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March 24, 2017

By Email and First Class Mail

Donna Jerry
Senior Health Policy Analyst
Green Mountain Care Board
89 Main Street, Third Floor City Center
Montpelier, Vermont 05620

RE: Docket No. GMCB-010-15con, Proposed Ambulatory Surgical Center

Dear Donna:

Please find enclosed ACTD LLC's Response to Northwest Medical Center's Submission of Information in Opposition to Application and Vermont Association of Hospitals and Health Systems Memorandum in Opposition to the Green Mountain Surgery Center Certificate of Need Application. Also enclosed is a Verification Under Oath duly sworn by Amy Cooper on behalf of ACTD LLC.

Thank you for your consideration.

Sincerely,

Eileen Elliott, Esq.
Dunkiel Saunders Elliott Raubvogel & Hand, PLLC

cc: Judy Henkin, Esq., General Counsel, Green Mountain Care Board
Marisa Melamed, Health Policy Analyst, Green Mountain Care Board
Lauren Layman, Esq., Vermont Association of Hospitals and Health Systems
Anne Cramer, Esq., Vermont Association of Hospitals and Health Systems
Jill Berry Bowen, CEO, Northwestern Medical Center
Jonathan Billings, V.P. of Planning & Community Relations, Northwestern Medical Center
Lila Richardson, Esq., Office of the Healthcare Advocate
Kaili Kuiper, Esq., Office of the Healthcare Advocate

STATE OF VERMONT
GREEN MOUNTAIN CARE BOARD

IN RE: APPLICATION OF ACTD LLC	**)**	
FOR GREEN MOUNTAIN SURGERY	**)**	**GMCB-010-15CON**
CENTER	**)**	

ACTD LLC REPLY TO NORTHWESTERN MEDICAL CENTER SUBMISSION OF INFORMATION IN OPPOSITION TO APPLICATION; AND VERMONT ASSOCIATION OF HOSPITALS AND HEALTH SYSTEMS MEMORANDUM IN OPPOSITION TO THE GREEN MOUNTAIN SURGERY CENTER CERTIFICATE OF NEED APPLICATION

ACTD LLC ("Applicant") hereby replies to Northwestern Medical Center's ("NMC") Submission of Information in Opposition to Application and Vermont Association of Hospitals and Health Systems' ("VAHHS") Memorandum in Opposition to the Green Mountain Surgery Center Certificate of Need Application. NMC's and VAHHS' arguments build from the premise that Vermont's Certificate of Need ("CON") laws prohibit all competition with Vermont's hospitals, and therefore require the Green Mountain Care Board ("the Board") to deny Vermonters the option to obtain and provide outpatient surgery services at the Green Mountain Surgery Center ("GMSC" or "the Proposed Project") if hospitals are capable of providing such outpatient surgery services at twice the cost, and in a different environment that some patients and providers find disadvantageous. These contentions are false. Moreover, VAHHS and NMC have not established that hospitals that are reasonably accessible to residents of Chittenden County actually have excess capacity to timely serve the patients expected to obtain services from GMSC. Finally, VAHHS and NMC offer no evidence that the Proposed Project will negatively impact hospitals' revenues, services, or charges, or increase the cost of health care services in Vermont. For these and other reasons detailed below, VAHHS and NMC fail to show that the Proposed Project will not meet the CON criteria pursuant to 18 V.S.A. § 9437, and fail to establish any reason the Board should not approve the application and issue a CON.

I. The Application Establishes "need" for the proposed project pursuant to 18 V.S.A. § 9437(3).

A. Applicant is not required to prove insufficient hospital capacity to provide the services the GMSC will offer.

VAHHS and NMC contend that Vermont CON laws prohibit an ambulatory surgery center ("ASC") from competing with hospitals, and therefore require the Applicant to show that area hospitals lack capacity to provide the surgeries and procedures the GMSC will provide in order to prove "need" pursuant to 18 V.S.A. § 9437(3). But this is not what the law requires. CON criterion (3) provides only that the Board must find "an identifiable, existing, or reasonably anticipated need for the proposed project, which is appropriate for the applicant to provide." 18 V.S.A. § 9437(3). Vermont statute also generally provides that health care projects should be developed in a manner which avoids unnecessary "duplication" of services. 18 V.S.A. § 9431.

The State of Vermont Department of Banking, Insurance, Securities and Health Care Administration ("BISHCA") considered these issues in its review of the Vermont Eye and Laser Surgery Center's CON application. *See,* Exhibit A, *In re. Application of Eye Surgery Center and Laser Center of Vermont,* Docket No. 05-058-H, Statement of Decision (May 10, 2007). That application raised the issue of "whether an ambulatory surgery center which will compete for eye surgery services with area hospitals should be granted a certificate of need, in circumstances in which the area hospitals are providing generally similar services." *Id.* at 12. BISHCA found "[w]hether or not competition in health care services is a good or bad phenomena" irrelevant under the CON laws.[1] *Id.* at 12-13. BISHCA further found that "[w]hether or not a hospital or

[1] To the extent CON laws constitute barriers to entry that inevitably do restrict or at least delay competition to some degrees, the Federal Trade Commission and U.S. Department of Justice advise that they benefit incumbent firms at the expense of consumer choice, and stifle innovation, while largely failing to control costs or improve quality. *See, e.g.,* Exhibit B, Joint Statement of the Federal Trade Commission and the Anti-Trust Division of the U.S. Department of Justice on Certificate-of-Need Laws and South Carolina House Bill 3250 (January 11, 2016).

other health care provider has the capacity to provide eye surgery services in general is . . . not dispositive of the question of whether the Applicant's project is needed." *Id* at 13. BISCHA concluded the Vermont Eye Surgery and Laser Center ("Vermont Eye Surgery Center" or "Center") met the "need" criterion and would not "duplicate" services offered by hospitals based on evidence that the services the Center would provide were in demand by patients and materially different from those available at hospitals due to their lower cost; the different environment and patient experience the Center would offer; the Center's convenience for patients and providers; and the Center's anticipated efficiency and ability to schedule surgeries more quickly. *Id.* at 13, ¶¶ 26, 30, 33.

Thus, VAHHS and NMC cannot prove the Application fails to meet the "need" criterion solely with evidence that area hospitals have capacity to offer surgical procedures with the same CPT codes as the GMSC will offer. Rather, the Applicant has shown that there is a need for an alternative model, standing alongside traditional models, to provide less complex outpatient surgical services in an appropriately scaled, "right-sized" facility that will meet the needs of both patients and providers in ways that hospitals cannot. The Application meets the "need" criterion, and demonstrates it will not improperly "duplicate" hospital services, with a strong showing that the GMSC will offer services at a substantially lower cost to public and private payers and self-pay patients than hospital outpatient surgery departments; increased price transparency; a different patient experience that some patients prefer due to a less institutional and intimidating environment; greater efficiency in the use of facilities and physician time; less delay in scheduling surgeries and procedures; and benefits to physician recruitment to the Burlington area. ACTD LLC Certificate of Need Application (July 2, 2015) ("Application") at 64-68; Applicant Response to Board Questions 001 (12/23/15) ("Response to Board Q.001") at Q.6;

Applicant Response to Board Questions 003 (7/15/16) ("Response to Board Q.003) at Q.6, Q.7, Q.12, Q.17; Applicant Response to Board Questions 006 (1/25/17) ("Response to Board Q.006) at Q.5.

According to the 2016 Chittenden County Community Health Needs Assessment, eighty-three percent (83%) of county residents believe there is a high or moderate need for affordable health care, up from eighty-two percent (82%) in 2013.[2] The GMSC will meet that need. Indeed, the strong demand for the Proposed Project has become increasingly clear during the time the Application has been pending before the Board. Most recently, BlueCross BlueShield of Vermont supported the application, noting that "[o]ur members benefit from having a robust network that offers a choice of settings in which they can receive care. For this reason, we credential and contract with any qualified provider that can offer high quality care to our members at competitive prices, as collectively we work toward reducing overall health care expenditures in Vermont." BCBS Letter of Support (March 16, 2017). Similarly, Cigna recently stated in its letter of support for the Proposed Project "[ha]ving an ambulatory surgery center in the Burlington, Vermont area should increase access for Vermont residents to quality, cost-effective services. Consumers gaining access to the right care, in the right setting, at the right price is a goal Cigna supports." Cigna Letter of Support (March 6, 2017). Other letters of support, all speaking to the demonstrable need in the community for the Proposed Project, have been filed by businesses, non-profit organizations, and public interest groups including but not limited to MVP Health Care, AARP Vermont, Seventh Generation, Burton, Burlington Housing Authority, Flex-A-Seal, Main Street Landing, Lake Champlain Chocolates, Rhino Foods,

[2] https://www.uvmhealth.org/medcenter/Documents/About-Us/CHNA.pdf at p. 144.

Champlain Cable Corporation, ReArch Company, Vermont State Employees' Association, Vermont Troopers Association, Vermont Campaign for Health Care Security Education Fund, Vermont Education Health Initiative, The Boys and Girls Club of Burlington, and the Town of Colchester.

B. VAHHS and NMC have not shown that hospitals have sufficient capacity to serve prospective GMSC patients in a timely manner.

Even if VAHHS and NMC could prove the Proposed Project fails to meet the need criterion merely by showing area hospitals have adequate capacity to serve prospective GMSC patients, they have not done so. The Applicant expects the great majority of GMSC patients (96.7%) would otherwise obtain treatment at the University of Vermont Medical Center ("UVMMC"). Response to Board Q.001 at Q.5. VAHHS and NMC have not shown either that UVMMC has adequate capacity to timely serve these patients, or that they are likely to seek service at NMC or any other Vermont hospital if UVMMC cannot serve them in a timely manner.

1. Available Operating Room (OR) and Procedure Room (PR) capacity identified at hospitals outside Chittenden County is not relevant to whether there is a need for more capacity in Chittenden County.

VAHHS's consultant KaufmanHall reports a low (2%) level of "outmigration" of patients from Chittenden County to obtain surgical services in the surrounding area. KaufmannHall, The Green Mountain Surgery Center (GMSC): Need Assessment (March 1, 2017) ("KaufmannHall Report"). While VAHHS argues this statistic proves there is sufficient capacity in Chittenden County, in fact, it proves only that residents of Chittenden Country are not effectively using capacity that may be available at NMC, or other area hospitals.

There are many reasons why residents of Chittenden County might be choosing not to have surgery outside the county. Many patients want to see a specific physician, and most specialty physicians in Vermont who perform surgeries and procedures do not maintain privileges at multiple hospitals. A physician who only maintains privileges at UVMMC cannot use OR time at hospitals outside Chittenden County. Also, some patients may find it burdensome or impossible to travel to a hospital outside Chittenden County for outpatient surgery. VAHHS seems to assume, for example, that an elderly woman living alone in South Burlington should have to find a new physician with privileges at NMC, and then drive or take a bus over thirty miles in order to access a simple procedure. This is unreasonable. This patient should be able to access routine and preventive care from a physician she knows, in a timely manner, and close to home.

2. VAHHS has not proven that UVMMC has excess OR and PR capacity.

The information VAHHS and its consultant KaufmannHall submitted does not establish that UVMMC has excess capacity for several reasons. First, Applicant's evidence that wait times to obtain outpatient surgery services at UVMMC are substantial and exceed ASC industry benchmarks that GMSC expects to meet is uncontroverted, because UVMMC does not measure wait times. Applicant's evidence is that the wait time for a screening colonoscopy with an independent gastroenterologist at UVMMC is 2.5 to 3.5 months. Application at 66. Wait times for common pain management procedures are 4-6 weeks. Response to Board Q.003 at Q.9. GMSC aims to meet ASC industry benchmarks of 1 month for a colonoscopy and less than 1 month for pain management procedures. Response to Q.003 at Q.10. Applicant defines "wait time" as the time between the date a patient or referring physician makes a request for a procedure or surgery and the date the surgery or procedure is scheduled. VAHHS and NMC

note that this interval is sometimes in part determined by variables other than capacity, such as the physician's vacation schedule. Applicant submits that this is not the typical scenario, and lengthy typical wait times reported by the Applicant *are* in fact an indication of capacity constraints.

Second, VAHHS has not provided the information necessary to verify whether capacity allegedly available at UVMMC and other hospitals is actually available for effective use. This information includes the ratio of intake rooms to ORs and PRs, and the availability of staff to support higher volume use of ORs and PRs. A bottleneck due to an insufficient number of intake rooms would mean "excess" OR and PR capacity is actually unavailable. NMC argues the ratio of intake rooms to ORs and PRs is a measure of efficiency, not capacity. But efficiency of course impacts whether capacity can be used; inefficiency limits usable capacity. With respect to staffing, the KaufmannHall analysis "implicitly assumes that existing surgical suites are able to staff appropriately." KaufmannHall Report at 22 n. 4. Yet no evidence is provided to support this assumption, and the Applicant questions whether UVMMC could readily ramp up nurse and other employee staffing to increase OR and PR use based on publicly reported information concerning staffing issues at UVMMC. *See,* Exhibit C. It may be that current utilization of actually available capacity is 100% at UVMMC, and Applicant and the Board cannot determine this without reviewing room layout and staffing protocols.

Third, utilization of capacity during the times when patients generally want and need to have pre-scheduled surgery is almost certainly higher than the rates hospitals have reported for all operating hours. KaufmannHall compares area hospitals' utilization rates to a national "median prime-time utilization rate" of 75%, where "prime-time" is defined as an eight-hour period from 7am to 3pm. KaufmannHall Report at 22, 22 n.1. VAHHS and KaufmanHall report

utilization rates for the UVMMC Main Campus ORs and the endoscopy suite of 74% and 71%. KaufmanHall Report at 22. But those utilization rates are not for "prime-time" hours; they are for hours of operation that vary by room from 10.5 hours to 24 hours per day. *Id.* at 22 n.4; Response of University of Vermont Medical Center to Board's Request for Information (May 6, 2016). It is well documented by OR management journals and consultants that utilization is heaviest during the first "prime-time" hours of the day, and drops off considerably during the later hours of the day.[3] Prime-time hours are busy, because they are generally the best time for patients to have procedures for safety and convenience reasons. For example, it is common protocol for patients to fast the day before a colonoscopy, and a patient who has fasted is best able to endure the procedure physically and mentally if it is scheduled early in the day following the fast. In sum, as UVMMC is reporting full-day operating hours utilization rates of above 70% on the main campus, utilization rates during the prime-time hours when most patients actually need and want to have surgery are likely well above that rate.

Fourth, the 75% "prime-time utilization" rate that VAAHS and KaufmannHall posit as the standard the Board should use to determine whether there is excess capacity is problematic. VAHHS does not represent that 75% is UVMMC's or other hospitals' actual utilization target. The Applicant is not aware of an industry standard for optimum OR utilization. If ORs are over-utilized, it is not possible to accommodate urgent cases at the last minute, or make up for a late start to the first surgeries of the day, or a delay in a procedure, without significantly delaying, inconveniencing, or rescheduling patients scheduled later in the day. In practice, many hospitals may intentionally keep utilization well below 100% and even well below the median reported

[3] http://enhancehc.com/wp-content/uploads/2014/03/Uncovering-Key-Data_0314_HFM_Reprint-stiefel.pdf, page 2.

"prime-time" rate of 75%, because they find that excess delays, rescheduling of procedures, patient inconvenience, or overtime staffing costs result too frequently if ORs are utilized above a certain threshold. In short, the utilization rate that UVMMC and other area hospitals actually consider optimal is unclear and may not be 75%. Also, UVMMC's practical ability to increase its utilization is questionable due to the hospital's size, complexity, and bureaucracy. The myriad complications associated with efforts to effectively utilize OR and PR time at large, traditional hospitals have been reported at length in the peer-reviewed literature. *See,* Exhibit D.

Fifth, in 2014, UVMMC proposed to construct 72,000 additional square feet of outpatient space in South Burlington, including recommendations from consultants that an ASC with six new ORs be added.[4] This proposal suggests that UVMMC does in fact see the need for additional OR capacity in Chittenden County.

Finally, VAHHS and KaufmannHall cite Chittenden County population growth projections based on 2010 census data, which are lower than the projections included in the Application based on a study published in 2000. This data does not undermine Applicant's arguments supporting need for the Proposed Project, as the Application does not rely significantly on future population growth assumptions. Rather, Applicant argues the Proposed Project is needed today, as previously discussed. Also, VAHHS does not dispute that the Chittenden County population is aging, which will drive demand for surgical services even if the total population size does not increase significantly.

II. The Proposed Project Will Not Increase the Cost of Health Care Services In Vermont.

[4] Ambulatory Clinics Master Plan Final Report (July 12, 2013) at 55-56, submitted in support of CON Application by Fletcher Allen Health Care, Inc. to Acquire Real Estate in South Burlington (June 2, 2014).

Vermont statute generally provides that new health care projects should be developed in a manner that contains or reduces increases in the cost of services. 18 V.S.A. § 9431. CON Criterion (2) in part requires the Applicant to prove the Proposed Project will not "result in an undue increase in the cost of medical care" in light of factors including "(i) the financial implications of the project on hospitals and other clinical settings, including the impact on their services, expenditures, and charges; and (ii) whether the impact on services, expenditures, and charges is outweighed by the benefit of the project to the public." 18 V.S.A. § 9437(2)(B).

VAHHS and NMC do not dispute that the GMSC will significantly reduce costs for the patients it serves, as well as the government programs and private payers that insure them. Applicant will be able to charge public and private health insurers substantially less than a hospital would charge for the same surgeries and patients' cost-sharing obligation will be lower. Reimbursement for a procedure at an ASC is typically 40-60% less than for the same procedure performed in a hospital. Indeed, Applicant estimates the GMSC will save the Medicare program over $8,000,000 in its first four years of operation. Application at 10, 22-25.

Nonetheless, VAHHS and NMC argue based entirely upon conclusory allegations that the Proposed Project does not meet CON Criterion (2), or the policy stated in 18 V.S.A. § 9431, because it will result in reduced hospital revenues, causing hospitals to either reduce services, or increase their rates for services. *See*, VAHHS Memorandum in Opposition to the Green Mountain Surgery Center Certificate of Need Application at 15 ("[H]ospitals will still need to generate the revenues necessary to provide the full range of services. That means that people who do not have 'the option' to get services outside of the hospital are likely to pay proportionately more for those services."); NMC Submission of Information in Opposition to Application at 9 ("The opening of the GMSC will siphon profitable surgery away from NMC,

potentially forcing us to make decisions about what unprofitable services must be discontinued.").

