Dunkiel Saunders
ELLIOTT | RAUBVOGEL | HAND

91 College Street, PO Box 545
Burlington, VT 05402-0545
tel 802.860.1003 | fax 802.860.1208
www.dunkielsaunders.com

Brian S. Dunkiel +
Eileen I. Elliott
Shawn Gordon * ø
Geoffrey H. Hand
John B. Kassel
Drew Kervick *
Justin W. McCabe * ¤
Elizabeth H. Miller
Andrew N. Raubvogel
Jonathan T. Rose
Zoë E. Sajor * °
Mark A. Saunders
Karen L. Tyler
Victoria M. Westgate

May 3, 2019

By Electronic Mail and U.S. Mail

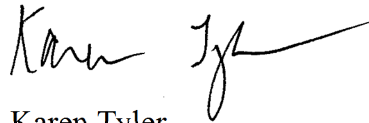
Michael Barber
General Counsel and Hearing Officer
Green Mountain Care Board
144 State Street
Montpelier, VT 05620

RE: Docket No. GMCB-010-15con – Green Mountain Surgery Center – Post-Hearing Brief

Dear Mr. Barber:

Enclosed please find ACTD LLC d/b/a Green Mountain Surgery Center's *Post-Hearing Brief*. Please let us know if you have any questions.

Sincerely,



Karen Tyler
For the Firm

Encls.

cc: Donna Jerry, Senior Health Policy Analyst
Anne E. Cramer, Esq.
Julia Shaw, Esq.
Kaili Kuiper, Esq.
Jill Berry Bowen

Eric Citron, Esq.
Goldstein & Russell, P.C.
7475 Wisconsin Avenue, Suite 850, Bethesda, MD 20814
ecitron@goldsteinrussell.com
Attorneys for ACTD, LLC

May 3, 2019

Michael Barber
General Counsel and Hearing Officer
Green Mountain Care Board
144 State Street
Montpelier, Vermont 05620

Re: Docket No. GMCB-010-15con, Green Mountain Surgery Center GMSC Post-Hearing Brief to 4/17/2019 Hearing

Dear Mr. Barber,

On July 10, 2017, the Green Mountain Care Board granted ACTD, LLC a Certificate of Need for "a multi-specialty ambulatory surgery center (ASC) to be known as the Green Mountain Surgery Center in Colchester, Vermont." The Board specified several conditions to be met before construction could begin, *see* CON ¶¶1-7, and many more for which we were required to "appear before the Board prior to commencing operations to demonstrate" our compliance. *Id.* ¶¶8-29. Although some of these conditions were logically impossible to meet and needed to be amended (*see* Order Amending Certificate of Need, Mar. 9 2018), GMSC has worked diligently to fulfill all of them. Accordingly, in our pre-hearing letter and at the hearing held on April 17, 2019, we demonstrated that we have complied with the Board's requirements and that we are ready to open a project of the kind, scope, and capacity set forth in our application, our Certificate of Need, and the Board's accompanying Statement of Decision.

We are eager to get on with that work, which has already started to show the dividends contemplated by GMSC's application and this Board's well-considered decision to grant it. When we started planning this project in the fall of 2014, we predicted that the introduction of a multi-specialty ASC in Chittenden County would attract physicians to the area, make the provision of care more efficient, and improve access to care for many patients. That was correct. To give one example, while the only hospital in Chittenden County lost multiple gastroenterologists in the last year alone to retirements or moves out of state, an independent GI practice in Colchester has recently managed to recruit to Vermont an experienced physician from the Yale New Haven hospital system, in part due to the availability of Vermont's first ASC as an attractive place for his procedures. One physician, of course, will not replace the several who were lost to the area last year, but it will help maintain access to services for patients and alleviate the need for the local hospital to bear the cost of recruiting all necessary physician replacements to the area. The Green Mountain Surgery Center's impending opening has also played a critical role in convincing a plastic and reconstructive surgeon and a sub-specialist gynecological surgeon to move to Chittenden County within the past several months. Even before opening, GMSC is having a beneficial effect on Vermont's ability to recruit and maintain its healthcare workforce. And by increasing the supply of talented physicians, and creating one

593 Hercules Drive • Colchester, Vermont 05446 • (802) 488–5350
www.greeenmountainsurgery.com

small alternative to the dominant tertiary-care medical center in Chittenden County, GMSC will help to improve care and lower costs for Vermonters now and into the future.

Nor is it only doctors (and patients) who will be recruited to the state and/or benefitted by the introduction of GMSC's additional facilities. Nurses who lack alternative employers outside the dominant hospital—and are known to be undercompensated as a result—will gain from GMSC's opening as well. Moreover, GMSC is already attracting other talented and essential support staff to Vermont, including a Nurse Director we have recruited from Rochester, NY and a manager we have recruited from Utica, NY. The addition of the GMSC's facilities is thus certain to benefit doctors, patients, nurses, and support staff, while also helping in the long-term challenge of recruiting healthcare talent to Vermont. *See, e.g.*, '*Waiting Pains: The Challenge of Wooing Doctors to Vermont'*, WCAX, Burlington April 18, 2019. ("It's hard to recruit," said Kevin Mullin, the chair of the Green Mountain Care Board. "If we don't start doing things more creatively, if we don't start adding capacity at our programs, we're just not going to have enough people to take care of the medical needs of the citizens of the state.").

