients – including the indigent. Although CON laws may seek to promote indigent care, research shows that safety net hospitals are no stronger financially in CON states than in non-CON states.[47]

Additionally, CON programs are a blunt tool for accomplishing the specific goal of providing care to the indigent and in medically underserved areas. They tend to sweep broadly, limiting competition for a wide variety of health care services. Although the Agencies do not endorse any particular mechanism for funding indigent care, we note that solutions more narrowly tailored to a state's recognized policy goals may be substantially less costly to consumers, and ultimately more effective at achieving the desired social goals, than a CON regime.[48]

V. Conclusion

The Agencies recognize that states must weigh a variety of policy objectives when considering health care legislation. But, as described above, CON laws raise considerable competitive concerns and generally do not appear to have achieved their intended benefits for health care consumers. For these reasons, the Agencies historically have suggested that states consider repeal or retrenchment of their CON laws. We respectfully suggest that the Work Group and the General Assembly consider whether Virginia's citizens are well served by its COPN laws and, if not, whether they would benefit from the repeal or retrenchment of those laws.

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[47] The Lewin Group, An Evaluation of Illinois' Certificate of Need Program: Prepared for the State of Illinois Commission on Government Forecasting and Accountability, at ii, 27-28 (Feb. 2007), *available at* http://cgfa.ilga.gov/Upload/LewinGroupEvalCertOfNeed.pdf ("Through our research and analysis we could find no evidence that safety-net hospitals are financially stronger in CON states than other states."); Cutler, *supra* note 45, at 63 (2010) (finding that, following repeal of Pennsylvania's CON program, incumbent hospitals "were not put in a precarious position by the elimination of CON").

[48] *See, e.g.*, LEWIN GROUP, *supra* note 47, at 29 (discussing various financing options for charity care in Illinois); DOJ-FTC Illinois Testimony, *supra* note 19, at 9; Joint Comm'n on Health Care, A Plan to Eliminate the Certificate of Public Need Program Pursuant to Senate Bill 337 22 (2000), *available at* http://www.vdh.state.va.us/Administration/documents/COPN/Prior%20Virginia%20Studies/JCHC%20COPN%20Deregulation%20Plan%20SB337%20of%20%202000.pdf (plan to eliminate Virginia's COPN program included "several provisions to help cushion hospitals and the AHCs from the impact of being less able to cost-shift and subsidize indigent care, low revenue-generating services, and undergraduate medical education").