VAHHS and NMC do not quantify the revenue impact of the Proposed Project on hospitals. Though GMSC has provided detailed information regarding the anticipated impact of the Proposed Project on hospitals, NMC and VAHHS entirely ignore it.[5] Applicant predicts the Proposed Project will draw 170, 200, and 202 patients from NMC in its first, second, and third years of operation, respectively. Response to Board Q.003 at Q.6. Rather than respond to this information, NMC cites the impact of the Vermont Eye Surgery Center, and notes that it would lose $1 million annually if all its endoscopy patients sought care at the GMSC. There is no evidence before the Board that all NMC's endoscopy patients will be diverted to the GMSC, or that the Vermont Eye Surgery Center's impact on NMC predicts the impact of the GMSC.

Nor have VAHHS and NMC provided any information demonstrating that the Proposed Project will increase systemic health care costs, other than bald allegations that hospitals will increase their fees to make up (unquantified) revenue diverted to GMSC. VAHHS and NMC would need to provide detailed analysis based on proprietary information regarding hospitals' operations and finances in order to prove the diversion of patients to GMSC would result in revenue impacts to which hospitals could respond only by cutting services or increasing fees, as opposed to by increasing efficiencies or developing new lines of service. The information necessary to support this type of analysis is not available to the Applicant, and the hospitals have elected not to provide it.

[5] *See*, Application at 27, Table 5, 6; Applicant's Confidential Response to Board Questions 001(1/22/2016) at Q.4; Applicant's Response to Board Questions 002 (3/31/16) at Q.9; Response to Board Q.003 at Q.6; Applicant's Confidential Response to Board Questions 004 (7/15/16) at Q.2; Applicant's Response to Board Q.004 at Q.1; Response to Board Q.006 at Q.7.

The Board therefore finds itself in the same position BISHCA did when it considered these same arguments in opposition to the Vermont Eye Surgery Center:

> [Hospitals] all argued before the Commission that their financial condition would suffer if the Applicant's project were to be granted a Certificate of Need. . . . No credible evidence, as opposed to unsupported assertions of concerns, was offered that a net revenue loss would in fact occur. In the absence of such evidence, the Commissioner cannot find that [Hospitals] would lose net revenue as a result of the Applicant's project. To find that [Hospitals] would lose net revenue, the Commissioner would have to also find that revenue derived by the Applicant from ambulatory surgical center surgeries would be paid to the hospitals in the absence of the project, and that the hospitals would be unable to offer other revenue-producing surgical services to replace the revenue lost from the ambulatory surgical center surgeries. The Commissioner cannot make such a finding in the absence of credible evidence to support the finding.
>
> * * *
>
> The interested parties have the capacity, and have had the opportunity to develop rational, credible and persuasive information and analysis on the issue of financial impact of the project on overall system costs, but have failed to do so. In contrast, credible evidence supports the conclusion that the project will mitigate health care inflation, by lowering costs for certain eye surgeries.

Exhibit A, *In re. Application of Eye Surgery and Laser Center of Vermont,* State of Vermont Department of Banking, Insurance, Securities and Health Care Administration, Docket No. 05-058-H, Statement of Decision (May 10, 2007) ¶ 23, p.15.

III. <u>The Proposed Project Will Improve Access and Quality of Care Pursuant to 18 V.S.A. § 9437(4).</u>

The Proposed Project will improve quality of care. Applicant has cited research showing that ASCs can yield better health outcomes than hospital outpatient departments. Application at 9. In addition, in its review of the Vermont Eye Surgery Center's CON application, BISHCA found that "quality of care" encompasses more than safety or clinical outcome measures, and the Center would improve quality of care in the sense that it would offer patients lower costs,

convenience, better patient experience, and reduced delays. *Id.* at ¶ 36. The GMSC will improve quality of care in this same sense.

The Proposed Project will improve access to care by reducing delays in scheduling procedures and by offering service at a substantially lower cost than hospital outpatient departments, and with greater price transparency.

IV. The Proposed Project is not Inconsistent With the Direction of Healthcare Reform.

VAHHS argues the Proposed Project will be an impediment to achieving health care reform objectives, because it will charge for its services on a fee-for-service basis. NMC, on the other hand, contends that the Proposed Project will "create silos" in a statewide system that has invested in collaboration and care coordination.

The Proposed Project is not inconsistent with healthcare reform, or otherwise contrary to good public policy for either of these reasons. GMSC intends to become an integrated part of the health care delivery system in cooperation and collaboration with hospitals and other providers (though collaboration is naturally a two way street). Application at 36; Response to Q.003 at Q.19. Financials for the Proposed Project were developed based on fee-for-service payment assumptions, because other payment models are uncertain, including those to be implemented pursuant to the recently approved all-payer waiver. The fact that Applicant's financial model is based on currently available fee-for-service payment estimates in no way implies that Applicant will not look for ways to move away from pure fee-for-service payment models in the future. Applicant cannot be expected to know or predict the future form of healthcare and payment reform. But, as previously explained in response to the Board's questions, GMSC expects to eventually offer bundled payments for surgical procedures. GMSC also plans to be a valuable resource for ACOs managing the total cost of care under a global budget, or attempting to

achieve shared savings by managing actual fee-for-service spending that is below expected fee-for-service spending. Response to Board Q.003 at Q.21.

V. The Proposed Project Will Serve the Public Good.

Finally, for all the reasons set forth in the Application, the Proposed Project will serve the public good pursuant to CON Criterion 6, 18 VSA 9437(6), by:

- Lowering the cost of outpatient procedures for patients, payers and the health care system;
- Providing greater price transparency;
- Expanding access to critical health care services, including diagnostic and screening procedures, which have been shown to improve population health;
- Offering a smaller-scale, more personal alternative to hospital-based care, which will facilitate access to health care for a segment of the population;
- Enabling patients to schedule procedures quickly;
- Enabling physicians to perform procedures more efficiently; and
- Offering high-quality, efficient health care in a patient-friendly setting.

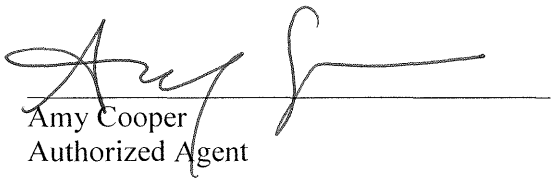
See, Application at 70-74.

VI. Conclusion

For all of the foregoing reasons, VAHHS and NMC fail to show that the proposed project will not meet any CON criterion pursuant to 18 V.S.A. § 9437, and fail to establish any reason the Board should not approve the application and issue a CON. The Application should be approved.

Dated in Burlington, Vermont this 24th day of March, 2017.

ACTD LLC

By: 

Amy Cooper
Authorized Agent

Exhibit A

STATE OF VERMONT
DEPARTMENT OF BANKING, INSURANCE, SECURITIES
AND HEALTH CARE ADMINISTRATION

In re: Application of Eye Surgery and Laser Center of Vermont	))	Docket No. 05-058-H

STATEMENT OF DECISION

Findings of Fact

Procedural History, Parties and Jurisdiction:

1. This matter comes before the Commissioner of the Department of Banking, Insurance, Securities and Health Care Administration (the "Commissioner") on a Certificate of Need application entitled "Application of Eye Surgery and Laser Center of Vermont."

2. The Applicant is Vermont Eye Surgery and Laser Center LLC ("the Applicant").

3. The Division of Health Care Administration ("the Division") of the Department of Banking, Insurance, Securities and Health Care Administration ("the Department") is considered a party in all certificate of need proceedings. (HCA Division Bulletin No. 112, Section 5.B)

4. Fletcher Allen Health Care ("FAHC") and Northwestern Medical Center ("NMC") requested interested party status, and were granted such status by letters dated December 20, 2006. Porter Hospital ("Porter") and the Vermont Association of Hospitals and Health Systems ("VAHHS") requested amicus curiae status and were granted such status by letters dated December 30, 2006.

5. On November 2, 2005 the Applicant submitted a letter of intent proposing to build an ambulatory eye surgery center to be called the Vermont Eye Surgery Center.

6. A Jurisdictional Determination was made on November 9, 2005, in which it was determined that the proposed project would require a Certificate of Need because the Applicant proposes to offer a new health care service or technology which is anticipated to have annual operating expenses exceeding $500,000 for either of the next two years. The Applicant, a non-hospital health care facility, is also proposing to make capital expenditures in excess of $1,500,000.

7. The Application was filed on March 28, 2006, and the application was ruled complete on December 11, 2006 for the purpose of beginning the formal review process.

8. On December 12, 2006, public notice of the Application, and of the time and place of the hearing before the Public Oversight Commission ("the Commission") was made in newspapers having general circulation throughout the state.

9. The Division issued its Staff Report on December 28, 2006. The Staff Report stated that the Application would be reviewed with respect to the following statutory criteria (18 V.S.A. § 9437):

Statutory Criterion No. 1. The Application is consistent with the Health Resources Allocation Plan ("HRAP"). All HRAP standards were determined to be applicable to the Application, except for HRAP Standard Nos. 8-16, 18-20, and 22-23.

Statutory Criterion No. 2. The cost of the project is reasonable because: (i) the applicant's financial condition will sustain any financial burden likely to result from completion of the project; (ii) the project will not result in an undue increase in the costs of medical care; and (iii) less expensive alternatives do not exist, would be unsatisfactory, or are not feasible or appropriate.

Statutory Criterion No. 3. There is an identifiable, existing, or reasonably anticipated need for the proposed project which is appropriate for the applicant to provide.

Statutory Criterion No. 4. The project will improve the quality of health care in the state or provide greater access to health care for Vermont's residents, or both.

Statutory Criterion No. 6. The project will serve the public good.

10. The Commission held a public hearing on the Application on January 10, 2007. After the public hearing the Commission, through the Division, requested additional information from the Applicant and the interested parties.

11. On February 7, 2007 the Commission voted to recommend approval of the Application on a 6-2 vote. The Commission issued the following (in italics) in connection with its recommendation:

Findings and Observations:

1. *The proposed Eye Surgery and Laser Center of Vermont will be a freestanding ambulatory surgery center with two sterile operating rooms located in South Burlington. The proposed ambulatory surgery center will offer ophthalmology and procedures related to the eye and eyelid. ESLCV, as proposed, will be wholly owned and operated by Vermont-based ophthalmologists and will have a medical staff open to Board certified or Board eligible ophthalmologists residing in the service area. The ESLCV will seek Medicare and Medicaid certification.*
2. *ESLCV retained Surgery Center Services of America to assist in the development of the project. The applicant has secured a lease for the proposed facility; the lease agreement includes the cost of interior construction of the ambulatory surgery center. The expected capital outlay to the applicant is $533,988 for equipment and furnishings. Lease payments over ten years amount to $2,007,250. Development, zoning and construction costs will be the responsibility of the lessor. Surgery Center Services of America has assisted the applicant in developing policies and procedures required for certification and accreditation.*
3. *The applicant expects to offer cataract, laser, refractive, pediatric, eyelid and glaucoma surgeries at the center. A very small minority of the cases are anticipated to require general anesthesia. ESLCV has indicated that it will be*

able to accept responsibility for post-operative care and follow-up care. The applicant states that the facility will perform only low-risk ambulatory surgery procedures that do not require overnight stays. The facility will be located less than 5 miles from a licensed general hospital with three or more operating rooms, that being Fletcher Allen Health Care.

4. *Demographic projections point to a significant increase in demand for eye surgery in the coming decade. Massachusetts Institute for Social and Economic Research estimates the 65 and over population in the applicant's proposed service area will increase by 44% from 2005-2015. This demographic cohort is the primary consumer of outpatient eye surgery, suggesting that there will be a significant increase in demand for outpatient eye surgery in the coming decade. This proposed new surgical capacity addresses the IOM aim of timeliness. Though the testimony of several hospitals indicates that Vermont hospitals have capacity to meet current outpatient eye surgery demand, this proposed facility would likely accommodate this anticipated surge in demand.*
5. *The proposed facility would likely provide patients with improved access to eye surgery. The additional specialized operating room capacity for eye surgeons and two-room operating room set-up is likely to reduce delays for patients. The ability to perform morning surgery (a more convenient situation for patients) with greater frequency would also be a benefit to patients. These benefits to patients address the IOM's aims of timeliness, effectiveness and safety.*
6. *Ophthalmology has been cited as a challenging specialty for recruitment to Vermont. Increased operating room capacity, and the improved physician productivity available in a freestanding specialty surgery center may serve to bring more highly qualified physicians to Vermont, addressing IOM's aims of patient-centeredness, timeliness and efficiency.*
7. *Eye surgery performed at freestanding surgery centers is less expensive, and addresses the IOM's goal of efficiency. Medicare reimbursement rates for eye surgery performed at freestanding surgery centers are significantly below that reimbursed for in-hospital eye surgeries. Approximately 75% of the patients in the proposed facility are Medicare patients. The anticipated savings for a cataract procedure (the most common outpatient eye procedure) is $675.54. It is expected that savings would accrue to both Medicare and the patient (via lower copay).*
8. *While no specific outcomes data were presented, the applicant stated that complication and infection rates for eye surgeries performed in freestanding ambulatory surgery centers are lower than complication and infection rates for eye surgeries performed in hospitals, based on national data. This addresses the IOM's goal of safety.*

9. *The applicant will privately finance the project.*

Concerns:

1. *The potential for duplication of services was cited as a concern by both interested parties and members of the Public Oversight Commission. There was significant debate about current capacity utilization of existing hospital operating room facilities.*
2. *The system impact of a freestanding ambulatory surgery center relative to potential cost savings and patient centeredness was cited as a concern.*
3. *Interested parties have raised concerns regarding significant financial impact to several Vermont hospitals. However, demographics discussed above suggest a continuing increase in demand for all hospital surgical services, potentially minimizing this financial impact.*
4. *Reporting standards for a freestanding ambulatory surgery center are significantly different than those required for hospitals.*
5. *There is the potential to increase fixed costs for health care delivery in Vermont.*

Based on the information and testimony provided by the Applicant and the interested parties, and with consideration of the above findings, the Public Oversight Commission recommends to the Commissioner of BISHCA that the CON for this Docket be approved with the following condition:

1. *The scope of the project shall be limited to eye surgery and related procedures.*

12. Following the Commission's recommendation, the Commissioner, pursuant to HCA Bulletin 112, Section 5.M.6, contracted with The Center for Evaluative and Clinical Sciences to obtain additional information necessary to adequately consider the Application. The parties were afforded an opportunity to be heard concerning this additional information at a hearing held on April 9, 2007.

13. The Commissioner issued a Notice of Proposed Decision pursuant to 8 V.S.A. § 9440(d)(6) on April 10, 2007, and pursuant to 18 V.S.A. § 9440(d)(4), the Commissioner extended the review period an additional 30 days to accommodate the need for further hearings. The parties were afforded an opportunity to file exceptions and present briefs and oral argument, and were afforded an opportunity to be heard at a hearing before the Commissioner on May 3, 2007. The parties were offered an additional opportunity to present further written argument on May 7, 2007.

Project Description:

14. The proposed Eye Surgery and Laser Center of Vermont ("the Center") would be a freestanding ambulatory eye surgery center with two sterile operating rooms located in South Burlington Vermont. The Center would be wholly owned and operated by Vermont-based ophthalmologists who live and practice in the service area, with no out-of-state or corporate ownership. The Center would have a medical staff open only to Board-certified or Board-eligible ophthalmologists residing in the service area. The

Center intends to offer only ambulatory surgical procedures of the eye and eyelid. The surgical payor mix for participating ophthalmologists at the Center is projected at 75% Medicare, 10% Medicaid, 11% commercial, 1% self-pay, 3% bad debt, and 1% charity.

15. The Applicant proposes to retain six ophthalmologists to perform eye surgeries at the Center. Four ophthalmologists are prepared to commence surgeries as soon as the Center begins operations. The Applicant will seek to recruit and retain two additional ophthalmologists.

16. The Applicant has represented that the four ophthalmologists identified as physicians to be retained by the Center are expected to perform 1,351 eye surgeries in 2007 (assuming a full year of operation), 1,647 eye surgeries in 2008, and 1,806 eye surgeries in 2009. The Applicant did not offer projections of how many eye surgeries will be performed at the Center by the six ophthalmologists proposed to be retained, but the Commissioner finds that it is reasonable to assume that the two additional ophthalmologists will perform on average the number of eye surgeries performed on average by the four identified ophthalmologists. If the two additional ophthalmologists performed on average the number of eye surgeries performed on average by the four identified ophthalmologists, the six ophthalmologists would be expected to perform 2,027 eye surgeries in 2007 (assuming a full year of operation), 2,471 eye surgeries in 2008, and 2,709 eye surgeries in 2009. If a 5% estimating margin is used for unanticipated growth, the six ophthalmologists would be expected to perform 2,128 eye surgeries in 2007 (assuming a full year of operation), 2,595 eye surgeries in 2008, and 2,844 eye surgeries in 2009:

Vermont Eye Surgery and Laser Center
Projected Surgical Procedures by Physician 2006-2009

Physician	2006 procedures	2007 procedures	2008 procedures	2009 procedures
Dr. A	280	422	464	511
Dr. B	475	712	949	1044
Dr. C	120	126	132	139
Dr. D	80	91	102	112
Dr. E [1]	239	338	412	452
Dr. F. [2]	239	338	412	452
Total	**1433**	**2027**	**2471**	**2709**

[1] Dr. E is assumed to be one of two new ophthalmologists proposed to be retained by the Applicant. Projections for procedures performed by Dr. E assumed that Dr. E will perform on average the number of eye surgeries performed on average by the four identified ophthalmologists. See Para. 16.

[2] Dr. F is assumed to be one of two new ophthalmologists proposed to be retained by the Applicant. Projections for procedures performed by Dr. F assumed that Dr. F will perform on average the number of eye surgeries performed on average by the four identified ophthalmologists. See Para. 16.

17. There is sufficient credible, material and relevant evidence in the record to support the description of the project in the Commission's "Findings and Observations" Nos. 1 through 3, which are adopted and incorporated herein.

The Applicable Certificate of Need Criteria:

Statutory Criterion No. 1. The Application is consistent with the Health Resources Allocation Plan ("HRAP").

18. There is sufficient credible, persuasive, material and relevant evidence in the record to find that the Application is consistent with the HRAP with respect to HRAP Standard Nos. 2, 4, 5, 6, 7, 17, and 21. HRAP Standard No. 1 (need), and Standard No. 3 (reasonable cost to payers) are addressed in Finding Nos. 16 to 25, below, relating to Statutory Criterion No. 2 (reasonable cost) and Statutory Criterion No. 3 (need). The evidence in the record is uncontroverted as to the HRAP standards other than HRAP Standard Nos. 1 and 3, and to the extent evidence was introduced in the record to the contrary, the Commissioner finds the evidence offered by the Applicant to be of greater weight, and more credible and convincing.