That said, given the outsized attention this project has received, it is important to keep in mind just how small it is on absolute level. Our projections of between $4-6 million annually in net patient revenue for each of the first four years of operation represent less than 0.5% of the local hospitals' annual budget of $1.2 billion. The same is even more apparent in the number of employees. Our projections show that we initially plan to accommodate 24 physicians at the center, and even if that number were to grow to 25 or 30 independent physicians over the next several years, the local hospital employs 613 physician FTEs. The surgery center thus represents only one very small alternative option for physicians and patients in Vermont's most populous county and is certainly not an existential threat to the existing hospitals or their cost structures, as this Board correctly determined in granting our CON. *See* Statement of Decision at 16 ("[W]e do not foresee calamitous and irreversible financial implications resulting from decreased surgical volumes.").

Nonetheless, Chittenden County badly needs whatever additional supply and competition GMSC can provide. While the Burlington Metropolitan Area is Vermont's most populous—with over 220,000 residents[1]—it is important to remember that it is also the most isolated in terms of access to alternative healthcare options. Residents in the eastern and southern parts of the state are only a short drive away from surgery centers in bordering states, and many residents in these areas can and do seek more affordable and accessible care in those out-of-state facilities. In contrast, residents in the northwest part of Vermont must currently drive multiple hours to find competing options for surgical care. That is why it is imperative that we create and sustain options close to home.

[1] https://vtdigger.org/2019/04/23/woolf-can-done-reverse-vermonts-population-decline/

Our goals are simple, they are reflective of the policy priorities of the Board, the Legislature, and the Governor, and they are good for Vermont's physicians and patients alike. Our *goal* in opening a multi-specialty ambulatory surgery center is to provide an option for outpatient surgery that lowers costs for Vermont patients and healthcare payors, while also providing better and more accommodating facilities for appropriate procedures to Vermont doctors. That will help us attract medical talent to the State, and to alleviate the ongoing harm caused to patients and all insurance-premium-paying citizens by the needlessly high cost structures inherent in a system with hospital-only provision of routine outpatient surgeries.

We nonetheless understand the Board to have expressed certain concerns at the most recent hearing, and so we endeavor in this letter to address each of those concerns in turn. We identified five principal issues that we will discuss below: (1) compliance with Condition 12 regarding below-hospital-level reimbursement rates; (2) changes in the physician mix from our initial projections; (3) the nature of our anticipated ophthalmological services; (4) compliance with Condition 10 regarding evidence-based procedures; and (5) our request to comply with Condition 21 regarding procedure data in a way that protects the identities and privacy of physicians. The general point, however, is that our multi-specialty surgical center project has not changed in any way from the one we described and sought approval for in our application, that we remain earnestly committed to the goal of improving care and lowering costs in Chittenden County, and that we have thus complied to the greatest extent possible with the Board's conditions on the project we designed to meet that goal. It has been wonderful for us to see how much progress we have been able to make already before opening, and it has been edifying to see how much of what has transpired is exactly as we anticipated (and hoped for) in our original application. We look forward to doing so much more once we can finally open our doors to the public and begin serving Vermonters in need of faster, better, and more affordable and convenient options for routine care.

I. Compliance With Condition 12 Regarding Below-Hospital Reimbursement Rates

One concern expressed at the hearing on April 17 concerned how we proposed to comply with Condition 12. That condition requires GMSC to "negotiate with Blue Cross and Blue Shield of Vermont to accept reimbursement that is below the community fee schedule rate" and, for insurers that "do not use a community hospital schedule," to "negotiate reimbursements that it can demonstrate are below reimbursements for the same procedures/surgeries when performed in a hospital setting." As we explain below, the exact terms of this condition do not map perfectly onto our role in the Vermont healthcare industry, and so the *letter* of this condition may be logically impossible to meet. But we want to emphatically underscore our desire and intent to fully comply with the *spirit* of this condition, and to negotiate reimbursement rates that are consistently below what our hospital competitors are currently charging for the same services. In fact, we understand that very intent to explain why the Vermont Association of Hospitals and Health Systems remains so determined to artificially limit the services available at GMSC, *see* Brief of Interested Party VAHHS (May 3, 2019), while doctors, patients, and ordinary

Vermonters universally clamor for our approval. *See https://gmcboard.vermont.gov/board/comment/previous* (identifying over 30 public comments since public hearing, *all* supporting full approval for GMSC).

It is possible that some of the concerns regarding our compliance plan for Condition 12 stem from a slight but important misunderstanding about how Blue Cross and Blue Shield of Vermont determines reimbursement rates for *hospital facility* services. In its explanation of the rationale behind Condition 12, the Statement of Decision notes that Blue Cross "uses a community fee schedule for independent physicians and community hospitals, and an academic medical center reimbursement schedule for UVMMC." *See* Majority Op. 17 (citing Green Mountain Care Board Report to the Vermont Legislature, The Advisability and Feasibility of Expansion to Commercial Health Insurers the Prohibition on Any Increased Reimbursement Rates or Provider-Based Billing for Health Care Providers Newly Transferred to or Acquired By a Hospital at 7 (Feb. 1, 2017)). That is correct, but importantly, the billing practices described in the cited report relate to how Blue Cross reimburses hospital or physician practices for *physician* services, not *facility* services. *See* Report at 1 (stating that report describes "billing practices in Vermont as they relate to physician practice transfers and acquisitions"). Blue Cross does not use the same fee schedule rates for facility-services reimbursements, and such reimbursements are kept confidential by essentially all insurers and hospitals. On a practical level, it is thus impossible for GMSC to comply with Condition 12 in the precise manner contemplated by that condition and the understanding thereof set forth in the Statement of Decision. To put it very simply, we have no way to identify a schedule of rates that any insurer (including Blue Cross) pays other (hospital) facilities for identical services and then peg our rates to some fraction of those.

Notably, this practical confusion cannot be attributed to our application, which made very clear that GMSC would bill exclusively for facility services, and that it was thus impossible to compare our rates to hospitals' other than by comparing facility charges to facility charges. Under 'Charge Structures and Patient Savings' we said:

> [T]he Center will not employ physician staff …. Its billings, income and expenses will be totally separate from those of the surgeons who will perform surgical cases there. The ASC's charges for surgery, which include room time, medications, and recovery, will be separate and independent of the surgeons' and/or anesthesiology provider's professional charges for performing the surgeries. Therefore, unless otherwise stated, any financial comparisons to hospitals provided in this application are facility-to-facility cost comparisons."

See Application at 23.

Nevertheless, we are quite confident that our reimbursement rates will be below the competing hospitals' current rates for comparable services. In order to comply with Condition

12, we thus offered in our pre-hearing letter to the Board on March 26, 2019 to obtain from commercial insurers a letter confirming that our negotiated reimbursements with them are below the average equivalent reimbursement that they pay to hospitals for the same services. I want to stress that we put forward this proposal in the best possible faith. We simply do not have access to data on competing hospitals' reimbursement rates, how those hospitals code, bill, or structure charges for any given surgery, or even their average reimbursement rates for most procedures by CPT code.[2] As the New York Times recently reported, *see They Want It to Be Secret: How a Common Blood Test Can Cost $11 or Almost $1,000* (April 30, 2019), and academic studies have shown, this secrecy on the part of hospitals is intentional, and reimbursement rates for the same procedure can vary wildly across geographic areas, providers, and even within the same health-care facility.[3] Unless the Board itself intervenes to require (for example) that the University of Vermont Medical Center provide a transparent accounting of and explanation for its reimbursements on each procedure GMSC will offer, we cannot conceive of a workable alternative to requiring certification from insurers that we are a lower-cost provider for the comparable facility service. And given the capacity for wide variation in reimbursement rates even within the same hospital (not to mention across geographies outside GMSC's catchment area), some kind of averaging seems to be the only plausible way to assess whether GMSC's reimbursements are "below reimbursements for the same procedures/surgeries when performed in a hospital setting."

Thus, to be perfectly candid, when we referred to averaging in our proposal, we did not even consider the possible distinction between the arithmetic mean and the median rate, let alone consider which would theoretically allow GMSC to charge higher rates without violating the Board's condition. And that is because we have no intention whatsoever of pushing the boundaries of this condition in any way, nor do we believe that we are likely ever to bump up on this cap on reimbursement rates. Our *business model* is to be a lower-cost provider than the existing exclusive provider of facility services in Chittenden County, which is currently charging high rates for routine procedures to insurers in Vermont's dominant population area, driving up insurance premiums statewide. We hope that our business model will attract patients to our nascent, lower-cost and higher-convenience surgical center, and in turn lower the costs of individual procedures and drive down the premiums all Vermonters pay. Conversely, it is not

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[2] CMS did require hospitals to publish lists of charges on their websites beginning January 1, 2019. However, the lists published by each hospital do not show a consistent list of procedure codes among hospitals, nor are the lists comprehensive—*i.e.*, they omit many outpatient hospital facility codes for which a hospital bills. We have only managed to find charges for codes that overlap with about one-quarter of the outpatient codes on our initial CPT list. But, in *all cases* where we did find comparable data, our charges will be lower.

[3] *See* Cooper et al., Variation in Health Spending Growth for the Privately Insured from 2007-2014, available at https://www.healthaffairs.org/doi/10.1377/hlthaff.2018.05245.

part of our model to try to have prices *above* the competing hospitals, and it is in fact hard to imagine why insurers would agree to pay GMSC *more* than they already pay hospitals for the same procedures in a *less* competitive environment.

To see this most clearly, consider the Medicare context, where we do have some insight into reimbursement rates for different facilities. ASC reimbursement rates are universally at or below hospital rates for Medicare procedures, but we are happy to perform these procedures because our goal is simply to soak up the obvious excess demand for care in the area. The same is equally true for us with respect to other payors. Greater price transparency from our competing hospitals—allowing us to be verifiably lower-cost for the same procedures as often as possible—would thus only serve the business goals we have set for ourselves. But unless the competing hospitals want to turn over their pricing and negotiated reimbursement information voluntarily, or this Board intervenes to require it, we believe that the very best we can do to confirm our lower-cost status is to obtain the certifications we proposed in our pre-hearing letter. In short, if we could do more than that, we would.[4]