19. HRAP Standard No. 17 contains the HRAP criteria for approval of an ambulatory surgical center such as the Center proposed by the Applicant. The Applicant has demonstrated that its operations will be in conformance with the specific criteria for approval contained in HRAP Standard No. 17. No credible or persuasive evidence has been offer that the Applicant will not be in conformance with the specific criteria for approval contained in HRAP Standard No. 17. While an actual transfer agreement has not yet been executed between the Center and a hospital, the Applicant has stated its intention to seek such an agreement with FAHC, and FAHC has stated its intention to discuss with the Applicant an appropriate transfer agreement with the Applicant.

Statutory Criterion No. 2. The cost of the project is reasonable because: (i) the applicant's financial condition will sustain any financial burden likely to result from completion of the project; (ii) the project will not result in an undue increase in the costs of medical care; and (iii) less expensive alternatives do not exist, would be unsatisfactory, or are not feasible or appropriate. (See also HRAP Standard No. 3)

20. The Applicant's financial condition is such that it can sustain the anticipated costs of the project. The Applicant anticipates very profitable operations from the project. There is sufficient, credible, material and relevant evidence in the record to support Finding No. 9 of the Public Oversight Commission relative to the private financing of the project, and such evidence outweighs any evidence offered to the contrary. Accordingly, Finding No. 9 of the Commission is adopted and incorporated herein.

21. The project is an ambulatory surgical center that proposes to offer specific types of eye surgery on an outpatient basis. Because the surgeries will be performed in an ambulatory surgical center, the Applicant will be able to charge the public or private health insurer substantially less than the charge for such surgeries at a hospital. Likewise, because of the lower cost of eye surgery at the proposed project, in many cases the patient's cost sharing obligations will be lower than if the eye surgery were to be

performed at a hospital. For example, the evidence was uncontroverted that for each cataract reimbursed by Medicare in 2007, the total savings on Medicare facility fees if the surgery were to be performed in the ambulatory surgical center would be $675.54, with a $540.43 savings to the public health insurer (Medicare) and with a $135.11 savings to the patient (out-of-pocket savings; or savings to the patient's Medicare Supplemental health insurer). A hospital simply cannot, because of the design of its operations and infrastructure, provide the same service at an economically competitive price. Calculated for 2005, aggregate savings with respect to Medicare patients would have been $362,000, and aggregate savings with respect to non-Medicare patients would have been $163,030. There is sufficient, credible, material and relevant evidence in the record to support Finding No. 7 of the Public Oversight Commission relative to anticipated cost savings from the project, and such evidence outweighs any evidence offered to the contrary. Accordingly, Finding No. 7 of the Commission is adopted and incorporated herein.

22. There is sufficient, credible, persuasive, material and relevant evidence in the record to find that because of the unique nature of the project, including the totality of the circumstances found in Para. 26 (reduced costs, reduced scheduling delays, increased productivity, enhanced recruitment of ophthalmologists, a better experience for patients, and new surgical techniques and technology) the Center will not result in an undue increase in the costs of medical care. The evidence in the record is also clear that less expensive alternatives do not exist, since not only is the nature of eye surgery performed at the hospitals different from the nature of eye surgeries proposed to be performed at the Applicant's Center, but eye surgery at hospitals is a more expensive procedure. The Commissioner cannot find sufficient support in the record for the contrary assertions or proposed findings of the interested parties with respect to the cost of the project.

23. FAHC, NMC and Porter all argued before the Commission that their financial condition would suffer if the Applicant's project were to be granted a Certificate of Need. FAHC and NMC offered evidence of the number of cataract surgeries offered at their respective hospitals, and calculated the gross revenue loss that could be anticipated if the specified number of such surgeries were to be performed at the Applicant's ambulatory surgical center rather than their respective hospital. Amicus curiae Porter also offered assertions to the same effect as FAHC and NMC, without offering such evidence because of Porter's status as amicus curiae. No credible evidence, as opposed to unsupported assertions or concerns, was offered that a net revenue loss would in fact occur. In the absence of such evidence, the Commissioner cannot find that FAHC, NMC or Porter would lose net revenue as a result of the Applicant's project. To find that FAHC, NMC or Porter would lose net revenue, the Commissioner would have to also find that revenue derived by the Applicant from ambulatory surgical center surgeries would be paid to the hospitals in the absence of the project, and that the hospitals would be unable to offer other revenue-producing surgical services to replace the revenue lost from the ambulatory surgical center surgeries. The Commissioner cannot make such a finding in the absence of credible evidence to support the finding.

24. Even if credible evidence had been offered to support a finding that FAHC, NMC or Porter would suffer a financial loss in net revenue if the Applicant's project is

developed, there is no credible evidence to further find that, as a result of the loss of net revenue at FAHC, NMC, or Porter, the project will result in a negative financial impact on health care payers, including public and private health insurers, employers, consumers through out-of-pocket payments, the uninsured, and government. See HRAP Standard No. 3. After the Applicant offered evidence demonstrating that it will be able to offer eye surgeries at a significantly lower cost than the area hospitals, the interested parties contesting the Application had numerous opportunities provided by the Public Oversight Commission and the Commissioner to demonstrate that the project would have a negative impact on Vermont health care costs, but the interested parties failed to do so. In the absence of contrary, rational, persuasive and credible evidence in the record, the Commissioner must find that the financial impact of the project on Vermont health care payers will be positive, not negative.

Statutory Criterion No. 3. There is an identifiable, existing, or reasonably anticipated need for the proposed project which is appropriate for the applicant to provide.

25. Substantial and conflicting evidence was offered by the Applicant and the interested parties with respect to whether the Applicant met its burden of proving a need for the project.

26. The Applicant offered credible evidence that the project is needed because it will reduce costs for Vermont health care payers, reduce delays in scheduling surgeries, increase productivity in terms of the number of eye surgeries that can be performed, make it easier to recruit new ophthalmologists to northwestern Vermont, provide a more comfortable and less intimidating experience for patients including seniors, and provide new types of eye surgery procedures (for example, the most current generation phacoemulsification machines, matching state-of-the-art/modern microscopes for two rooms, or reasonable cost elective accommodative IOL surgery).

27. The interested parties did offer evidence that hospital operating rooms at FAHC and at Northwestern Medical Center are used at less than 100% capacity, and that some of the ophthalmologists proposing to use the Applicant's Center have unused operating room block time available. The Applicant responded with a credible argument and evidence that theoretically available operating room time is not actually available if it cannot be used for patients when they need or want to be scheduled for eye surgery.

28. The interested parties argued that the record did not support a finding of increased productivity anticipated from the Applicant's Center. On the contrary, the Commissioner finds ample, credible and persuasive evidence in the record of this proceeding that the nature of an ambulatory surgery center specializing in eye surgeries is inherently more efficient and offers greater productivity for the ophthalmologists and other health care providers retained by the Center.

29. The parties offered conflicting evidence on whether an ambulatory surgery center is needed in Vermont to assist with the recruiting of new ophthalmologists to the area. The Commissioner finds the weight of the credible evidence supports a finding that a new, ambulatory opthamological surgical center, with the capacity to offer new

techniques and procedures not currently available as a general rule at hospitals, is an important factor in ophthalmologist recruitment, notwithstanding the efforts and achievements in recruiting demonstrated by the interested parties. The recruitment assistance factor is another circumstance demonstrating, along with other relevant factors identified in Para. 26, above, that demonstrates there is an identifiable, existing, or reasonably anticipated need for the proposed project which is appropriate for the Applicant to provide.

30. The interested parties argued that in the absence of evidence that patients find their eye surgery at area hospitals to be "uncomfortable" or "intimidating", the record does not support the finding in Para 26, above that the Applicant demonstrated a need for the project because patients will find the environment at the Center more comfortable or less intimidating. It is not a criticism of area hospitals for the Applicant and others to observe, and the Commissioner so finds and takes administrative notice, that many Vermont patients would prefer, if available and appropriate, to have health care services provided in a non-hospital setting.

31. The interested parties asserted that there is no evidence in the record to support a finding that the Applicant's Center will support new types of eye surgery procedures, by arguing that the CPT codes for eye surgeries proposed for the Applicant's Center are also performed at the area hospital. The Applicant responded credibly and persuasively that the same CPT codes can be used for surgeries using standard techniques and technologies, as well as new techniques and technologies, and that some of the new techniques and technologies could not be performed, or are not being performed at hospitals at a cost that is comparable to the Center's projected costs. The Commissioner finds, based on the weight of the credible and persuasive evidence, that the Applicant's Center will be able to offer new techniques and technologies in eye surgery, and will be able to do so in a less costly manner.

32. There is sufficient, credible, persuasive, material and relevant evidence in the record to support Finding No. 6 of the Public Oversight Commission relative to the recruitment of ophthalmologists to Vermont, and such evidence outweighs any evidence offered to the contrary. Accordingly, Finding No. 6 of the Commission is adopted and incorporated herein.

33. The interested parties argued that the project was not needed because the Applicant would be offering "duplicative" services. The interested parties offered little credible evidence that the project would not provide services in demand by patients; rather, the evidence offered by the hospitals is that they have the capacity to offer surgical procedures with the same CPT codes, but in a very different manner and environment, and using new techniques and technology, as found in Para 26, above. It is on this basis that the hospitals argue that the project is "duplicative" and not needed. Such evidence is not of the type sufficient to support a finding that the project proposes to offer services that are not needed, or that there is "excess capacity" for the proposed services.

34. Both the Applicant and the interested parties offered conflicting evidence concerning (i) the extent to which the aging of the "baby boom" generation will increase the demand for, and therefore the extent of the need for out-patient eye surgical services, (ii) whether the hospitals have the capacity to meet the anticipated increased need, and (iii) ultimately whether the ambulatory surgical center project proposed by the Applicant is therefore needed. The Commissioner requested information and analysis from the Center for Evaluative and Clinical Sciences ("CECS") concerning the project. As the interested parties correctly note, CECS opined that "age impacts aren't likely to have tremendous impact on system demand." CECS also opined, however, that "if the age distribution of the VT medicare population shifts upward, the demand for eye procedures is likely to increase." CECS notes earlier in its report that "a disproportionate share of [eye service] procedures occur among 75-84 year olds. An increase in this age category would be expected to produce an increase in demand for eye procedures (assuming the baseline age-specific rate stays the same over time)." While the CECS analysis cautions not to over-estimate the impact of changing demographics on the need for eye surgery capacity in Vermont, the evidence is uncontroverted that as the demographics of the Vermont population increases in age, the need for medical system capacity to perform eye surgeries will increase as well. Notwithstanding arguments about the extent of the need, and whether or not the hospitals can also meet part of the demographic need, the evidence is clear and convincing that the Applicant's project is well-suited and needed to meet the demand for part of this identifiable, reasonably anticipated need.

35. There is sufficient, credible, persuasive, material and relevant evidence in the record to support Finding No. 4 of the Public Oversight Commission relative to demographic projections, and such evidence outweighs any evidence offered to the contrary. Accordingly, Finding No. 4 of the Commission is adopted and incorporated herein.

Statutory Criterion No. 4. The project will improve the quality of health care in the state or provide greater access to health care for Vermont's residents, or both.

36. There is sufficient persuasive, credible, material and relevant evidence in the record to find that the project will offer quality care to patients, although the evidence is in dispute as to whether the project will offer "improved" quality of care. After weighing the competing evidence, the Commissioner finds that the project will offer improved care in the sense that it will offer eye surgical procedures of a different nature, which many patients and doctors find to be more attractive for the totality of the circumstances and reasons set forth in Finding No. 26, above, (reduced costs, reduced scheduling delays, increased productivity, enhanced recruitment of ophthalmologists, a better experience for patients, and new surgical techniques and technology). The argument of the interested parties that there is no evidence in the record to support a finding of improved quality of care rests on too narrow a reading of the statutory criterion, and too narrow an understanding of the word "quality". As established in the HRAP, the quality of a proposed project should be considered with respect to its relationship to the quality goals and values expressed by the Institute of Medicine: safety, effectiveness, patient-

centeredness, timeliness, efficiency and equity.[3] The Commissioner finds that "quality of care" encompasses more than safety or clinical outcome measures, and a finding of improved quality of care does not require evidence of deficiencies by hospitals which also provide eye surgery services.

37. While the interested parties offered some evidence that the area hospitals have adequate capacity to provide eye surgery to patients in northwest Vermont, there is sufficient, persuasive, credible, material and relevant evidence in the record to find that the Applicant's project will provide access to ambulatory eye surgery of a type and in an environment not currently available. The argument of the interested parties that there is no evidence that the project will improve access to health care for Vermont residents simply restates their argument that the Applicant's Center proposes to provide "duplicative services", whereas the Commissioner has found that the eye surgery services proposed by the Applicant are very different from the eye surgery services provided by the hospitals, for the reasons and the totality of the circumstances and reasons set forth in Finding No. 26, above, (reduced costs, reduced scheduling delays, increased productivity, enhanced recruitment of ophthalmologists, a better experience for patients, and new surgical techniques and technology). The Commissioner also finds that access to care for Vermont residents is inextricably linked to the cost of care, and to the extent that the Applicant's project will reduce the cost of eye surgeries, Vermont residents will have greater access to eye surgeries.

38. There is sufficient, credible, persuasive, material and relevant evidence in the record to support Finding No. 5 of the Public Oversight Commission relative to improved access to eye surgery, and Finding No. 8 of the Commission relative to quality and safety, and such evidence outweighs any evidence offered to the contrary. Accordingly, Finding Nos. 5 and 8 of the Commission are adopted and incorporated herein.

Statutory Criterion No. 6. The project will serve the public good.

39. There is sufficient credible, persuasive, material and relevant evidence in the record to find that the project will serve the public good, and to the extent that contrary evidence was offered, the Commissioner finds that the contrary evidence is out-weighed by the evidence that the project will serve the public good.

40. The interested parties offered evidence, and Porter offered argument and comment that the Applicant's project would not serve the public good because it would hurt area hospitals financially. This evidence in itself is not relevant to whether the project satisfies Statutory Criterion No. 6, in the absence of evidence that the Applicant's project would also impose unreasonable, additional costs on Vermont's health care system as a whole.

41. The interested parties offered evidence, and Porter offered argument and comment that the Applicant's project would not serve the public good because the area hospitals could also perform the eye surgeries proposed by the Applicant, and as a result

[3] HRAP: Section Four. Institute of Medicine, *Crossing the Quality Chasm, a New Health system for the 21st Century*, 2003.

the project's services would be "duplicative". This evidence in itself is not relevant to whether the project satisfies Statutory Criterion No. 6, in the absence of evidence that the public will be adversely affected as a result of the project.

Adoption of Evidence

42. The entire record of testimony and evidence given to support the Findings of Fact and Conclusions of Law in this matter, in particular, the cited findings relating to need, are hereby adopted as credible, persuasive, convincing, material and relevant to this Statement of Decision and the Certificate of Need.

Representations of the Applicant

43. All representations made by the Applicant throughout this process are considered material representations of fact submitted by the Applicant in order to gain approval of its application.

Conclusions of Law

A. The Certificate of Need law requires the assertion of jurisdiction over the proposed project, based on proposed capital expenditures in excess of $1,500,000, and based on the anticipated annual operating expense of the project for the next two years, which is estimated to exceed $500,000. 18 V.S.A. § 9434(a)(1) and (5).

B. The Application is consistent with the HRAP, provided the Conditions established in Para. I, below, are attached to the Certificate of Need. 18 V.S.A. § 9437(1). The Application's consistency with most of the HRAP Standards is uncontroverted, notwithstanding any contrary conclusions which could be made from the evidence. Conclusions of Law with respect to the project's relation to HRAP Standard No. 1 (need) and HRAP Standard No. 3 (cost) are made in Paras. C and D, below.

C. Provided the Conditions established in Para. I, below, are attached to the Certificate of Need, the Applicant has met its burden of demonstrating that there is an identifiable, existing, and reasonably anticipated need for the proposed project which is appropriate for the Applicant to provide. 18 V.S.A. § 9437(3). The critical issue raised by this application is whether an ambulatory surgical center which will compete for eye surgery services with area hospitals should be granted a certificate of need, in circumstances in which the area hospitals are providing generally similar services.

More specifically, the law places a legal obligation on the Commissioner in reviewing Certificate of Need applications: "A certificate of need shall be granted if the applicant demonstrates and the Commissioner finds" that the statutory criteria have been met. 18 V.S.A. § 9437. While this statutory standard confers on the Commissioner considerable discretion, the Commissioner is not authorized to deny an application unless the Applicant has failed to meet its burden of proof because the evidence demonstrates that a particular HRAP Standard or Statutory Criterion has not been satisfied.

There has been considerable uncertainty expressed by the parties in the record of this proceeding concerning what are the applicable standards and criteria with respect to "need" upon which the project is to be reviewed. Whether or not competition in health

care services is a good or a bad phenomena is irrelevant to the Certificate of Need proceeding. Whether or not a hospital or other health care provider has the capacity to provide eye surgery services in general is relevant, but not dispositive of the question of whether the Applicant's project is needed. Under the current law, and under the current, approved HRAP Standards, unless there is insufficient evidence to demonstrate that the project is needed, the Application may not lawfully be denied on the basis of "need".

This is also not a project that presents the occasion to consider whether profitable patients are being "cherry-picked" by the Applicant, leaving less profitable patients for hospitals to provide care to, because no credible evidence was offered into the record to support a determination of intentional or de facto discrimination of this nature based on the medical condition of the patient. This is not a case, therefore, similar to the HealthSouth application, where the Public Oversight Commission determined that the application should be denied because of concerns based on evidence in the record about the impact of that project on Vermont health care system costs. Consequently, the Commissioner concludes, based on the evidence in the record, that the concerns of the interested parties in this regard are misplaced. Should evidence of "cherry-picking" be offered in a future Certificate of Need proceeding, the review process is capable of making a determination as to the factual merits of the concern, and if the concern has factual merit the review process is capable of making a determination of whether an applicant has met its burden of demonstrating that its project will serve the public good such that a certificate of need should be granted. 18 V.S.A. § 9437(6).

This is also a very different case from that presented in the CON application *In re: Fletcher Allen, Inc., Docket No. 02-012-H.* In that matter, FAHC had filed a competing application to a CON application by HealthSouth under the CON law as it existed before 2003. The HealthSouth application was later withdrawn. The Commissioner denied FAHC's competing application to open additional operating rooms at the Fanny Allen campus, in part because the evidence introduced into the record, and FAHC's own assertions, demonstrated that the additional operating rooms would create excess operating room capacity. This proceeding presents very different circumstances, because the Applicant's Center is narrowly focused on offering specialized eye surgery procedures, not the general operating capacity of concern in Docket No. 02-0120H. As has been found in Finding Nos. 24-34, above, and as has been concluded in this Para. C, while the interested parties and amicus curiae do offer eye surgery services at their hospitals, the surgery services proposed by the Applicant's Center are materially different, in terms of the environment in which the eye surgeries will be performed, the new techniques and technologies which will be used, the increased efficient and productivity of the Center, and the other factors and circumstances found in Paras. 25-35, above. Because of these material and substantial differences, the Commissioner concludes that the Center, as described in the evidence in the record, and as limited by the terms, conditions and other requirements imposed in Para. I, below, will not create excess capacity such that Vermont health care system costs will be adversely affected.