II. Our Project Remains The Same In Kind, Scope, And Capacity.

Another area of concern for Board members surrounded very modest changes in our physician mix from our initial projections, including a very small number of physicians practicing different specialties from those of the participating providers we had at the time of the application several years ago. These changes, however, are entirely consistent with our application and the Board's CON and Statement of Decision approving it, and they do not create any change whatsoever to the substance of our project. Importantly, *any* surgical facility—be it an academic hospital or an ambulatory surgical center—is a fluid business that cannot exercise total control over which doctors want to practice there, how long they will stay, and what other specialties, sub-specialties, and/or procedures the facility will attract. Nor can we control what procedures patients need. As we explained at the hearing, our projections regarding our total procedures and their mix among specialties have changed from those in our initial application for *precisely* this reason—because doctors have changed their plans for reasons beyond our control in the intervening years—and they will no doubt change again in modest ways as doctors with

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[4] We note that, tellingly, VAHHS's post-hearing brief does not refer to this condition, or offer any assistance in meeting it. We believe that is because the hospitals have no interest in telling us or their patients how much they actually charge, given that—on any transparent examination of hospital reimbursement rates for comparable procedures—we are almost certain to be the lower-cost provider no matter what. That is particularly true because, unlike the local hospitals that provide emergency and other indispensable services to their members, insurers do not need to have us in their networks. In fact, insurers are unlikely to contract with us ***unless*** we can offer better prices than what they currently pay for the same services at the hospital. And this is precisely why our business interest in being the low-cost provider so aligns with our freestanding goal of lowering costs for the Vermont healthcare system.

different practice focuses come and go from the county or state. Our responsibility as a multi-specialty, ambulatory surgery center is not to ensure an unchanging set of providers performing an unchanging set of procedures, but rather to demonstrate that the facility complies with all of *its* obligations and every condition set forth in its CON. Because that demonstration has been made, there is no legal basis for concern about modest shifts in the provider and specialty mix.

A. Modest changes in provider mix do not amount to a material change.

The change in provider mix from our application is certainly not a "material change" of the kind that would require a new CON proceeding. The statute defines a material change as "a change to a health care project for which a certificate of need has been issued which: (A) constitutes a new health care project as defined in section 9434 of this title; or (B) increases the total costs of the project by more than 10 percent of the approved amount." *See* 18 V.S.A. § 9432(11). Section 9434 in turn defines a "new health care project" as meeting any one of six conditions including (1) major capital building expenditures, (2) changes in the number of beds, (3) offering home health services, (4) purchases of expensive equipment, (5) adding new services with operating expenses in excess of $500,000, and (6) building an ASC itself. In fact, given that the statute defines *establishment* of an ASC as a material change, it is virtually certain that small changes to the physician staffing at an ASC do not constitute a change of the scale contemplated by the statute.

In any event, on January 31, 2019, we submitted information to the Board demonstrating that GMSC's provision of plastic surgery and/or ophthalmology services will not increase project costs by more than ten percent. At the same time, we also submitted information demonstrating that GMSC's provision of plastic surgery and/or ophthalmology services is not a "new health care project," because its capital costs will not exceed $1,500,000.00; it will not require the purchase, lease, or other arrangement for a single piece of equipment costing in excess of $1,000,000.00; and it will not have an annual operating expense that exceeds $500,000.00. No party has contested these facts, and we do not understand them to be subject to reasonable dispute. It is therefore clear that these inevitable fluctuations in our provider and specialty mix are not material changes to our project.

Notably, VAHHS's sole argument in its post-hearing brief for further delay in approving GMSC's opening is that fluctuations from the initial projections are material changes that require a new, formal CON approval process. *See* VAHHS Post-Hearing Brief at 6-7. But it does not even *try* to tie that argument to the statutory text. The sole support it provides for its assertion is a parenthetical description of the presence of ophthalmologists and plastic surgeons at GMSC as "(*i.e.* a new service)." *Id.* But the statute expressly says that offering a new "health care service" constitutes a material change only if that service has "an annual operating expense that exceeds $500,000." *See* 18 V.S.A. §9434(a)(5). VAHHS does not suggest—and could not seriously suggest—that opening GMSC to a handful of ophthalmologists and/or plastic surgeons will add $500,000 to its operating expenses. Accordingly, even if these were "a new service" (which they

are not), it would be an unambiguous violation of the statute to further delay GMSC's opening for the endless series of CON proceedings VAHHS evidently desires.

B. Modest changes in provider mix do not constitute non-material changes.

Nor do changes in provider mix—specifically, the addition of a small number of focused plastic surgery and ophthalmology practitioners—constitute non-material changes for purposes of 18 V.S.A. §9432(12). The statute defines a "non-material change" as "a modification that does not meet the cost threshold of a material change… but otherwise modifies the *kind, scope, or capacity* of a project for which a certificate of need has been granted." *Id.* (emphasis added). We believe it clear that, because the contemplated plastic surgery and ophthalmology services fit squarely within the scope of a "multi-specialty ambulatory surgery center" and are fully consistent with the application, Statement of Decision, and every express condition of the CON, these kinds of changes to the provider mix do not qualify as changes to the "kind scope or capacity" of the GMSC project that the Board approved.[5] We also note that VAHHS does not even argue that these constitute non-material changes presumably because, even if they were non-material changes, such minor changes to a project would normally be approved in the ordinary course and without further delay.