The interested parties also argue based on the reasoning used by the Commissioner in the CON application *In re: Fletcher Allen, Inc., Docket No. 02-012-H* that the likelihood

of changing demographics of the Vermont population cannot serve as the basis for a finding of need. The project proposed in that CON proceeding was the opening of general operating rooms at the Fanny Allen campus, at a time shortly after a Certificate of Need had been awarded to FAHC for an Ambulatory Care Facility. The proposal to open Fanny Allen operating rooms was made as a competing application to an independent application by HealthSouth for an ambulatory surgery center. The Commissioner found in that proceeding that FAHC had not demonstrated a need for increased operating room capacity, and found that FAHC's argument based on Vermont demographics was not persuasive in those circumstances. The Applicant in this proceeding, however, has demonstrated on the basis of credible, persuasive evidence that its narrow focus on eye surgeries, coupled with evidence of on-going demographic changes in the Vermont population, will result in an increased need for medical system capacity to perform eye surgeries to some degree. On the basis of the record in this very different proceeding, involving a very different project, the Commissioner concludes that the evidence is clear and convincing that the Applicant's project is well-suited and needed to meet the demand for part of an identifiable, reasonably anticipated need for eye surgeries for the aging population of Vermont residents.

D. Provided the Conditions established in Para. I, below, are attached to the Certificate of Need, the Applicant has met its burden of demonstrating that the cost of the project is reasonable, because: (i) the applicant's financial condition will sustain any financial burden likely to result from completion of the project; (ii) the project will not result in an undue increase in the costs of medical care; and (iii) less expensive alternatives do not exist, would be unsatisfactory, or are not feasible or appropriate. 18 V.S.A. § 9437(2).

As is the case with regard to the question of "need", there has been considerable uncertainty expressed by the parties in the record of this proceeding concerning what weight, if any, should be given in a Certificate of Need proceeding to evidence that a proposed project might adversely impact the financial condition of an incumbent health care provider, such as the area hospitals which are interested parties or amicus curiae in this matter. Prior to the amendment to the Certificate of Need laws in 2003, and before the expiration of the Certificate of Need Guidelines and their replacement with the HRAP in 2005, adverse impact on an incumbent competitor was relevant. The former law explicitly created a higher burden on competitive services by providing that "the Commissioner shall not grant a certificate of need" unless "in the absence of the proposed new service, patients would experience serious problems * * * in obtaining care of the type proposed." Former 18 V.S.A. § 9437(3). The current statutory standard establishes a less stringent standard of need with respect to the capacity of other health care providers.

The Certificate of Need Guidelines authorized under former 18 V.S.A. § 9437(5) established explicit, high hurdles for ambulatory surgical centers. Under the former Guidelines, "a CON to establish an Ambulatory Surgical Center should not be granted unless * * * the Department takes into special consideration the financial implications of additional surgical capacity on existing hospital and other clinical settings." In sharp

contrast, the successor to the Certificate of Need Guidelines relating to Ambulatory Surgical Centers, HRAP Standard No. 17, contains no reference whatsoever to the financial impact of a project on incumbent providers. Instead, the statutory criterion relative to adverse impact of existing services is Statutory Criterion No. 5: The project will not have an undue adverse impact on any other existing services *provided by the applicant*. (emphasis added) 18 V.S.A. § 9437(5).

Upon consideration of the legislative amendments to the Certificate of Need laws, and the replacement of Certificate of Need guidelines providing some measure of incumbent protection with HRAP standards with no such incumbent protection, the Commissioner concludes that, in the circumstances presented by the evidence of the record of this proceeding, denying the Application because of its potential financial impact on area hospitals would be contrary to the legal authority granted to the Commissioner in administering the CON program. Financial impact on hospitals and other providers, under current law and HRAP standards, might be relevant to the Certificate of Need review if a negative impact on health care system costs in general can be demonstrated, but the interested parties did not offer credible or convincing evidence that the project would negatively impact Vermont health care system costs. Contrary to the argument of the interested parties (Memorandum of Interested Parties - April 25, 2007), the Commissioner has not only not ignored the impact of the Applicant's project on overall system costs; to the contrary, the Public Oversight Commission and the Commissioner have provided numerous opportunities for the interested parties to demonstrate in a rational, credible and persuasive manner that the project will increase overall system costs. The interested parties have the capacity, and have had the opportunity to develop rational, credible and persuasive information and analysis on the issue of the financial impact of the project on overall system costs, but have failed to do so. In contrast, the credible evidence supports the conclusion that the project will mitigate health care inflation, by lowering costs for certain eye surgeries.

E. Notwithstanding the Conclusions of Law reached in Paras. C and D, above, the Commissioner is cognizant that the Applicant's Center will be the only ambulatory surgical center in Vermont. Vermont does not have significant experience with ambulatory surgical centers, and the Commissioner is concerned about the rising cost of health care in Vermont, and the potential adverse consequences of rising costs on access to, and quality of care. The Commissioner also concludes that the impact of the project can only be assessed by reference to the specific details and projections of the project offered by the Applicant and entered into the record during the course of this CON proceeding. Accordingly, it is reasonable and in furtherance of the purposes of the CON law that the terms, conditions and other requirements of the Certificate of Need issued to the Applicant include appropriate limitations (or "caps") on the number of ophthalmologists to be retained by the Applicant, and the number of procedures to be performed at the Center. These limitations are based on the evidence and projections offered by the Applicant. The Commissioner further concludes that it is reasonable, equitable, and in furtherance of the purposes of the CON law for the Applicant to be

afforded the opportunity to petition the Commissioner for amendment or termination of such limitations in appropriate circumstances.

F. The decision of the Commissioner is consistent with the recommendation of the Public Oversight Commission in that the Commission voted to recommend that a Certificate of Need be issued to the Applicant; however, the Commission recommended that the project be subject to a single condition related in general to the scope of the project. The Commissioner concludes, pursuant to 18 V.S.A. § 9440(d)(6)(B), for the reasons set forth in Para. E, above, that additional terms, conditions and requirements must be attached to the Certificate of Need because of the Commissioner's concerns (echoed by the Public Oversight Commission) relating to the potential impact of the project on health care costs in Vermont in general. Accordingly, specific limitations on the number of ophthalmologists to be retained by the Applicant, and on the number of procedures to be performed at the Center will be attached to the Certificate of Need, and the Commissioner concludes that such limitations are necessary to further the policies and purposes of the CON law. The Commissioner also concludes that the other terms, conditions and requirements set forth in Para. I, below, are reasonable, based on the record of evidence in this proceeding, and necessary to further the policies and purposes of the CON law.

G. The Applicant has met its burden of demonstrating that the project will improve the quality of health care in the state, provided the Conditions established in Para. I, below, are attached to the Certificate of Need. 18 V.S.A. § 9437(4).

H. The Applicant has met its burden of demonstrating that the project will serve the public good, provided the Conditions established in Para. I, below, are attached to the Certificate of Need. 18 V.S.A. § 9437(6).

I. Accordingly, the Commissioner concludes that the law requires that the Certificate of Need must be granted; and in furtherance of the purposes of the CON law the following conditions and requirements must be attached to the Certificate of Need. 18 V.S.A. § 9437; 18 V.S.A. § 9440(d)(5):

1. The Applicant shall comply with the scope of the project as described in the Application, and as described in evidence in the record presented by the Applicant. In particular:

    a. The Applicant, and any other persons seeking to use the ambulatory surgery center developed by the Applicant, shall not offer or provide surgeries other than surgeries of the eye of the type and nature described in the Application or described in evidence in the record presented by the Applicant.

    b. No more than six ophthalmologists shall provide services at the Center; provided that the Commissioner, in her or his discretion, and after notice and an opportunity to be heard, may amend or terminate this limitation, either upon the Commissioner's own motion or upon a showing by a party

that the limitation is no longer necessary, or that changed circumstances justify amending or terminating the limitation.

c. The Center shall contain no more than two operating rooms.

d. The Applicant shall not perform more than the number of eye surgeries projected in the Application and in Para. 16, above, to be performed at the Center. A 5% estimating margin has been incorporated into the limitations imposed by this condition. Consequently, the Applicant shall not perform more than 2,595 eye surgeries during 2008, and 2,844 eye surgeries during 2009; provided that the Commissioner, in her or his discretion, and after notice and an opportunity to be heard, may amend or terminate this limitation, either upon the Commissioner's own motion or upon a showing by a party that the limitation is no longer necessary, or that changed circumstances justify amending or terminating the limitation.

e. The Applicant shall provide the charity care as proposed to be provided in the Application, and in the evidence offered in the record by the Applicant.

f. The Applicant shall provide after hour care as described in the Application, and as described in evidence in the record presented by the Applicant.

g. The Applicant shall develop and maintain a transfer agreement with at least one nearby hospital, as well as a transport agreement with an EMS service for its emergency transport requirements.

h. The Applicant shall in all respects develop and operate the project in compliance with the elements of the business plan for the project as described in the Application, and in the evidence offered in the record.

2. Noncompliance with any provision of this Certificate of Need constitutes a violation of this Certificate of Need and may be cause for enforcement action pursuant to 8 V.S.A. §15, 18 V.S.A. § 9445 and any other applicable laws and rules.

3. This Certificate of Need is not transferable or assignable and is issued only for the premises and persons named in the application.

4. This Certificate of Need is limited to the project described herein.

5. If the Applicant contemplates or becomes aware of a non-material or material change to the scope or cost of the project described in its Application and as designated in this Certificate of Need, the Applicant shall file a notice of such change immediately with the Division. The Division shall review the proposed change and advise the Applicant whether the proposed change is subject to review under chapter 221 of Title 18, Vermont Statutes Annotated.

6. For purposes of this Certificate of Need the terms "material change" and "nonmaterial change" shall be defined as in Sections 8.F and 8.G, respectively, of Regulation H-99-3, Certificate of Need Regulations adopted November 29, 1999, and Bulletin 112, dated March 12, 2004 as amended.

7. The Applicant shall file implementation reports with the Division six months after the date of issuance of this Certificate of Need, and at six-month intervals thereafter until seven years following completion of the last component of the project. The conditions and requirements attached to the Certificate of Need shall remain in effect for the duration of the reporting period.

8. The implementation reports shall include the following information and analysis:

    a. An overview of the project, including the information and analysis demonstrating that the project is in conformance with the scope of the project as described in Condition No. 1, above.

    b. Certification that the assurances required by HRAP Standard No. 17 have been implemented and maintained.

    c. Information identifying the number of patients served, the residence of patients by zip code, the type and cost of services provided to patients, and other information relative to utilization, services and cost as the Commissioner may prescribe.

    d. The results of the Applicant's recruiting efforts for ophthalmologists.

    e. Information concerning the number of charity care cases, the amount of financial assistance provided, the specific types of services provided, and such other information relating to charity care as the Commissioner may prescribe.

    f. Certification that no material or non-material changes are contemplated or have occurred.

9. The Commissioner, in her or his discretion, and after notice and an opportunity to be heard, may make such further orders as are necessary or desirable to accomplish the purposes of this Certificate of Need, and to ensure compliance with the terms and conditions of this Certificate of Need.

10. The Commissioner, in her or his discretion, and after notice to the parties and an opportunity to be heard, may order the earlier termination or amendment of these Certificate of Need conditions, either on the Commissioner's own motion or upon a showing by a party that the condition is no longer necessary or that changed circumstances justify amendment of the condition.

11. All reports, notices, forms, information or submissions of any kind required to be submitted to the Division or the Commissioner as a condition of this Certificate of Need shall be signed by the Applicant's chief executive officer and verified by the chief executive officer, or by her or his designated representative. Such

verification shall be made on the form prescribed by HCA Bulletin No. 112 or by administrative rule, as applicable. The project as approved shall be implemented within two years from the date of this Certificate of Need or the Certificate of Need shall become invalid and be deemed revoked.

Order

Accordingly, it is hereby ORDERED, that a Certificate of Need shall issue in accordance with the terms, conditions and requirements established herein.

Dated at Montpelier, Vermont this 10th day of May, 2007.

Paulette J. Thabault, Commissioner

cc: Project file
Applicant
Interested parties and Amicus Curiae

Exhibit B

FEDERAL TRADE COMMISSION
Washington, DC 20580

DEPARTMENT OF JUSTICE
Washington, DC 20530

Joint Statement of the Federal Trade Commission and the Antitrust Division of the U.S. Department of Justice on Certificate-of-Need Laws and South Carolina House Bill 3250
January 11, 2016

The Federal Trade Commission (the "FTC" or the "Commission") 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 and South Carolina House Bill 3250 (the "Bill"), which would narrow the application of and ultimately repeal South Carolina's CON laws.[1]

CON laws, when first enacted, had the laudable goals of reducing health care costs and improving access to care.[2] However, after considerable experience, 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 expansion, limit consumer choice, and stifle innovation. Second, incumbent firms seeking to thwart or delay entry or expansion by new or existing 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 South Carolina repeal its CON laws.

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[1] Letter from Governor Nikki R. Haley to Marina Lao, Director, Office of Policy Planning, Fed. Trade Comm'n (Nov. 13, 2015).

[2] CON programs originated under the National Health Planning and Resources Development Act of 1974. 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).

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

Competition is the core organizing principle of America's economy,[3] 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.[4] The Agencies work to promote competition through enforcement of the antitrust laws, which prohibit certain transactions and business practices that harm competition and consumers, and through competition advocacy, whereby the Agencies advance outcomes that benefit competition and consumers via comments on legislation, discussions with regulators, and court filings, among other means.

Because of the importance of health care competition to the economy and consumer welfare, this sector has long been a priority for the Agencies.[5] The Agencies have extensive experience investigating the competitive effects of mergers and 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.

In particular, the Agencies have examined the competitive impact of CON laws for several decades. For example, staff from the FTC's Bureau of Economics conducted several studies of CON laws in the late 1980s, both before and after repeal of the federal law that had encouraged the adoption of CON laws across the United States.[6] In addition, the Agencies jointly conducted 27 days of

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[3] *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.").

[4] *See, e.g.*, Nat'l Soc'y of Prof'l Eng'rs v. United States, 435 U.S. 679, 695 (1978) (noting that 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.").

[5] 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.

[6] DANIEL SHERMAN, FED. TRADE COMM'N, THE EFFECT OF STATE CERTIFICATE-OF-NEED LAWS ON HOSPITAL COSTS: AN ECONOMIC POLICY ANALYSIS (1988) (concluding, after empirical study of CON programs' effects on hospital costs using 1983-84 data on 3,708 hospitals, that strong CON

hearings on health care competition matters in 2003, receiving testimony about CON laws and market entry, as well as testimony on many other aspects of health care competition pertinent to CON policy, such as the effects of concentration in hospital markets.[7] In 2004, based on those hearings, independent research, and a public workshop, the Agencies released a substantial report on health care competition issues, including those related to CON laws.[8] Finally, through their competition advocacy programs, the Agencies for many years have reviewed particular CON laws and encouraged states to consider the competitive impact of those laws.[9]

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programs do not lead to lower costs but may actually increase costs); MONICA NOETHER, FED. TRADE COMM'N, COMPETITION AMONG HOSPITALS (1987) (empirical study concluding that CON regulation led to higher prices and expenditures); KEITH B. ANDERSON & DAVID I. KASS, FED. TRADE COMM'N, CERTIFICATE OF NEED REGULATION OF ENTRY INTO HOME HEALTH CARE: A MULTI-PRODUCT COST FUNCTION ANALYSIS (1986) (economic study finding that CON regulation led to higher costs and that CON regulation did little to further economies of scale).

[7] *Health Care and Competition Law and Policy Hearings*, FED. TRADE COMM'N, https://www.ftc.gov/news-events/events-calendar/2003/02/health-care-competition-law-policy-hearings (last visited Dec. 2, 2015).

[8] FED. TRADE COMM'N & U.S. DEP'T OF JUSTICE, IMPROVING HEALTH CARE: A DOSE OF COMPETITION Exec. Summ. at 22, ch. 8 at 1-6 (2004) [hereinafter A DOSE OF COMPETITION], https://www.ftc.gov/sites/default/files/documents/reports/improving-health-care-dose-competition-report-federal-trade-commission-and-department-justice/040723healthcarerpt.pdf.

[9] *See, e.g.*, 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 (Oct. 26, 2015), *available at* 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_copn1.pdf; 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 & 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.

II. South Carolina's CON Program and House Bill 3250

South Carolina established its CON program in 1971 "to promote cost containment, prevent unnecessary duplication of health care facilities and services, guide the establishment of health facilities and services which will best serve public needs, and ensure that high quality services are provided in health facilities in this State."[10] The program requires providers to obtain a CON from the Department of Health and Environmental Control (the "Department") before initiating a wide range of projects. Covered projects include the construction or expansion of acute care hospitals, psychiatric hospitals, alcohol and substance abuse hospitals, nursing homes, ambulatory surgery facilities, hospice facilities, radiation therapy facilities, rehabilitation facilities, residential treatment facilities for children and adolescents, intermediate care facilities for persons with intellectual disability, and narcotic treatment programs.[11] Additionally, facilities must obtain a CON before adding certain services, acquiring certain medical equipment, and making certain capital expenditures.[12] In reviewing an application for a CON, the Department considers, among other factors, the need for the project, the financial feasibility of the project, the suitability of the proposed site, the availability of physicians and other required staff, and any adverse effects on other facilities.[13]

South Carolina's CON process can be time-consuming and costly, potentially involving multiple layers of review and spanning many months or years. A party seeking a CON must publish a notification in a newspaper 20 days prior to filing its application.[14] After receiving an application,[15] the Department has 30 days to request additional information.[16] The review period commences once the application is complete and the Department has notified "affected persons,"[17] including competitors of the proposed project.[18]

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[10] S.C. Code Ann. § 44-7-120 (2015).

[11] S.C. Code Ann. §§ 44-7-130(10), 44-7-160 (2015).

[12] S.C. Code Ann. § 44-7-160 (2015).

[13] S.C. Code Ann. § 44-7-190 (2015); S.C. Code Ann. Regs. 61-15 §§ 801-802 (2015).

[14] S.C. Code Ann. § 44-7-200(B) (2015).

[15] The requirements for the application span some 7 pages. BUREAU OF HEALTH FACILITIES & SERVICES DEVELOPMENT, SOUTH CAROLINA DEPARTMENT OF HEALTH & ENVIRONMENTAL CONTROL, REGULATION NO. 61-15: CERTIFICATE OF NEED FOR HEALTH FACILITIES AND SERVICES 9-16 (May 25, 2012), *available at* http://www.scdhec.gov/Agency/docs/health-regs/61-15.pdf.