The best evidence that these minor deviations from our initial projections in the provider mix do not constitute even non-material changes to the project comes from the face of the CON itself. In its very first sentence, the CON makes clear that the Board is approving a "multi-specialty ambulatory surgery center." *See* CON at 1. And then, in the many carefully drafted and detailed conditions the CON imposes on the nature and scope of GMSC's project, it does not in any way suggest that "multi-specialty" means something other than what it says, and that GMSC was in fact constrained to a narrow set of specialties. Indeed, apart from the approval of a "multi-specialty surgery center," neither the word "specialty" nor any variant of it appears in the CON again, apart from a condition requiring GMSC to post physicians' "area(s) of specialization" on its website. *See* CON at 1. Accordingly, the "scope" of the project here is a

[5] On September 14, 2018, we sent a letter regarding our change in provider mix on the understanding that these new specialties might constitute non-material changes "pursuant to Rule 4.600." That rule distinguishes material changes from non-material changes, but unlike the statutory text, it does not suggest that there are *any* limits on what constitutes a non-material change. Put another way, the rule suggests that there are only material and non-material changes, and fails to explain that there are some kinds of alterations that do not qualify as changes at all. Upon reviewing the statute, we recognized that a change that does not affect the "kind, scope, or capacity" of a project does not qualify as a non-material change. Accordingly, we did not concede and do not believe that our change in providers qualifies as a non-material change under the governing statute.

multi-specialty surgery center that is limited to ambulatory procedures, not a surgery center limited to specifically defined specialties or the like.

That conclusion is strongly reinforced by several aspects of our application. Critically, that application was not premised on the need for more surgical capacity for specific specialties, but rather on the general need for the type of affordable, high-quality alternative that a multi-specialty ambulatory surgery center would provide. Accordingly, we were very upfront about the likelihood that our physician and procedure mix would change over time, and that there would likely be demand for GMSC's facilities from doctors practicing a range of new and different specialties in the future. For example, the application expressly said that "[GMSC's] medical staff will be open to *any* Board certified or Board-eligible specialty physicians practicing in the service area and able to accept responsibility for patient post-operative care and follow-up, and who satisfy other customary criteria set forth in the ASC's medical staff bylaws." Application at 12 ¶2 (emphasis added). This alone makes perfectly clear that our application sought exactly what the Board's CON approved: A multi-specialty surgery center open to "any [qualified] specialty physician" doing procedures appropriate for an ambulatory setting.

But the application goes well beyond that in clarifying that neither the provider mix nor the particular areas of their specialization would be static. For example, it says:

- "The company expects to add additional minority owners, anticipated to consist of local physicians, upon approval of this Application." Application at 14 ¶3.
- "Due to interest from surgeons and patients in an ACS that offers lower costs, easier scheduling and greater efficiency for non-emergent surgeries and procedures than alternative sites of care, we anticipate that once the Green Mountain Surgery Center is up and running, there will be strong demand to provide operating and procedure room time for physicians *working in other specialties*, *including* orthopedics, gynecology and plastic surgery." Application at 20 ¶1 (emphasis added).
- "*At the time of this application*, ACTD has identified a minimum of 16 physicians who are extremely interested in performing cases at the proposed ambulatory surgery center." Application at 26 ¶1 (emphasis added).

And on January 25, 2017, in response to the Board's inquiry, ACTD further stated that:

- "In our planning, we have recognized the *likelihood* that, once the GMSC has been constructed and commenced operations, *other doctors or providers such as dentists, oral surgeons, or podiatrists* who have not yet expressed interest in utilizing the GMSC may do so." Response at 2 ¶5.

These are all very straightforward ways of communicating that the specialty mix at GMSC was expected to evolve over time. These materials mentioned no less than six additional specialties where interest in GMSC's facilities was already expressed or anticipated, and they make clear

that these are just examples of the kinds of providers who would be welcome at GMSC in the future. *See* Application at 20 ¶1 (anticipating demand from "*other* specialties *including* orthopedics…"); Statement of Decision at 6 ¶20 (nothing that "other providers *such as* dentists … may" be drawn to GMSC). Neither the Board nor any interested party could have reasonably misunderstood the scope of the project for which we were seeking approval. VAHHS's suggestion that our application was "focus[ed] entirely" on "the GMSC offering surgeries and procedures in five specialties" is thus absurd on its face, and premised on nothing other than the (logically inescapable) fact that our projections were based on the providers who had agreed to participate in the GMSC at that time. *See* VAHHS Post-Hearing Brief at 2.

In fact, it is quite clear from the Statement of Decision that the Board did not misunderstand the application, and that it was aware that GMSC was likely to embrace physicians working in different specialties in the future. In its finding of facts, the Board's Statement of Decision acknowledges ACTD's expectation that "once the ASC is fully operational, there will be strong demand for other specialties which may include oral surgery, podiatry, and plastic surgery." In re ACTD LLC d/b/a The Green Mountain Surgery Center, Dkt. No. GMCB-010-15con (July 10, 2017) at Findings of Fact ¶20. Notably, the specialties to which the Board here referred—introduced by the expansive and non-exclusive words "may include"—consist of entries from two separate lists of possibilities GMSC provided in two separate filings. *See supra* p.7. That conclusively demonstrates the Board's understanding that GMSC was seeking approval of a general multi-specialty ASC open to any physicians practicing appropriate specialties in the future, and that the particular, additional specialties listed are just examples of the kinds of providers who might be drawn to GMSC in the future.