[16] S.C. Code Ann. § 44-7-200(D) (2015).

[17] S.C. Code Ann. § 44-7-210(A) (2015).

Department staff then have 120 days to reach a decision, unless an affected person requests a public hearing, in which case the deadline is 150 days.[19] The staff decision becomes the final agency decision, unless an affected person requests a final review by the Department within 15 days.[20] The Department must hold any final review conference within 60 days of the request, and must issue a written decision within 30 days of the conference.[21] An affected party may appeal the Department's final decision to the Administrative Law Court, which has 18 months from the date of that appeal to file its final decision.[22] An aggrieved party may then seek judicial review of the Administrative Law Court's decision.[23] Therefore, even before any appeal to the judiciary, the CON process can delay entry or expansion by approximately two years.[24] Court challenges can add additional months or years to the process,[25] even in cases where, ultimately, a CON is granted.

House Bill 3250 would narrow the application of, and ultimately repeal, South Carolina's CON program. The Bill, if passed, immediately would amend the procedures for obtaining a CON (for example, placing additional limits on discovery in an Administrative Law Court proceeding and providing for attorney's fees if a party challenging the issuance of a CON at the Administrative Law Court does not prevail)[26] and revise the scope of the CON program (for

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[18] S.C. Code Ann. § 44-7-130(1) (2015) (defining affected person to include "persons located in the health service area in which the project is located and who provide similar services to the proposed project").

[19] S.C. Code Ann. § 44-7-210(A) (2015).

[20] S.C. Code Ann. §§ 44-1-60(E), 44-7-210(C) (2015).

[21] S.C. Code Ann. § 44-1-60(F) (2015).

[22] S.C. Code Ann. § 44-7-210(E)-(G) (2015).

[23] S.C. Code Ann. § 44-7-220(A) (2015). A party challenging the approval of a CON request must post a bond in the amount of the larger of five percent of the cost of the project or $100,000, and, if its appeal fails, the court awards the bond to the applicant and may award the applicant reasonable attorney's fees as well. S.C. Code Ann. § 44-7-220(B) (2015).

[24] *See, e.g.*, Final Order & Decision, Grand Strand Reg'l Med. Ctr., LLC v. S.C. Dep't of Health & Envtl. Control, No. 2012-ALK-07-0091-CC (Mar. 19, 2014) (application for a CON filed July 19, 2011, and Administration Law Court decision reversing the Department's denial of the application issued March 10, 2014).

[25] *See, e.g.*, Trident Med. Ctr., LLC v. S.C. Dep't of Health & Envtl. Control, 412 S.C. 341, 772 S.E.2d 177 (Ct. App. 2015) (application for CON filed on December 10, 2008, and Court of Appeals issued its decision affirming the Department's approval of the application on February 18, 2015, over six years later).

[26] H. 3250, 121st Gen. Assemb. §§ 4, 11-12 (S.C. 2015).

example, setting the threshold for CON coverage of capital expenditures at $5 million).[27] The Bill would repeal the CON program, effective January 1, 2018.[28]

III. Analysis of the Likely Competitive Effects of South Carolina's CON Laws

Competition in health care markets can benefit consumers by containing costs, improving quality, and encouraging innovation.[29] 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 care 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, [30] and now respectfully suggest that South Carolina repeal its CON program.

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

CON laws, such as South Carolina's, require new entrants and incumbent providers to obtain state-issued approval before constructing new facilities or offering certain health care services. By interfering with the market forces that normally determine the supply of facilities and services, CON laws can suppress supply, misallocate resources, and shield incumbent health care providers from competition from new entrants.[31] Specifically, CON laws can tend to do the following:

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[27] *Id.* §§ 7-8. The current threshold is $2 million. S.C. Code Ann. Regs. 61-15 § 102(1)(c) (2015).

[28] H. 3250, 121st Gen. Assemb. §§ 16(E)-(G) (S.C. 2015).

[29] A DOSE OF COMPETITION, *supra* note 8, at Exec. Summ. at 4.

[30] *See id.* 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.

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

- raise the cost of entry and expansion – by adding time, uncertainty, and the cost of the approval process itself – for firms that have the potential to offer new, lower cost, more convenient, or higher quality services;

- remove, reduce, or delay the competitive pressures that typically incentivize incumbent firms to innovate, improve existing services, introduce new ones, or moderate prices;[32] and

- prohibit entry or expansion outright, in the event that a CON is denied by regulators or the courts.

We urge South Carolina to consider that its CON law may have these results, to the detriment of health care consumers, and to consider the benefit to both patients and third-party payors if new facilities and services could enter the market more easily. This new entry and expansion – and the threat of entry or expansion – could restrain the price of health care, improve the quality of care, incentivize innovation in the delivery of care, and improve access to care.[33]

B. The CON Process May Be Exploited by Competitors Seeking to Protect Their Revenues and May Facilitate Anticompetitive Agreements

Incumbents may exacerbate the competitive harm from these entry barriers by taking advantage of the CON process – and not merely its outcome – to protect their revenues. For instance, an incumbent firm may file challenges or comments to a potential competitor's CON application to thwart or delay competition. As noted in an FTC-DOJ report, existing firms can use the CON

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[32] *See id.*; DOJ-FTC Illinois Testimony, *supra* note 30, at 6.

[33] One of the criteria used by the Department in reviewing CON applications is any "Adverse Effect on Other Facilities," including whether the proposed facility could be staffed "without unnecessarily depleting the staff of existing facilities or services or causing an excessive rise in staffing costs due to increased competition." S.C. Code Ann. Regs. 61-15 § 802(23)(b) (2015). Reducing competition among buyers – here, competition among hospitals for nurses and other medical professionals – not only can harm sellers – here, nurses and other medical professionals who may receive lower wages or reduced benefits – but also may harm downstream consumers – here, the loss of competition due to the CON regime may be reducing the quantity or degrading the quality of medical services. *See, e.g.*, Competitive Impact Statement at 8, United States v. UnitedHealth Group, Inc., No. 05-2436 (D.D.C. Mar. 3, 2006), *available at* http://www.justice.gov/atr/case-document/competitive-impact-statement-214 (explaining that a merger of two health insurers would have given the merged insurer the ability to unduly depress physician reimbursement rates, likely leading to a reduction in quantity or degradation in the quality of physician services).

process "to forestall competitors from entering an incumbent's market."[34] This use of the CON process by competitors can cause more than delay;[35] it can divert scarce resources away from health care innovation as potential entrants incur legal, consulting, and lobbying expenses responding to competitor challenges (and as incumbents incur expenses in mounting such challenges).[36] Repeal or retrenchment of South Carolina's CON law would eliminate or mitigate the opportunity for this type of exploitation of the CON process.

CON programs also 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.[37] In a separate but similar case, informal suggestions by 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.[38] While the Division secured consent decrees prohibiting these agreements between competitors to allocate services and territories,[39] such conduct indicates that CON laws can provide the opportunity for anticompetitive agreements.

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[34] A DOSE OF COMPETITION, *supra* note 8, Exec. Summ. 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").

[35] *See* text accompanying notes 14 - 23, *supra*; *see also* Yee et al., *supra* note 34, at 5 ("CONs for new technology may take upward of 18 months, delaying facilities from offering the most-advanced equipment to patients and staff.").

[36] What makes this conduct more concerning is the fact that, even if exclusionary and anticompetitive, it is shielded from federal antitrust scrutiny to the extent it involves protected petitioning of the state government. *See* DOJ-FTC Joint Illinois Testimony, *supra* note 30, at 6-7; FTC Florida Statement, *supra* note 9, at 8-9; FTC Alaska Statement, *supra* note 9, at 8-9.

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

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

[39] *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).

C. CON Laws Can Impede Effective Antitrust Remedies

As the FTC's recent experience in *FTC v. Phoebe Putney* demonstrates, CON laws can entrench anticompetitive mergers by limiting the government's ability to implement effective structural remedies to consummated transactions. *Phoebe Putney* involved a challenge to the merger of two hospitals in Albany, Georgia.[40] Seeking a preliminary injunction in federal court, the FTC alleged that the merger would create a monopoly in the provision of inpatient general acute care hospital services sold to commercial health plans in Albany and its surrounding areas. The district court dismissed the suit, finding that the merger was protected from antitrust scrutiny by the "state action doctrine."[41] The U.S. Court of Appeals for the Eleventh Circuit affirmed the district court's dismissal on state action grounds, although finding that "the joint operation of [the two hospitals] would substantially lessen competition or tend to create, if not create, a monopoly."[42] The Supreme Court reversed, holding that "state action immunity" did not apply.[43] However, the merger was consummated while appeals were pending, and Georgia's CON regime precluded structural relief for the anticompetitive merger.[44] 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."[45]

The Commission concluded 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

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[40] *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.

[41] FTC v. Phoebe Putney Health Sys., 793 F. Supp. 2d 1356, 1361-62 (M.D. Ga. 2011).

[42] FTC v. Phoebe Putney Health Sys., 663 F.3d 1369 (11th Cir. 2011).

[43] FTC v. Phoebe Putney Health Sys., 133 S. Ct. 1003, 1007 (2013).

[44] 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. 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. at 1011 (2013).

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

consumers."[46] That is, because CON laws can limit the supply of competitors, and not just the supply of health care facilities and services, they can foster or preserve provider market power. Thus, South Carolina should consider whether its CON laws could prevent divestiture as an effective tool to remedy anticompetitive mergers in appropriate cases.

D. Interim Provisions in H.B. 3250 Discriminate Against New Entrants

This statement focuses on the impact of CON laws generally because House Bill 3250 would repeal South Carolina's entire CON program, effective January 2018. This statement does not attempt to evaluate the Bill's various interim provisions, but one such provision deserves comment. Reducing the scope of CON laws can, in many cases, lower barriers to entry and enhance competition; for that reason, the Agencies generally have advocated for CON's retrenchment as well as its repeal. However, the Agencies are concerned about the likely competitive effects of the Bill's proposal to exempt certain facilities expansions or capital expenditures by incumbent providers from CON review, if undertaken prior to 2018, while requiring CON review and approval for similar expansions and expenditures proposed by new entrants.[47] This proposal, on its face, discriminates against the type of entry that would tend to reduce provider concentration. Lowering entry costs for incumbent providers might help them make more efficient investment decisions in the near term. At the same time, to remove CON requirements *only* for incumbent providers – while their potential competitors cannot enter – could facilitate the type of strategic investment that may harm competition going forward.[48] As such, the Agencies are concerned that it would preserve or exacerbate extant provider market power. Thus, this particular form of retrenchment might be anticompetitive on balance, and its anticompetitive effects could persist well past the repeal of the CON program in 2018.

IV. Evidence on the Impact of CON Laws

States originally adopted CON programs over 40 years ago as a way to control health care costs and mitigate the incentives created by a cost-based

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[46] *Id*. at 3.

[47] H. 3250, 121st Gen. Assemb. § 8 (S.C. 2015).

[48] *See, e.g.,* Leemore S. Dafny, *Games Hospitals Play: Entry Deterrence in Hospital Procedure Markets* 14.3 J. ECON. & MGT. STRATEGY 513, 536-37 (2005) (finding "evidence of investment for the purpose of entry deterrence" by U.S. hospitals in response to a change in Medicare reimbursement).

health care reimbursement system.[49] 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 evidence on balance suggests that CON 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 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.[50]

However, CON laws are likely to increase, rather than constrain, health care costs. First, as noted above, South Carolina's CON process is costly, due, in part, to its length and complexity.[51] For a wide range of facilities and diverse capital investments,[52] there are the legal and regulatory costs of preparing an application and, then, seeing that application through the approval process and potential third-party challenges. Such costs represent investments in an administrative process – they do not directly contribute to the construction of health care facilities or the delivery of health care services. They are, moreover, investments made at risk, to the extent that the result of a CON application is uncertain during the months or years that the application, or a challenge to it, is pending. The costs of the CON process – the investment, the time, and the risk – are among the costs of new, expanded, or improved health care facilities.

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

[50] *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.").

[51] *See* text accompanying notes 14-23, *supra*.

[52] *See* text accompanying notes 11-12, *supra*.

Second, those regulatory costs also can work as a barrier to entry, tending to discourage some would-be providers from entering certain health care markets, and tending to discourage some incumbent providers from expanding or innovating in ways that would make business sense, but for the costs imposed by the CON system. Further, even for providers willing to incur those regulatory costs, CON requirements stand as a hard barrier to entry in the event that a CON application is denied. Hence, CON laws can diminish the supply of health care facilities and services, denying consumers options for treatment and raising the prices charged for health care.

Empirical evidence on competition in health care markets generally has demonstrated that consumers benefit from lower prices when provider markets are more competitive.[53] Agency scrutiny of hospital mergers has been particularly useful in understanding concentrated provider markets, and retrospective studies of the effects of provider consolidation by Agency staff and independent scholars suggest that "increases in hospital market concentration lead to increases in the price of hospital care."[54] 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

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[53] *See, e.g.,* Martin Gaynor & Robert Town, *The Impact of Hospital Consolidation – Update*, ROBERT WOOD JOHNSON FOUNDATION: THE SYNTHESIS PROJECT (2012) [hereinafter *Impact of Hospital Consolidation*] (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); Martin Gaynor & Robert J. Town, Competition in Health Care Markets (Nat'l Bureau of Econ. Research, Working Paper 17208, 2011) (critical review of empirical and theoretical literature regarding markets in health care services and insurance).

[54] *Impact of Hospital Consolidation*, *supra* note 53, at 1 (citing, e.g., Deborah Haas-Wilson & Christopher Garmon, *Hospital Mergers and Competitive Effects: Two Retrospective Analyses*, 18 IN. J. ECON. BUS. 17, 30 (2011) (post-merger review of Agency methods applied to two hospital mergers; data "strongly suggests" that large price increases in challenged merger be attributed to increased market power and bargaining leverage); Leemore Dafny, *Estimation and Identification of Merger Effects: An Application to Hospital Mergers*, 52 J. L. & ECON. 523, 544 (2009) ("hospitals increase price by roughly 40 percent following the merger of nearby rivals"); Cory Capps and David Dranove, *Hospital Consolidation and Negotiated PPO Prices*, 23 HEALTH AFFAIRS 175, 179 (2004) ("Overall, our results do not support the argument that efficiencies from consolidations among competing hospitals lead to lower prices. Instead, they are broadly consistent with the opposing view that consolidations among competing hospitals lead to higher prices.")); *see also, e.g.,* Joseph Farrell et al., *Economics at the FTC: Retrospective Merger Analysis with a Focus on Hospitals*, 35 REV. INDUS. ORG. 369 (2009) (mergers between not-for-profit hospitals can result in substantial anticompetitive price increases).

suggests that consumers benefit from competition.[55] The Agencies strongly believe that competition can work in health care markets.[56]

The best empirical evidence suggests that greater competition incentivizes providers to become more efficient.[57] Recent work shows that hospitals faced with a more competitive environment have better management practices.[58] Consistent with this, there is evidence suggesting that repealing or narrowing CON laws can reduce the per-patient cost of health care.[59]

Finally, the Agencies have found no empirical evidence that CON laws have successfully restricted "over-investment."[60] CON laws can, however,

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[55] *Supra* note 5.

[56] 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).

[57] 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.

[58] *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.").

[59] *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.").

[60] 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

restrict investments that would benefit consumers and lower costs in the long run. Because CON laws raise the cost of investment for all firms, 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. In addition, CON laws shield incumbents from competitive incentives to invest.

B. Quality of Care Arguments Should Not Preclude CON 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.[61] 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 relevant 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.[62] Second, even for services where certain studies have shown a volume/outcome relationship, such as coronary artery bypass graft surgery,[63] evidence suggests that these volume effects may not offset the other effects of

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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%").

[61] 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.").

[62] *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.").

[63] *See* Gaynor et al., *supra*, note 61, at 244.

CON programs on quality.[64] 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 that repealing or narrowing CON laws is generally unlikely to lower quality, and may, in fact, improve the quality of certain types of care.[65] Moreover, additional empirical evidence suggests that, "[a]t least for some procedures, hospital concentration reduces quality."[66]

Finally, although the Agencies defer to the State of South Carolina to implement its health and safety priorities, we note that the states commonly have other, more direct means of regulating the quality of health care providers. For example, South Carolina already provides for the regulation of hospitals and other health care facilities,[67] and provides for the regulation of physicians, nurses, and other health care professionals.[68]

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[64] *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.").

[65] *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 59, 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").

[66] *Impact of Hospital Consolidation*, *supra* note 53, at 3; *see also* Patrick S. Romano & David J. Balan, A Retrospective Analysis of the Clinical Quality Effects of the Acquisition of Highland Park Hospital by Evanston Northwestern Healthcare (Fed. Trade Comm'n Bureau of Econ., Working Paper No. 307, 2010), *available at* https://www.ftc.gov/reports/retrospective-analysis-clinical-quality-effects-acquisition-highland-park-hospital-evanston.

[67] *See, e.g.*, S.C. Code Ann. § 44-7-250 (2015) (requiring the Department to "establish and enforce basic standards for the licensure, maintenance, and operation of health facilities and services to ensure the safe and adequate treatment of persons served in this State"); S.C. Code Ann. § 44-7-260 (2015) (barring hospitals and other facilities from operating in South Carolina without a license).

[68] *See, e.g.*, S.C. Code Ann. § 40-33-30 (2015) (requiring a license for the practice of nursing in South Carolina); S.C. Code Ann. § 40-47-30 (2015) (requiring a license for the practice of medicine

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. According to this argument, 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 medically underserved areas.

Although the Agencies appreciate the importance of ensuring access to health care for the indigent and in medically underserved areas, we urge South Carolina lawmakers to consider whether there are more effective or narrowly tailored ways in which to accomplish this public policy goal. We note, first, that the charity-care rationale is at odds with the cost-control rationale. That is, the notion that CON-protected incumbents will use their market power and profits to cross-subsidize charity care supposes that those providers will charge *supra*-competitive prices for non-charity care. Such *supra*-competitive pricing might harm many South Carolina health care consumers, including low-income or under-insured patients who are ineligible for charity care.

Moreover, as described in Section III.A., above, because CON programs impede entry and expansion, they can impede access to care for all patients, including the indigent and other low-income patients. Although advocates of CON laws might seek to promote indigent care, the evidence does not show that CON laws advance that goal. In fact, there is some research suggesting that safety net hospitals are no stronger financially in CON states than in non-CON states.[69] In addition, there is some empirical evidence contrary to the notion that

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in South Carolina); S.C. Code Ann. §§ 44-7-3410-3470 (2015) (Lewis Blackman Hospital Safety Act).

[69] Cutler, *supra* note 65, at 63 (finding that, following repeal of Pennsylvania's CON program, incumbent hospitals "were not put in a precarious position by the elimination of CON"); THE LEWIN GROUP, AN EVALUATION OF ILLINOIS' CERTIFICATE OF NEED PROGRAM: PREPARED FOR THE STATE OF ILLINOIS COMMISSION ON GOVERNMENT FORECASTING AND ACCOUNTABILITY ii, 27-28 (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.").

dominant providers use their market power to cross-subsidize charity care. For example, one empirical study of the relationship between competition and charity care found a "complete lack of support for the 'cross-subsidization hypothesis': that hospitals use increased market power to fund more charity care or, stated in the negative, that increased competition will harm patients who rely on charity care."[70]

Finally, 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.[71]

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 South Carolina repeal its CON laws.

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[70] Chris Garmon, *Hospital Competition and Charity Care*, 12 FORUM FOR HEALTH ECON. & POL'Y 1, 13 (2009).

[71] *See, e.g.*, LEWIN GROUP, *supra* note 69, at 29 (discussing various financing options for charity care in Illinois); DOJ-FTC Illinois Testimony, *supra* note 30, 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").

Exhibit C

DONATE

UVM MEDICAL CENTER NURSES THREATEN TO STRIKE

JUN. 18, 2015, 8:05 PM BY SARAH OLSEN 8 COMMENTS

Laurie Aunchman, interim president of the Vermont Federation of Nurses and Health Professionals, addresses the UVM Medical Center board of trustees Thursday. Photo by Sarah Olsen/VTDigger

The nurses' union at University of Vermont Medical Center is threatening to strike over pay and excessive overtime.

The president of the nurses' union at the University of Vermont Medical Center told the hospital's board of trustees she and other nurses are particularly concerned about staffing levels.

Laurie Aunchman, interim president of the Vermont Federation of Nurses and Health Professionals, addressed the trustees as they entered the final three days of negotiations for the new nursing contract at UVMMC.

Aunchman, who has been a registered nurse at the UVM Medical Center since 1976, said nurses are concerned about workplace safety at the hospital due to inadequate staffing.

"It is an honor and privilege to work here, and I sincerely mean that," Aunchman said.

But Aunchman said nurses are willing to strike over their differences with the hospital if management doesn't make concessions by the Monday deadline for negotiations. She gave the board a petition that had been signed by over 1,000 nurses and over 500 community members.

"I understand what you can and cannot do; I also understand what influence you have," Aunchman said to the board.

John Powell, chair of the board of trustees, told Aunchman that her message was received. "There are no ordinary people that work here," Powell said. "This hospital is staffed with really extraordinary people."

Aunchman said nurses are proud of their work and don't get upset until they believe their ability to deliver quality care has been compromised.

From April 2014 to March 2015, nurses worked 47,408.96 hours of overtime, Aunchman said. That's equivalent to 26 additional full-time employees a year, she said. The hospital has acknowledged that staffing is a problem, she said.

Aunchman said safety concerns arise when there aren't enough staff to move a patient without risk of nurses injuring themselves. According to the Occupational Safety and Health Administration, there should be five nurses to turn a 300-pound patient. Aunchman said often there are only two nurses available, and that means each nurse is deadlifting 150 pounds.

The new $187.3 million towers being built at the hospital will provide 128 patient beds and consist of only private rooms, increasing the percentage of private rooms from 30 percent to approximately 90 percent,

according to the UVM Medical Center website. Aunchman is asking that the nurses be included in the program design for the new towers in order to ensure that the spaces are designed for efficient delivery of care.

Aunchman said she doesn't know how many nurses need to be hired to become adequately staffed because

each unit is different. Aunchman works in the intensive care unit. That unit recently hired eight nurses, which she said she feels should be sufficient, but it will take time to get them up to speed. Nurses who are new to intensive care must go through 24 to 25 weeks of training before they can work independently, Aunchman said.

WORK-LIFE BALANCE

Two nurse practitioners were also at the board of trustees meeting. Tristin Adie, nurse practitioner of outpatient internal medicine, and Shannon Lyons, nurse practitioner of outpatient family medicine, are asking that 20 percent paid administrative time to be added to the contract. Lyons said the time would be used to help finish notes, make phone calls to patients and families and review lab notes, among other duties. Now, in order to keep up with the patient load and administrative duties, Lyons and Adie say they work from 15 to 20 hours of overtime a week.

"Working 12 hours a day, you're done — you're fried when you come home," Lyons said. "It makes it really difficult to have a balance between your work life and your personal life."

Adie agreed.

"If I'm not reviewing my notes every second that I'm not working and before I come into work, I won't be able to keep up," Adie said.

Adie and Lyons are also asking for limits on the number of patients they are assigned per week. Both said there was a cap on patient loads when they were first hired, but the limits were lifted as time went on. One nurse ended up working at 200 percent of her expected productivity because of the lack of patient load limits, they said.

Jess Fuller, UVM Class of 2015 and member of the Vermont Workers' Center, also spoke at the board meeting. She was hit by a car three weeks ago in a "traumatic experience," and ended up at the UVM Medical Center for her care, she said.

"The first people I could see taking care of me were nurses at some level or another," Fuller said.

Fuller said the nurses not only provided all the health care she needed with her injuries but calmed her down and contacted her mother and friends about the incident.

"She spent 20 minutes on the phone just explaining what had happened and answering any questions they had," Fuller said of her nurse.

One of the nurses who cared for Fuller told her that she "can't afford to live like this," Fuller said. The nurses' quality of life and salaries are part of the negotiation process, they said.

“Now is the time to recognize your employees who have lived through this recession, have received less than the cost-of-living increases over the last three years, are at status quo of CTO accrual and receive minimal financial incentive for professional development,” Aunchman said to the board.

She said the hospital needs to give nurses higher wages to recruit and retain the best quality of staff possible. UVM Medical Center nurses’ salaries are 40 percent of the national median, Auchman said.

“Our proposals will continue with UVMMC’s vision to create a culture of safety, wellness, equity and respect, but most importantly, a continuation of the excellence of care we provide at the bedside or in the clinic, every single day, 365 days of the year,” Auchman said.

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SUPPORT STAFF AT UVM MEDICAL CENTER SEEK TO UNIONIZE

DEC. 8, 2016, 7:43 PM BY ERIN MANSFIELD 12 COMMENTS

Dr. John Brumsted, center, the chief executive officer of UVM Medical Center, and his top executives listen to LNAs speak to them about why they should be able to unionize. Photo by Erin Mansfield/VTDigger

BURLINGTON — Hundreds of support workers at the University of Vermont Medical Center say they're being overworked, underpaid, and need a labor union to protect them.

The group of licensed nursing assistants and mental health technicians have been filling out union cards saying they want to join the Vermont Federation of Nurses and Health Professionals. That union already

represents registered nurses who work in the hospital.

Under state law, if the group of LNAs, mental health technicians and related workers can get enough cards filled out, they can elect a collective bargaining representative.

However, because the LNAs and mental health technicians are legally considered part of a larger bargaining unit that includes other hospital support staff, they are asking the hospital to allow just the LNAs and mental health technicians to bargain collectively.

To that end, dozens of LNAs attended the hospital's board of trustees meeting on Thursday afternoon to tell the administration why they should be allowed to join the union. The group also brought allies, including members of Rights and Democracy and the Vermont Workers Center.

"The work of nurse's aides and the work of frontline health care providers is so crucial," said James Haslam, the executive director of Rights and Democracy. "I've been here (as a patient) on nights when there hasn't been enough staff, and you're wondering and you're looking for answers."

Daniel Doynow, right, and Sheena Maynard, both LNAs at UVM Medical Center, want to join a union. Photo by Erin Mansfield/VTDigger

LNAs take a course after graduating from high school and get licensed through the state to take care of patient needs like bathing and changing bedpans. Mental health technicians, who have CPR and de-escalation training, sit with psychiatric patients, especially when patients are potentially suicidal. The LNAs say they're often asked to fill in for mental health technicians.

The workers are seeking to have the hospital hire more LNAs and mental health technicians to reduce their workloads, to pay a base wage of $15 per hour, to pay incentives when they are called in at the last minute, and to set a maximum number of patients they should be responsible for every shift.

Sheena Maynard, an LNA, said the starting wage for an LNA is between $11 and $12 per hour, but the hospital is so understaffed that sometimes an LNA will be called in at the last minute to serve 20 or 30 patients at a time.

"The staffing crisis that we have experienced puts patients in difficult and sometimes dangerous situations and needs to be addressed immediately," Maynard told the board.

She said when LNAs see call lights indicating that a patient needs help, they are supposed to respond within two minutes. Recently, she said those lights have been left on for up to 15 minutes.

"People are laying in their stool and their urine because we don't have time to get there," said Daniel Doynow,

another LNA. “We don’t feel … like we’re really being respected.”

Doynow added: “We’re just looking for better working conditions. We want to be able to offer the best care possible. It’s hard to leave and see a coworker crying because she or he wasn’t able to take care of a patient.”

After the event, the hospital released the following statement: “We recognize the right of the LNA group to organize. We’ll work with them through the process governed by federal law.”

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Erin Mansfield covers health care and business for VTDigger. From 2013 to 2015, she wrote for the Rutland Herald and Times Argus. Read more

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PATIENT SUPPORT STAFF AT UVM MEDICAL CENTER PRESS FOR CHANGES

JAN. 18, 2017, 9:46 PM BY MORGAN TRUE 0 COMMENTS

Staff from the University of Vermont Medical Center rally Wednesday in support of granting licensed nursing assistants and mental health technicians their own collective bargaining unit. Photo by Morgan True/VTDigger

BURLINGTON — Patient support staff at the University of Vermont Medical Center are continuing a push for their own union to address what they say are low wages and understaffing at Vermont's largest hospital.

A handful of UVM Medical Center staff gathered for a rally Wednesday next to new construction taking place on the hospital campus. They chose the location to highlight what they said is a disconnect between the hospital's $187 million investment in a new inpatient facility and its unwillingness to increase staffing and compensation for licensed nursing assistants and mental health technicians.

"Something has got to give," said Heather Duncan, a licensed nursing assistant for more than three decades. "Patient care has to come first."

Roughly 450 licensed nursing assistants and mental health technicians work at the UVM Medical Center, 75 percent of whom have filled out union cards to join the Vermont Federation of Nurses and Health Professionals, according to union organizer Matt McGrath. The union already represents nurses at the hospital.

State law allows the group of LNAs, mental health technicians and related workers to elect a collective bargaining representative if they get enough people to fill out cards.

However, the LNAs and mental health technicians are legally considered part of a larger bargaining unit that must include other hospital support staff, such as food workers. They're asking the hospital for permission to have their own bargaining unit because other support staff don't provide direct patient care.

Currently no union represents the support staff collective bargaining unit.

Several people at Wednesday's rally said having their own union would help them be taken seriously by the hospital administration when they advocate hiring more LNAs and mental health technicians to reduce workloads.

The group is also seeking a base wage of $15 an hour, pay incentives for being called to work at the last minute, and a limit on the number of patients they're responsible for during a shift.

Duncan, the LNA who spoke at Wednesday's rally, said she frequently has 13 patients during a shift. That's more than she can serve well, she said, and the result is she can't always get to them in a timely fashion if they fall or soil themselves. A more reasonable number per shift, she said, would be seven or eight.

LNAs take a course after graduating from high school and get licensed through the state to take care of patient needs like bathing and changing bedpans.

Mental health technicians, who have CPR and de-escalation training, sit with psychiatric patients, especially when patients are potentially suicidal. The LNAs have said they're often asked to fill in for mental health technicians.

Laurie Aunchman, a staff nurse at the hospital since 1978, said she couldn't do her job without the LNAs and mental health technicians, whom she characterized as overworked and underpaid. She said she supports their efforts to form their own collective bargaining unit and that it would improve patient care.

Chief Nursing Officer Kate Fitzpatrick said in a statement that patients are safe at current staffing levels. UVM Medical Center is experiencing a "long period of higher-than-normal numbers of hospitalized patients," she said.

Hospital administrators are working on new initiatives "to help all of our staff, including our LNAs, manage the workload," Fitzpatrick said.

"We also recognize their right to organize according to established rules and regulations," she said. "However, the union is requesting that we bypass the normal legal process by voluntarily allowing this group" to join the union.

Fitzpatrick also said she doesn't see a need for further unionization. "We have the ability to engage directly with our staff to hear and address their concerns," she said.

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Morgan True is VTDigger's Burlington bureau chief covering the city and Chittenden County.

Exhibit D

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Optimizing your operating room: Or, why large, traditional hospitals don't work

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ABSTRACT

Introduction: Caring for patients in traditionally designed, large teaching hospitals is often frustrating. Attempts at decreasing internal costs and inpatient length of stay are universally undertaken in order to address dwindling reimbursement, and patient care becomes more specialized and fractionated. These attempts have proven to be myopic, at best, and injurious to patient care and professional job satisfaction, at worst. This manuscript attempts to characterize the operational processes of our university operating room facility as well as make suggestions for operational improvements that can be applied to all hospitals.

Methods: Through a step-by-step approach, we analyze the patient's journey from the surgeon's office through the day of surgery to discharge. Using this approach, a series of studies designed to identify operational shortcomings and inefficiencies are undertaken, and the results of these shortcomings are elucidated.

Results: In our operating room, the peri-operative services are composed of multiple departments, each accountable to their own administrative silo. We found this to result in fragmented goals and objectives confounded by individualized and conflicting incentives. Consequently, we conclude with a recommendation that veers from process modification to a disruptive innovation of the hierarchical organization.

Conclusion: Nowhere in the hospital is this drive for cost containment and increased patient volume more evident than in the operating theatre. Long-term improvements must embrace radical reduction of OR costs and increased operative patient through-put, (i.e. per 8 h day; per fiscal year) by re-engineering the processes of operative patient care. In the end, the ultimate goal of safe and high-quality patient care must not be compromised.

1. Introduction

For those of us that work in large teaching hospitals of traditional design, providing efficient, high-quality patient care can be frustrating. New DRG and capitated/bundled reimbursement systems are exerting enormous financial pressures on us, and our hospitals. The initial response to succeed in this economic climate has been to offset the demands of decreasing reimbursement by curbing internal costs and decreasing inpatient length of stay; thus, pushing more patients through the hospital on a shoestring budget to maintain our operating margin. We hire physician extenders and nurse assistants; case managers and discharge planners; bed coordinators and insurance coders – more and more professionals to care for a smaller, specific piece of each patient's hospitalization. This approach has proven to be myopic, at best, and injurious to patient care and professional job satisfaction, at worst.[1–4]

Nowhere in the hospital is this drive for cost containment and increased patient volume more evident than in the operating theatre. Here, costs are measured in minutes and revenue gained on a per case basis. Long-term improvements must embrace radical reduction of OR costs and increased operative patient through-put, (i.e. per 8 h day; per fiscal year) by re-engineering the processes of operative patient care.[5] During the re-engineering processes, teaching hospitals must also preserve the mission of resident education. In the end, the ultimate goal of safe and high-quality patient care must not be compromised.

This manuscript attempts to characterize the operational processes of our university operating room facility. This is a large hospital system servicing the tertiary care needs of the New York Upstate. The process for a patient begins in the surgeon's office and continues through the day of surgery to discharge. We hope to offer specific plans to 1. Maximize revenue production by increasing patient through-put without increasing costs. 2. Maintain bench mark levels of patient safety. 3. Increase patient and employee satisfaction. We recognize that these objectives are inter-related

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and may even be in conflict. What's good for the hospital's bottom line might not always be good for the patient! The lessons learned from our specific process study are applicable to every large tertiary care hospital.

In our operating room, the peri-operative services are composed of multiple departments, each accountable to their own administrative silo: Surgery, Anesthesiology, Nursing, Materials Processing/sterilization, Transport/Housekeeping, clerical support, Information technology. This traditional teaching hospital structure leads to fragmented goals and objectives confounded by individualized and conflicting incentives. What's good for the surgeon might not be good for the nurse; what's good for the nurse might cost the materials processing division extra.[6,7] Consequently, we conclude with a recommendation that veers from process modification to a disruptive innovation of the hierarchical organization.

From our focused examination, we offer broad institutional suggestions that are applicable in any hospital setting, in any country, and across any hospital service. Operational considerations are inherently linked to the pattern of accountability. We have taken an in depth look at our hospital's work flow and are confident our findings and suggestions can spur process improvements in operating rooms everywhere. This will lead to an understanding of why the big, traditional hospital doesn't work.

2. Methods

2.1. "Does the operative day start on time?" (Study 1)

To answer this simple question in our OR, a cohort of 115 "first start" patients was examined. "First start" patients were those scheduled to start the day as the "first" patient in a given operating room. This group was chosen to eliminate the downstream effects that develop as the operative day progresses and delays/variabilities accumulate.[6] Variations of start time from scheduled start time were recorded. In theory, the patients scheduled for a "first start" should represent the best-case scenario for the operating room flow process.

2.2. "What does this delay cost us?" (Study 2)

A dollar value for operating room "down time" was assigned. This standard value was derived from the URMC – Office of the Director and reflects an activity-based (ABC) accounting of operating room costs.

2.3. "How many additional cases can be performed during lost time?"(Study 3)

300 consecutive cases performed in the Division of Pediatric Surgery were chosen and operating incision time to the time dressings were applied was used to calculate total time of the surgical case. From this data, we are able to extrapolate the number of cases that can be performed during "down time".

2.4. "Do we end the operating day on time?" (Study 4)

We examined the end of a typical operating room day by examining a full operating day. A "full day" of prime OR schedule is to end at 5 pm. All support staff is scheduled as such and the hospital budgets for a dedicated amount of overtime pay. We enlisted hospital financial records to determine the actual amount of overtime pay spent relative to the budgeted amount ($500,000).

2.5. "Are pre-operative documents completed on time?" (Study 5)

To grossly assess the end product of patient processing pre-operatively, 35 random charts were selected to represent the end products of pre-operative document management. These charts were examined to determine the presence of all necessary pre-operative documentation.

2.6. Analysis of area 1 (Study 6)

The entire surgical experience from decision to operate through surgery is evaluated in a step-by-step fashion. Three operational AREAS were evaluated in this process; Area 1 involves pre-operative planning, scheduling, insurance approval, and testing. Historical data was acquired in all areas that were studied utilizing existing hospital tracking technology.

2.7. Analysis of area 2 (Study 7)

Area 2 involves the mechanics on the day of surgery which process the patient from hospital arrival to the operating room. Data (times) were collected over a three-month period and were further refined to patients $\leq$ 18 years of age to focus analysis on pediatric providers.