Not only did the Board's decision demonstrate this understanding—and approval—of GMSC's project, it also relied on this understanding for its *rationale*. The Board's approval of the CON, and most notably its determination that ACTD met the "need" criterion set forth in 18 V.S.A. § 9437(3), did not rest on *any* specialty-specific findings. Rather, the Board identified a general need and demand for greater access to affordable healthcare services. Statement of Decision at 18-19. Put another way, the Statement of Decision in no way reflects a conclusion that additional facilities were needed in any particular specialties, let alone the five specific specialties in which providers were ready to participate at the time of the application. We thus had every reason to believe that the Board understood the case we were making for a multi-specialty facility, and had agreed with it.

In fact, that conclusion was reinforced not just by the CON, *and* the application, *and* the Statement of Decision's factfinding, *and* its rationale, but also by the only available precedents we could find. The only other ambulatory surgery center in Vermont is the Eye Surgery Center. And when the Board approved that project, it limited its scope to a specific set of procedures in express terms at the very outset of its CON. *See In re Application of Eye Surgery and Laser Center of Vermont*, Dkt. No. 05-058-H, Certificate of Need ("May 10, 2007) at ¶1(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."). Once again, this evidence strongly implies that when a CON is meant to limit the approval of a new health care project to specific specialties, it says so explicitly. Because the reticulated CON the Board granted here imposed a host of conditions but did not purport to limit the specialties that could be practiced at GMSC, the only reasonable conclusion was that the Board had not imposed any such limitation.

This conclusion is supported not only by positive precedent, but by negative precedent as well. We are not aware of any occasion on which one of our competitor hospitals has sought Board approval for a material or non-material change before absorbing new specialists or entire practice groups, branching out into new practice areas, or changing their provider mix. That is ostensibly because—in the absence of an express limitation in a CON or some other material regarding the types of providers or specialties approved for a given facility—a change in participating providers simply does not constitute a change in the kind, scope, or capacity of a health care *facility*. That makes perfect sense: We built a *kind* of facility (an ambulatory surgery center), with an approved *scope* (multi-specialty) of a certain *capacity* (*i.e.*, room or bed number), and a change in the physicians who perform their procedures there does not affect the nature of that facility at all. It is also beyond the power of a multi-specialty facility to control the specialty mix of the doctors who *choose* to practice there. This explains why no other multi-specialty facilities notify the Board of material or non-material changes to their CONs when their providers change on an almost daily basis, and why other surgery centers of a more limited scope are expressly confined to a certain scope in their certificates of need.

What is at stake here is not just the Board's interpretation of the CON it issued, but the substantial rights and reliance interests of ACTD and its member investors, not to mention the years of hard work we have sunk into making GMSC a reality. The Board's approval of a CON for a "multi-specialty ambulatory surgery center" without restriction as to the specialties in which that center might offer services was essential to GMSC's business plan and its investors. ACTD knew that it would need flexibility to respond to the changing makeup of the local physician workforce in order to keep the project afloat and deliver on its mission to provide Vermonters with an option to access routine outpatient surgeries at lower cost. Indeed, as ACTD explained in the materials its submitted in response to the Board's requests for information on November 19, 2018, its plan to provide plastic surgery and ophthalmology services was a response to the fact that, since the initial projections were prepared at the end of 2014, several included physicians have retired, moved, or changed their practices in a way that limits their eligibility to use the GMSC. In the meantime, additional physicians (some new to the area) have expressed an interest in using the center. There is no way GMSC can adapt to these kinds of changing circumstances if it needs a separate approval every time a new physician practicing in a new area wants to use its services for undisputedly ambulatory procedures. Accordingly, in reliance on the plain language of the CON, ACTD and its member-investors have proceeded

with development of the GMSC on the understanding that the approved multi-specialty surgery center was not so restricted.

These reliance interests may sound ethereal when stated in the abstract, but they are not. We are now committed to a lease of more than half a million dollars per year going forward. Physicians have moved states, offices, and practices to participate in the project. We have committed to take patients without regard to payment method and to provide charity care on the understanding that a viable overall business could subsidize these needy patients' procedures. These plans could easily fail if the Board takes the position that any change in provider mix or participating specialties can trigger (what certainly seems to be) an entirely new round of CON proceedings. And we cannot possibly recruit new healthcare talent to Vermont if we cannot credibly promise that these physicians will be allowed to practice at GMSC at all. For these reasons, the Board should conclude that modest changes to the provider mix at an approved "*multi-specialty*" ASC do not constitute material or non-material changes, and do not require CON amendments or other express approval from the Board.

C. Nonetheless, GMSC remains tightly regulated regarding future changes.

At the hearing, we understood that some Board members were concerned that, if changes to the specialties or provider mix at GMSC did not require a CON amendment, that would leave GMSC free to make all manner of changes without oversight from the Board. That is not correct. As we briefly explain below, the set of changes that can be made without the Board's approval is quite small. That is because strong limitations continue to apply through both the material and non-material change criteria, the CON conditions, and federal regulations.

Start with federal regulations, which effectively foreclose vast areas of health-care practice from ASCs. GMSC is required to establish eligibility for Medicare reimbursement, and ASCs that receive Medicare reimbursement are required to be certified and meet the Medicare Conditions of Coverage. *See* 42 C.F.R. Part 416. The Conditions of Coverage are standards developed to ensure patient safety, as well as the quality of the facility, physicians, staff, management, and services offered at the ASC. ASCs are required to demonstrate initial and ongoing compliance with these standards. Among other things, the Conditions of Coverage specify the procedures that are eligible for Medicare reimbursement when performed at an ASC, and forbid providing any service that is not an outpatient surgical procedure. That means that an ASC facility is not allowed to perform lab services, diagnostic testing, imaging, physician office, urgent care or any other separate services during the same hours or from the same location as an ASC is operating. Accordingly, even under the broadest possible conception of what services a multi-specialty ASC can provide, this is a very restricted license compared to hospitals or other healthcare facilities.