2.8. Analysis of area 3 (Study 8)

Area three involves the actions and events in the operating room itself. The operative time consisted of the interval when a patient enters the operating room, undergoes his/her procedure, and exits the room to recovery. Start time is currently defined in the data collection system as the time when the patient enters the room. Within the operating time, there are three specific steps that are performed by unique individuals. Step one of area 3 is the time from patient entering the room until he/she is ready for the surgical team to begin. Step 1 is attributable to the anesthesiologist and includes activities such as IV placement, patient transfer to the table, and anesthetic induction. Step 2 of area 3 is the time attributable to the surgical team and includes activities such as patient positioning, prep, and the surgical procedure itself. Step 2 is completed when the "dressing" is applied to the patient. Step 3 is again attributable to the anesthesia team and involves reversal of anesthesia, emergence and transfer of the patient out of the room.

Data for intra-operative processes are collected electronically: the time the patient physically enters the OR, time to anesthesia induction, time devoted to surgical preparation/patient positioning, operative duration from incision to closure, and time of anesthesia reversal.

2.9. Assessment of ASA status (Study 9)

We investigated the variability of the above 100 patient's ASA scores and their correlation with times dedicated to induction and reversal. Statistical analyses for all studies were carried out using SAS version 9.1 (SAS Institute, Inc., Cary, N.C.).

2.10. What account for delays and is the process stable? (Study 10)

In order to link time intervals to varying surgeon, anesthesiologist, nursing team, and ASA classification, a regression analysis was performed where complete data (times) were available. The primary analysis looked at the association of each independent variable on the time interval while controlling for the other variables (listed above) not being assessed. This was done in a univariate fashion. No adjustments for multiple comparisons were made.

We then attempted to ascertain whether or not this process is stable – if variation is minimal and expected – through X-bar and X-mR analysis.

2.11. Reliability of documented times (Study 11)

Direct observation was performed by independent nurses of randomly selected operating rooms and procedures to record reliability of; documented ASA class, patient arrival time, time of induction, induction complete, positioning time, incision time, skin closure/dressing, and patient out of room. An additional data sheet allowed the observer to record the common causes of delay.

3. Results

3.1. Study 1

Of the 115 "first start" cases, only 19 (16%) entered the operating room within 5 min of their scheduled 7:30 AM start. It is important to note that this "time in the room" does not equate with surgical start of the case. The actual operation itself does not begin until a later time. 28 cases entered the room between 6 and 15 min of the 7:30 AM start time representing 24% of the total. 64 cases (56%) entered the room between 16 and 20 min, and the remaining cases entered the room more than 20 min late. Breaking these cases down into delay categories in proportion to the 115 sample cases, 24% would be expected to be delayed approximately 10 min, 56% delayed 18 min and 3% delayed for some time longer than 20 min.

3.2. Study 2

The URMC Office of Director quotes a cost of $3600 per hour of unused operative time per operating room. This value excludes physician time lost and was estimated in the fall of 2007. Given this estimate, these delays represent a cost of $90,720 on a first case basis alone over a two-week observation period.

On a light day, our operating suite runs 30 rooms. Assuming 5 days a week for 50 weeks of the year (conservative estimates), this represents 7500 "first start" cases annually. Total delay time for "first start" cases would approximate 98,100 min annually and cost nearly $5.9 million. Separate data from the administrator of perioperative services in the fall of 2007 increased this time/value estimate to $100/minute or $6000/hour. Using these figures, the lost opportunity cost nearly doubles to $9.6 million for only first case delays.

3.3. Study 3

Using pediatric surgical divisional data, we find that the average pediatric operation requires 60 min and, even if we double that time to account for non-surgical activities, there are over 800 operations that could be additionally performed annually in those minutes lost at the start of the day. From our surgical chief's report, the average contribution margin per surgical case (including inpatient and out patient cases) approaches $6000 – that translates into potential profit of $4.8 million.

3.4. Study 4

For fiscal year 06–07 the operating room exceeded the overtime budget by $960,000. Total overtime pay for the nursing staff alone approached $1.4 million – a near 200% variance from budget.

3.5. Study 5

From the random sampling of pre-operative charts, we found that *no charts* were complete. Each chart was missing formal documentation that would require updating or completion on the day of surgery.

3.6. Study 6

A process map of area 1 (Exhibit 1) was created to diagram the flow of patients and their accompanying chart materials from the "decision for surgery" in the surgeon's office to "patient arrival" on the day of scheduled surgery.

The process starts immediately after a surgeon makes a decision to proceed with surgery and a patient consents. Two forms are generated in our hospital: the Assessment/History & Physical form (H&P), and the Consent for Medical or Surgical Procedure form (Consent Form). These forms are then provided to the surgeon's secretary. The secretary is the main resource of the document management process. The surgeon's secretary initiates the formal request for surgery with an electronic Form 973 (includes patient information, patient insurance, scheduling details, patient medical physician information, ICU, anesthesia requirements, pre-operative testing, special needs, and discharge needs, if any). The secretary also enters a CPT code (billing code provided by the physician), an ICD-9 code (diagnosis code), and LOS information (Length of Stay). The electronic form is then submitted to multiple departments: document management, scheduling, utilization review, financial counseling, and referral intake.

3.7. Study 7

Approximately 1300 patients were identified in our study age group. Data was surprisingly sporadic and incomplete with errors such as surgical start time entered before patient ready time. Less than 50% of these charts were suitable for examination. From this set, 100 clean cases were selected.

Patients check-in and register on the day of surgery and then wait, on average, 19 min before physically moving into the surgical center. The standard deviation of this wait time, however, is 28 min – exceeding the average time. Once in the surgical center, the patient changes clothes and waits over 1 h (67 min Average; SD 53 min). The next step is transport to the Pre-anesthesia unit where a typical wait averages 48 min (SD 28 min).

3.8. Study 8

As with the electronically recorded time data, standard deviations were high. The time credited to anesthesia induction was 13 min (SD 9). Surgical preparation and positioning was the same, averaging 13 min (SD 9). Average operative time is variable and was not isolated by CPT or ICD-9 for this analysis (Average 66 min; SD 67 min). Anesthesia reversal then consumes an additional 11 min and has a standard deviation of 15 min.

3.9. Study 9

Of the clean charts available, 84% of all patients were low risk with ASA classifications of 1 or 2. On average, the ASA status of the patient is not a predictor of the wide variation in the data presented above (Exhibit 4). In fact, the lower ASA patients required more time for anesthesia induction.

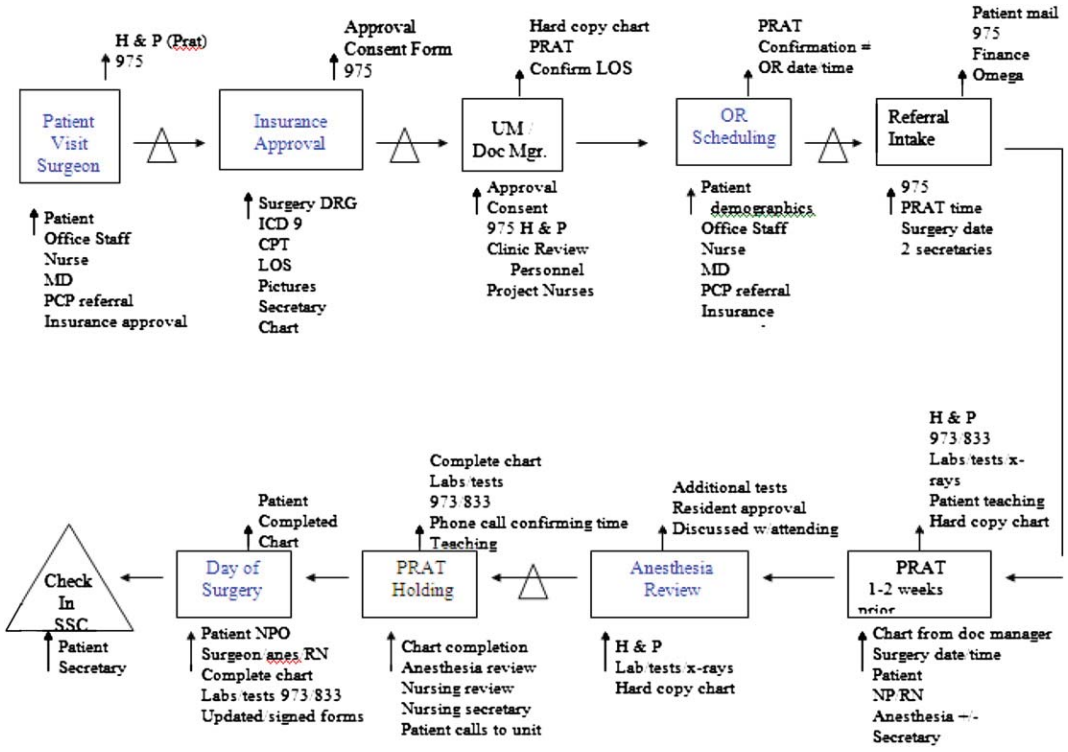


Exhibit 1. Pre-operative Planning: The activities performed during each step and the people/machines/materials utilized are included. The flow diagram documents the process of care for patients including the site of service, resources per service and those "value-added" (blue) steps as perceived from the patient's perspective. The activities performed during each step were identified and enumerated through interviews conducted with the individuals involved in each of the steps (surgeons, anesthesiologists, office managers, secretaries, and nurses).

3.10. Study 10

On average, turnover times consume 26 min with a standard deviation of 11 min. Time for anesthesia induction was found to be independent of anesthesiologist (Exhibit 5) but dependent on surgeon ($r = 0.65$, $p < 0.0001$). Time of induction was found to vary inversely with ASA classification. Given the limited data sets available, X-bar and X-mR analysis reveal an unstable system (Exhibits 6 and 7). Upper and lower control limits were set three standard deviations away from the mean or calculated from the observed moving range. Exhibits 6 and 7 demonstrate frequent process deviation above the limits.

3.11. Study 11

Generally, the times recorded in the electronic system matched our experimental results with respect to anesthesia induction and patient positioning – steps 1 and 2. However, the electronically

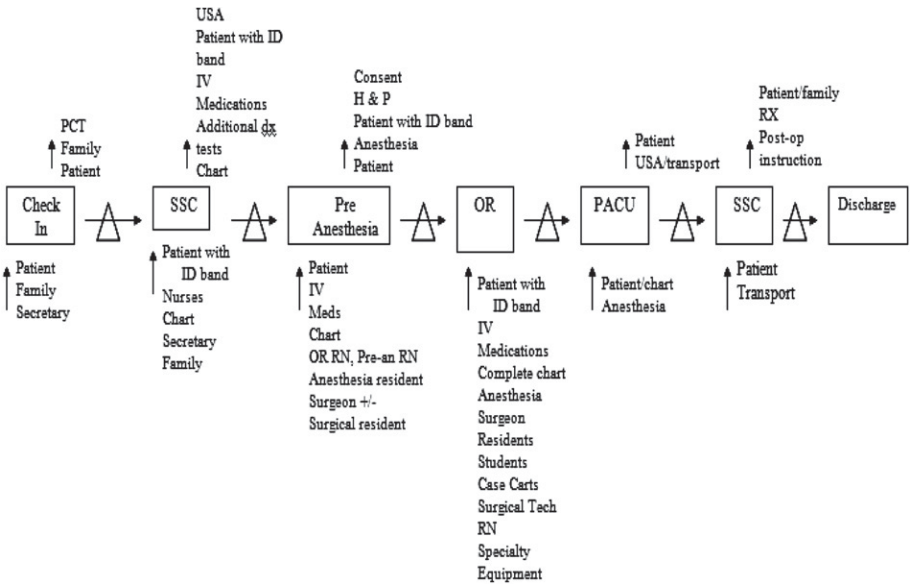


Exhibit 2. Day of Surgery: The patient's operative day is outlined here from arrival to discharge from the hospital.

ASA Classification

Class 1	Healthy patient, no medical problems
Class 2	Mild systemic disease
Class 3	Severe systemic disease, but not incapacitating
Class 4	Severe systemic disease that is a constant threat to life
Class 5	Moribund, not expected to live 24 hours irrespective of operation
An **e** is added to the status number to designate an emergency operation. An organ donor is usually designated as Class 6	

Exhibit 3. ASA Classification.

recorded times significantly *underestimate* the time required for patient emergence from anesthesia to patient leaving the room (Step 3). Our experiment documented a total non-operative in room time on average 51 min versus 34 min documented in ESI.

4. Discussion

We first asked a simple question "Does the operative day start on time?" (Study 1) Akin to any production schedule, first start activities have a downstream impact. Initial delays are amplified and culminate in overtime shifts, patient and employee dissatisfaction, and negatively impact financial measures – an ideal operating room should not waste resources.[6,8] When we asked what these delays cost, the results were significant (Study 2). Because lost minutes are only good if they can translate into additional cases or operations (Study 3), we feel that our estimation of additional cases has utility.[9–12] We recognize, again, that capturing delay time in 5 min intervals is difficult to translate into additional case contribution margin, but it must be acknowledged that recapturing even a percentage of this cumulative time delay would lead to additional case revenue.[11] This additional revenue, again, is not small.

It is possible that our assumption regarding "start time" was not relevant (Study 1) in that the operating room day was able to absorb the lax start times and still produce an adequate product.[6,12] We therefore examined the end of the typical OR day (Study 4). A "full day" of prime OR schedule is to end at 5 pm. Nursing shifts and support technicians are scheduled accordingly. Variability in room turnover, patient induction, and surgery times results in a high demand for nursing "overtime pay differential".[6] Some of this is unavoidable as an emergency trauma case or transplant occurs; consequently nearly $500,000 a year is budgeted by our hospital for nursing overtime demand. Actual overtime pay far exceeded this budgeted amount.

Surgical delay is a significant issue and improvement in this area could confer a large financial benefit. We submit that a goal of improved adherence to a schedule is one way to achieve improved patient through-put with the corollary benefits of decreasing overtime costs and increasing employee/patient satisfaction. In addition, a stable schedule, like a stable production line, is then in a position for process analysis and optimization.[7] The problem is clear: in large teaching hospitals we don't start on time and we don't finish on time. These delays in the morning cost us revenue opportunities and lead to delays at the end of the day. It isn't too much of a stretch to see how this impacts staff and patient satisfaction.

It is important to explore the role of incentives in this system.[8] In this electronic system, the web database is accessible by all those involved in the process, resulting in a system of relative checks and balances. It tries to foster a pattern of accountability for completion of the documentation process quickly and accurately. However, there is no single individual in charge of this process and, therefore, no evaluation metric for this pre-operative phase – no reward, or punishment for incomplete/inaccurate patient records. There are no incentives. An economist would argue that people behave according to their incentives, or people behave to maximize the good and minimize the bad. This mechanism is completely lacking in the big university scheduling system.

In Study 6 we see that the electronic system has placed the surgeon's secretary in a central role for the pre-hospital phase

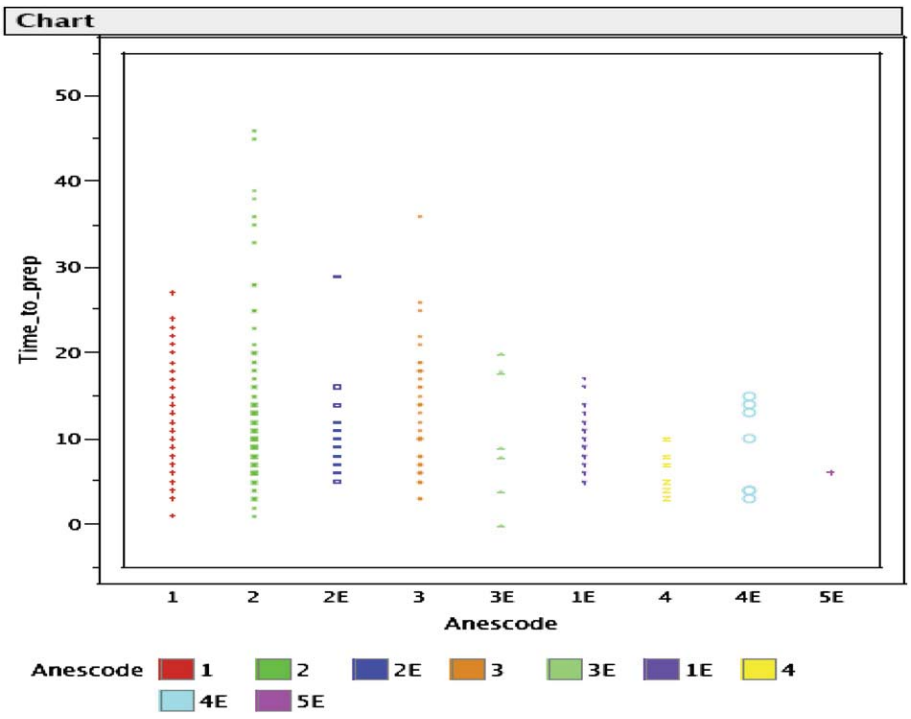


Exhibit 4. The variability of ASA status is correlated here with duration to surgical preparation. The "sicker" patients are induced faster than the more healthy patients.

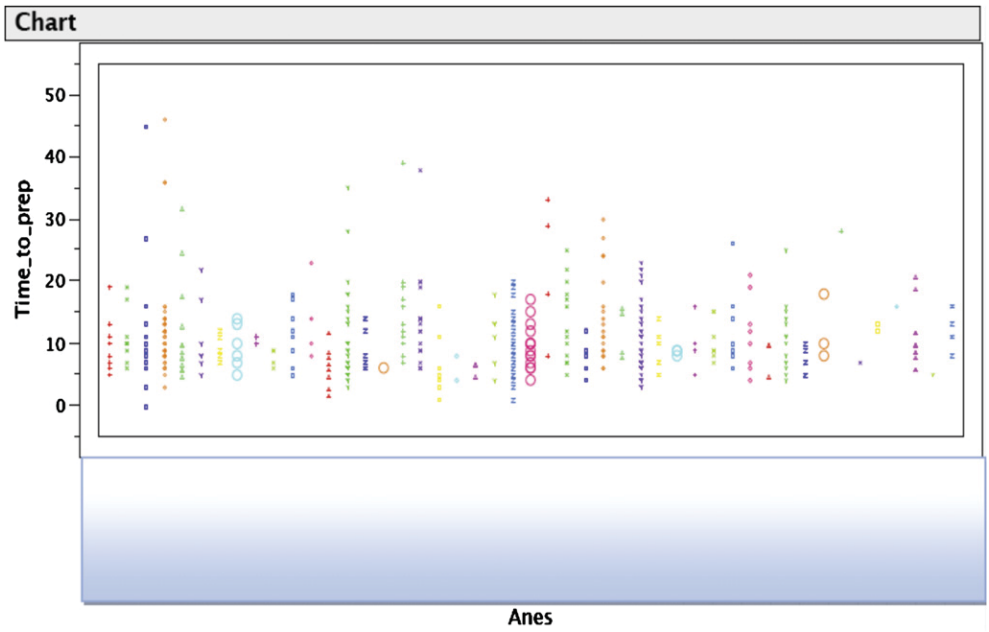


Exhibit 5. Individual Anesthesia providers are shown here with their individual times from entrance of room to surgical preparation. Regression analysis revealed that time to induction was independent of Anesthesia provider and dependent on surgeon.