Next consider the stringent limitations that apply under the material change criteria of the statute. Because the total approved cost for GMSC was only $11.6 million, *any* change in the

project cost that exceeds $1.16 million will automatically trigger a material change under 18 V.S.A. §9432(11). So, too, would any effort to purchase or lease any medical equipment costing more than $1 million. Perhaps most importantly, even adding services that cost more than $500,000 annually to provide will trigger a material change and the need for a CON amendment. There is thus no way for GMSC to expand in unforeseen ways—or offer radically different services—without running into the objective barriers posed by this statutory provision.

For example, it is not uncommon for many outpatient procedures such as laparoscopic surgeries, gallbladder and hernia surgeries to be performed robotically using systems such as the da Vinci Surgical System. Several surgeons in the area are trained users of the da Vinci robot for surgery. But while many ASCs in the country do have such robotic surgical systems installed, GMSC could not consider this avenue, or even contemplate such a purchase, without first applying for CON and appearing again in front of the Board, because these robotic systems cost approximately $2 million.

Finally, the biggest practical barriers to making any serious change to the services or specialties offered at GMSC come from the scope of an ambulatory surgery center itself. While some orthopedic surgeries are appropriate for an ambulatory setting, many are not—including many that serve as key revenue centers for the competing hospitals, like hip replacements. GMSC can only expand into specialties that can be performed on an outpatient basis, using equipment that costs no more than $1,000,000 to purchase, and is not allowed to add capacity without triggering (at least) a non-material change. So even if one conjures a hypothetical world in which GMSC is wildly successful and attracting attention from many unforeseen specialists, it will not be able to accommodate them unless this Board approves the equipment, capacity, or changes in scope necessary to expand services beyond those available at an *ambulatory* surgery center of GMSC's current size and cost profile.

The upshot is that there is nothing for the Board or interested parties to fear from acknowledging that GMSC's existing CON permits the participation of specialties beyond those specifically forecasted *five years ago* when we initially applied for our CON. The set of procedures that can be performed at an ASC in *any* specialty is circumscribed, and doubly so given GMSC's limited ability to expand in capacity or specialized equipment without Board approval. The sole consequence of our position is that, *just like all the competing multi-specialty facilities*, we do not need to come to the Board every time a specialist leaves or a new one wants to move to Vermont to participate. And because all of the materials from the CON process support that conclusion, the Board should adopt it.

III. To The Extent That A Variance Between GMSC's Current Provider Mix And Its 2014 Projections Constitute A Non-Material Change, That Change Should Be Approved.

Even if the Board were to determine that the addition of specialties outside of the 2014 projections constitutes a non-material change to the GMSC project, that change should be easily approved. The Board's principal concern appeared to relate to ophthalmology services, and so we focus our discussion there.[6] As we explain, the contemplated ophthalmology services are limited, arose organically from the stated needs of practicing physicians, will have no substantial impact on the Eye Surgery Center, and are certain to save money for patients and the state through lower Medicare reimbursement of common procedures in the ASC setting.

As an initial matter, we want to emphasize that we did not discover that there was a need for additional ophthalmology facilities until after the CON was issued. This was largely because we had assumed that the Eye Surgery Center, which was granted a CON to offer the full range of ophthalmology services in 2007, was filling any need in this specialty. Indeed, one of our founders was Dr. Dowhan—an ophthalmologist who was one of only two physicians in the state with experience opening an ASC—and even he did not anticipate or intend to perform eye surgeries at GMSC, given his view that his needs and his patients' needs were at that time already being met by the Eye Surgery Center.

Our change in understanding arose from the experience of Dr. Weissgold, an ophthalmology surgeon practicing at the Retina Center of Vermont who became officially involved with Green Mountain Surgery Center in 2016. Dr. Weissgold offered his time and expertise in helping to realize the GMSC project—without any promise of being able to perform surgeries at the center—based on his experience as a founding member of HealthFirst independent physicians' association in 2010 and his long-standing interest in supporting independent practice in Vermont. As Dr. Weissgold testified at the April 17th hearing, he and his partner continued to pursue options to operate at the Eye Surgery Center and Northwest Medical Center through 2016 and 2017, even after beginning discussions with GMSC. Only after the CON was approved, and we were approached by other ophthalmologists asserting the need to move their surgeries out of the hospital setting and into the ASC environment, did we become convinced that there was a need in this specialty that GMSC could meet, and that it would be cost-effective for us to do so. That is because the cost of the microscope, other equipment, and specialized staff needed for retina surgeries is prohibitively high unless there are other types of eye surgeons using the equipment, allowing the costs to be more widely spread.

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[6] At the hearing, there did not appear to be any dispute regarding the need for the plastic surgery services at issue. Nor could there be any argument that the addition of these services constitutes a material or non-material change, given that future demand for plastic surgery services at GMSC is expressly contemplated in the Board's own Statement of Decision. *See* Findings of Fact ¶20. Likewise, although a few questions were posed regarding the modest orthopedic services at issue (which are principally focused on hand-related procedures), the future addition of orthopedic services was expressly discussed in ACTD's application, and does not appear to be the subject of any controversy.