(Area 1), providing them with decision rights over the documentation management process. These individuals have decentralized specific knowledge about individual procedure requirements, surgeon availability and preferences, and patient variables (age, geography, insurance, and co-morbidities). When we discuss evaluations and incentives, we find that secretaries are employed by the hospital. Their pay scale is rigidly defined. They are evaluated by the rules established by HR across the entire University. The surgical secretary is paid and evaluated in the same fashion as the secretary working in the pathology department (or, the English Literature division). The effective implementation of incentive systems may require a restructuring of the current administrative silos. It may be that the secretarial pool is reassigned under the managerial governance of the operating room where their decision rights have a direct and measurable impact.

When the charts of "Same Day" admit patients delivered to the surgical center the day prior to surgery (Study 5) were assessed as the end product of this Area, it was found that no charts were complete. According to the flow diagram, these charts should be complete and ready for processing the morning of surgery. Each chart was missing formal documentation that would require updating or completion on the day of surgery. No feedback loop exists to inform those that generate or pass on incomplete or flawed data. This also results in a potential compromise of the quality of care, as patients were not uniformly treated with Veno-thromboembolic (VTE), Antibiotic, and peri-operative Myocardial Infarction prophylaxis. To maintain safety, surgical delay is incurred as these measures are manually corrected on the day of surgery.

Performance data from our institution based on procedures scheduled per-week found that 62% of ICU beds needed on the day

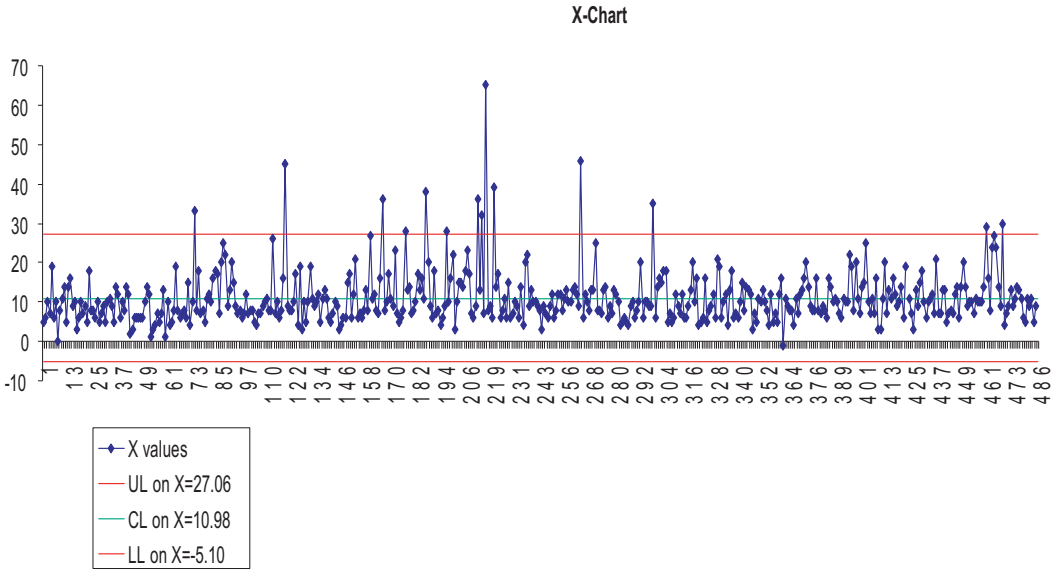


Exhibit 6. X-bar and X-mR analysis of control charts reveals variation (stability) of the system is not minimal.

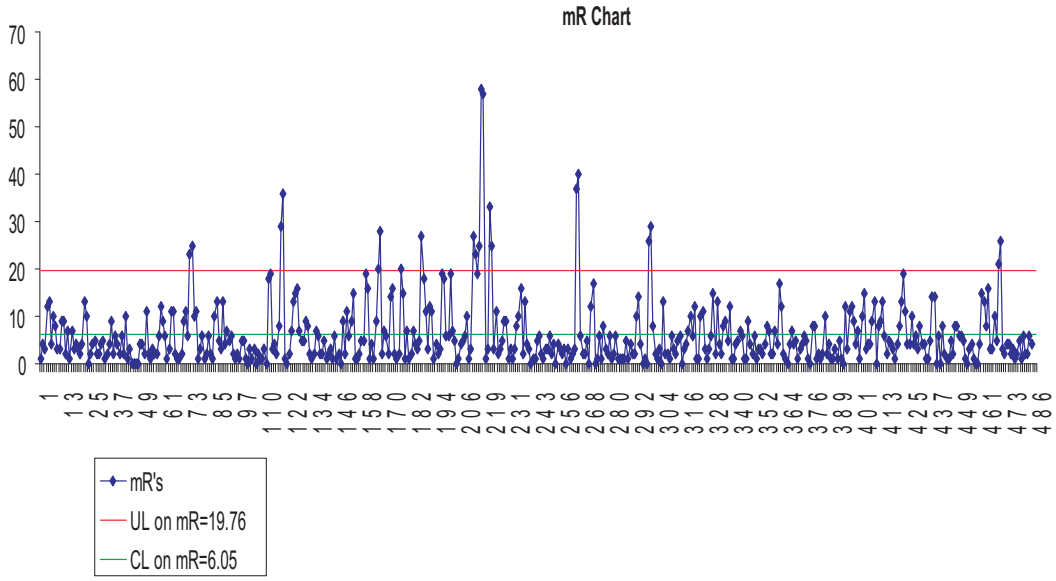


Exhibit 7. Upper and lower control limits are set 3 standard deviations from the mean or calculated from the observed moving range.

of surgery were not scheduled and nearly 10% of scheduled cases were booked with the incorrect level of care (Outpatient, 23-h stay, same day admit). Fully 83% of patients arriving for surgery had incomplete chart documentation. Thirty-one percent had no chart documentation whatsoever on the day of surgery. These data are supported by previous reports that suggest operational errors may impact patient flow time on the day of surgery and compromise quality of care.[7,8]

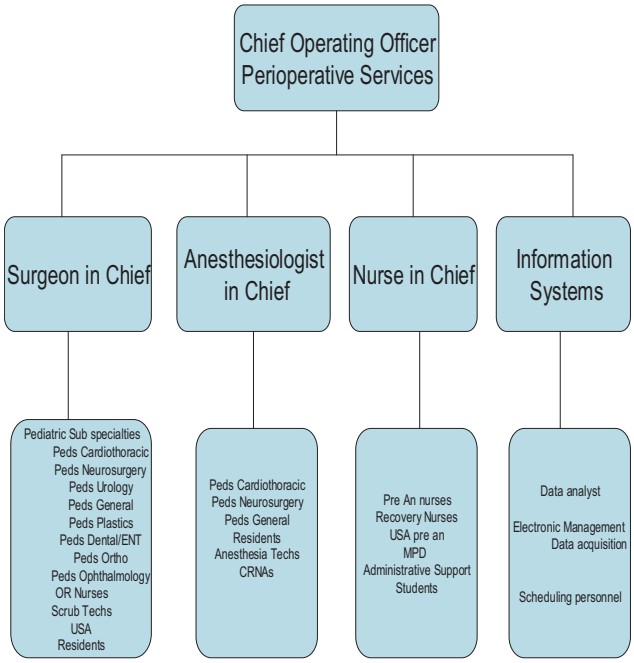
When patients arrive for surgery (Exhibits 2 and 3), their process though the operating suite is closely followed (Study 7). In recent years, a computerized system includes the electronic processing of patient documents in the pre-operative period. Data collection begins in this computer program when the patient arrives at the operative suite on the day of surgery. The system tracks the patient through the operating room and to the PACU for recovery and discharge via bar code scans. The cases that were selected in Study 7 represented cases where all time data were available from check-in through discharge. Again, it is important to note that there is no feedback loop to correct data entry or any incentive for providers or transporters to accurately enter this data. Consequently, the holes in the electronic flow chart are not surprising.

In total, Area 2 consumes 134 min in waiting and processing and has virtually no "value-added" merit. We expect that this has a negative impact on patient satisfaction.[7–9] One cannot separate waiting time from actual raw activity/service time. The wide variation in the time is also significant. Because this is clearly not a stable it cannot be optimized. Furthermore, the 134 min consumed in non-operative activity is offset by patients asked to arrive 90 min before their scheduled operative time – again, a potential negative impact on patient satisfaction.

As configured, the electronic system is effective in documenting patient location and time in the hospital, but it does not offer any extractable mechanism to identify causes for delays. In addition, the current pattern of accountability in peri-operative services does not evaluate what data there is for system improvements. Because of the separate managerial silos existing in peri-operative services, any delay leads to a finger pointing mentality rather than unified problem solving. One must proceed nearly to the director's office before the independent silos intersect with a common leadership. The agency costs associated with this system clearly are a detriment to efficient operations, quality patient care, and revenue generation. Individual "utility maximizing behavior" is rampant and does not equate with "hospital or patient maximizing behavior." This system processes patients; it is not patient centered. This is another argument in favor of hierarchical restructuring.

It is important to understand that each operation is scheduled based on the surgeon's estimate of his/her raw activity time to perform the posted procedure. The operating room schedule only takes this predicted time into consideration – exclusive of times/activities incurred by the anesthesia team. Under this system, delays are inevitable. Each operative room must have a turnover time to prepare and set up for the next case. This period involves cleaning the room, opening new and case-specific instruments, and setting up a new anesthesia circuit. It is a process that requires the teamwork of nursing staff, anesthesia staff, and the materials/processing group – all who belong to different managerial silos with different incentive structures. As such, there is no documentation of the reasons for delay occurring at this step. There is no data tracked for the time expended, or by whom, on these activities. Similarly, there is no extractable data that documents reasons for delay in this turnover process. Conceivably, by tracking the personnel involved in the turnover process, (i.e.: surgeon, USA staff, RN, Tech, Anesthesia) the times required for each activity, and reasons for delay, we could standardize the process and decrease the turnover times. In addition, we would recommend metrics to institute a reward structure for those who perform above benchmarks. Decreasing turnover times by 10 min each over a standard operative day could lead to one additional operative procedure performed in that room/day. If we apply the financial measures above, that leads to $30,000 additional contribution margin for the hospital weekly, or $1.5 million over a year. Or, even if that case doesn't happen, the ability to end on time will significantly decrease the overtime burden! The non-financial costs of overtime and an unpredictable schedule such as demoralization of the staff, dissatisfied patients, and future lost clients are difficult to quantify but should be acknowledged.[10]

Anesthesiologists were found to share similar times of induction regardless of patient specific variables or nursing team (Study 10). However, they performed significantly faster for different operative surgeons, suggesting a bias for providers to perform more efficiently when working with surgeons who offer incentives for good performance, however tangible or intangible these incentives may be. Incentives for good performance range from interpersonal praise to



Tree Diagram 1. Proposed restructured hierarchy with elimination of traditional department structures (silos) in the surgical suite.

offering rewards for timely service, and anything in between. That is to say anesthesiologists took more time – for non-productive activities – on healthy patients and moved more rapidly when the patients were more complicated. It is not surprising that emergent patients, where intubation and access was accomplished in the emergency room or ICU, took less induction time. While it is possible that specific patients required more detailed anesthesia preparations with their patient population, this was outside of the scope of this examination and not likely to have impacted our results significantly due to the fact that only the pediatric surgical service was studied.

Taken together, operative delays are a very significant source of operating room cost. A "full" operative day for a surgeon is to end at 5:00. However, because of these hidden times, the full day frequently runs into the evening shift. Differential pay for nursing is substantially greater than the standard rate and occurs daily. Smoothing the scheduling in this fashion leads to more predictable allocation of resources. Scheduling must account for the additional times that are not predicted by the posting surgeon – these should include an estimate of the anesthesia and nursing related activity times. At the very least, a goal of improved adherence to a schedule may be one way to achieve improved patient through-put with the corollary benefits of decreasing overtime costs and increasing employee/patient satisfaction. In addition, a stable schedule, like a stable production line, is then in a position for process analysis.

As we discussed with room turnover times, surgery involves the coordinated action of many different team members – surgeons, nurses, materials/processing, anesthesiologists. Each of these individuals are said to be on the "operative team," but they report to very different hospital divisions. These divisions have various incentive structures and expectations. We may be a team when we are facing a patient, but we are frequently in competition within the hospital for time, resource allocation, or even parking spaces.

5. Conclusions: why large, traditional hospitals don't work

The analysis of our operating room identified many duplicated processes. It also identified many areas where improvements could be directly linked to increased revenue, patient safety benchmarks, and potentially, staff satisfaction. This study identified the following:

1. Pre-operative charts are incomplete.
2. Operating room scheduling is inaccurate.
   a. Operating room doesn't start on time.
   b. Operating room doesn't end on time.
3. Anesthesia activity times are not incorporated in scheduling.
4. Patients experience long queue times.
5. Patient through-put on the operative day is an unstable system.
6. Data collection is inadequate and inaccurate.
7. There is no feedback mechanism or pattern of accountability to correct errors.
8. There are no incentives or consequences for improved patient care, through-put, cost containment, chart readiness, or adherence to schedule. In fact, the fragmented "silo" structure of the operating room leadership leads to conflicting incentives.

There are many suggestions that we could make to identify process changes aimed at fixing the areas that our study found to be flawed. For example, we suggest that the operating room could stagger the room start times so that attending anesthesiologists need not be in two rooms at once and the first case delay is minimized; or that all surgeons use a standard procedure to submit operative consent forms.

However, the current leadership structure in most large teaching hospitals is one of traditional "silo" organizations comprised of nursing services, anesthesia, materials processing, administrative support, and surgery. It focuses on the *components* of patient care and not on the patient. Consequently, each faction is prone to maximizing individual utility and excellence rather than patient centered, team care. Our findings illustrate these inadequacies. Ultimately we want to improve the experience and outcomes for our patients who require surgical care and simultaneously enhance the work environment in a cost effective fashion. The operating room needs to become a single service area where multiple professionals provide coordinated care, identify strategic priorities, and share the risks/rewards.

Based on our findings, we propose that elimination of the traditional department structures in the surgical suite will lead to a restructuring that is more patient focused and outcome driven. We are currently pursuing this restructuring at our institution. (Tree Diagram 1). The first step is to establish a managerial team with primary leadership recruited from outside the hospital. This chief operating officer cannot be perceived as "belonging to" one of the traditional silos or departments of nursing, anesthesia, or surgery. His/her direct reports will include representation from these groups and also an information technology officer. This last member is essential as operations become "on line" but also because evaluation of outcomes/data will guide strategy decisions. We cannot over state the importance of this objective position. As we discussed above, the electronic system in the operating room only marks the location of the patient during the day of surgery, but not any extractable data about providers or reason of delay and the document managing systems that follow the patient's chart, insurance, and paperwork similarly can't provide information about how the chart is prepared or who is doing a good job.

This leadership structure needs to become patient focused and not department focused. Evaluation metrics will be jointly agreed upon by the leadership team and gathered by the Information Systems division. By eliminating the traditional silos, evaluation metrics can be uniformly applied to all OR personnel. For example,

if a surgeon is routinely late for his/her case, then they might loose the privilege of a first start. This will be applied and enforced from the operating room COO even if the surgeon is the "chief" of a surgical division. Similarly, Anesthesia personnel that do not perform up to their peers (locally or nationally) could be reassigned or penalized financially – even if the anesthesiologist is "chief" of a division. This objective evaluation of the IT data and adjustment of behavior works best when everyone functions under a single patient centered team. Currently, each team member reports to a different silo, so when a dispute emerges between a cleaning worker and a nurse; a doctor and a nurse, there is no central authority to mitigate the conflict. Similarly, each team member currently has different reward metrics administered by their respective silo chairperson and individual utility maximizing behavior does not lead to hospital/operating room/patient utility maximization. This can change by restructuring the pattern of accountability.

Process analysis and performance evaluation is an on going activity – not an end point. We must balance the benefits of incentives/performance metrics with the cost of acquiring and evaluating that data. We recognize that incentives cannot be too small or too infrequent that people loose interest in performing well; however, acquiring and analyzing performance data on a daily basis is expensive and time consuming, and fails to consider outliers. There is a role of incentives in motivating performance.

Your large tertiary hospital doesn't work because every employee is focused on his/her individual division and not on the patient. The prevalent accountability metric favors performance within each department – within each silo – not in a patient centered culture. A patient centered service center restructuring would be beneficial to all hospitals. This is the only way to align everyone's incentives and ultimately break down departmental silos and conflicting interests. This investigation will be repeated once this restructuring has taken place at our institution.

Conflict of interest
None of the authors has a financial interest in any of the products, devices, or drugs mentioned in this article.

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Ethical approval
This study was approved by our institutional research subjects review board.

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Form A – Verification Form

STATE OF VERMONT
GREEN MOUNTAIN CARE BOARD

In re: ACTD LLC MULTI-SPECIALTY AMBULATORY SURGERY CENTER	)	Docket No. GMCB-010-15con

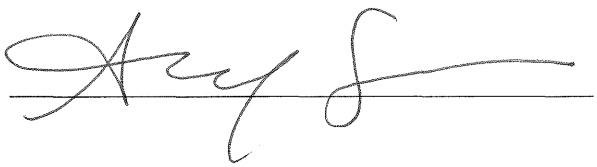
Verification Under Oath
Response to the Northwestern Medical Center's Submission of Information In Opposition to Application and the Vermont Association of Hospitals and Health Systems Memorandum in Opposition to the Green Mountain Surgery Center Certificate of Need Application

Amy Cooper, being duly sworn, states on oath as follows:

1. My name is Amy Cooper. I am the manager of ACTD LLC. I have reviewed the Response submitted with this Verification to support the Certificate of Need Application for the Green Mountain Surgery Center ("Response").

2. Based on my personal knowledge, after diligent inquiry, the information contained in the Response is true, accurate and complete, does not contain any untrue statement of a material fact, and does not omit to state a material fact necessary to make the statement made therein not misleading, except as specifically noted in the Response.

3. In the event that the information contained in the Response becomes untrue, inaccurate or incomplete in any material respect, I acknowledge my obligation to notify the Green Mountain Care Board and to supplement the Response, as soon as I know, or reasonably should know, that the information or document has become untrue, inaccurate or incomplete in any material respect.



On March 24, 2017, Amy Cooper appeared before me and swore to the truth, accuracy and completeness of the foregoing.

Notary public 

My commission expires February 10, 2019