Accordingly, it was not until we understood that there were a sufficient number of providers interested in operating at GMSC that we could identify both a need for additional facilities and our ability to provide them.

The existence of this need is not surprising or controverted, however. Ophthalmology is the second most common service performed in multi-specialty ASCs nationally (second only to gastroenterology), and it is very common throughout the country for ophthalmologists to use multiple surgery centers when available in order to increase patient convenience and maximize the efficient use of the surgeon's time.[7] It also seems clear that the Eye Surgery Center is approaching full utilization, given the uncontroverted testimony from the hearing and other ACTD submissions that it either turned away or was not able to offer acceptable block times or terms to three separate doctors over the past three years (Drs. Weissgold, Young, and Doyle). Making ophthalmology services available at GMSC is thus likely to serve an existing need and improve patient and physician choice without harming the Eye Surgery Center's business.

Moreover, there is no question that increasing the ability to perform cataract surgery in ASC settings is likely to save patients and the state a sizeable amount of money over the coming years. The need for cataract procedures is certain to increase substantially as the population ages in Vermont, because indications for this surgery are directly correlated with age and it is the most commonly performed outpatient surgery in the United States.[8] The same age correlation also virtually guarantees that the cost of most of these procedures will fall on the state and its taxpayers through Medicare. But Medicare reimburses ASCs $977 for this procedure, while hospitals receive nearly twice as much ($1,917)[9]—even though physicians and their patients seem to prefer the ASC setting. Accordingly, it is squarely in the interests of Vermont and its citizens that ASCs who have available facilities be allowed to use those facilities to provide ophthalmology services.

Flexibility to allow GMSC's facilities to be used in this specialty (and other specialties) is also important given that the addition of any future operating-room capacity over the next several years in Northwest Vermont is very unlikely. VAAHS testified that hospitals do not see a need to add more operating-room capacity for 20 years in this region. *See* Kaufman Hall's 'Green

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[7] See VMG Health 'Multi-Specialty ASC Study Intellimarker 2017' at 17.

https://vmghealth.com/wp-content/uploads/2018/01/VMG-Health-Intellimarker-Multi-Specialty-ASC-Study-2017.pdf

[8] Cataract in the Adult Eye Preferred Practice Pattern, © 2016 by the American Academy of Ophthalmology http://dx.doi.org/10.1016/j.ophtha.2016.09.027 Published by Elsevier Inc. ISSN 0161-6420/16.

[9] https://www.medicare.gov/procedure-price-lookup/cost/66984.

Mountain Surgery Center: Need Assessment' p.8 (submitted March 3, 2017). Hospitals also lack an effective incentive to increase capacity given that supply constraints facilitate monopoly pricing, even in regulated monopolies. Moreover, in its Statement of Decision for this CON, the Board discouraged any entity similar to GMSC from adding additional operating space in the foreseeable future. *See* Statement of Decision at 22 (conclusion). It would therefore be prudent to allow GMSC to operate within the full scope of its multi-specialty license and to utilize its operating space to meet the needs of the four ophthalmologists we have identified—as well as the other demands for operating or procedure room space that will unavoidably arise from the evolving health-care landscape over the coming years.

IV. We Have Supplied, And Will Continue To Supply, Evidentiary Support For All Procedures As Required By Condition 10

Another discussion at the hearing concerned whether and how GMSC would make further efforts to demonstrate compliance with Condition 10 of the CON, which requires us to show that the procedures we plan to offer are evidenced-based and properly within the scope of a multi-specialty ambulatory surgery center. In our initial effort to fulfill this condition, we submitted several studies per specialty on March 18, 2019. These studies set forth some of the evidence used to support the most common procedures in each specialty that we currently plan to offer, as well as the efficacy of those procedures when performed in an ASC setting. But even beyond the evidence we have offered—and further evidence we could offer were it deemed necessary—this is one area in which the several conditions imposed by the CON are overlapping and redundant in a way that should give the Board substantial comfort regarding the evidentiary basis for any procedure GMSC will offer.

That is because the CON requires that GMSC maintain its Medicare certification, and CMS only permits ASCs to perform procedures that it has deemed appropriate for that setting based on its extensive evidentiary reviews and expertise. *See supra* p.12. According to the Medicare Claims Processing Manual, Chapter 14:

> "the ASC list of covered surgical procedures is comprised of surgical procedures that CMS determines do not pose a significant safety risk and are not expected to require an overnight stay following the surgical procedure. Surgical procedures are defined as Category I CPT codes within the surgical range of CPT codes, 10000 through 69999. Also considered to be included within that code range are Level II HCPCS and Category III CPT codes that crosswalk to or are clinically similar to the Category I CPT codes in the range. *The surgical codes that are included on the ASC list of covered surgical procedures are those that have been determined to pose no significant safety risk to Medicare beneficiaries when furnished in ASCs* and that are not expected to require active medical monitoring at midnight of the day on which the surgical procedure is performed (overnight stay). Procedures that are included on the inpatient list used under Medicare's

> hospital outpatient prospective payment system are deemed to pose significant safety risk to beneficiaries in ASCs and are not eligible for designation and coverage as ASC covered surgical procedures."[10]

The simple point is that GMSC is constrained to offer evidence-based, ASC-appropriate procedures not only by the CON, but by federal regulation as well. Evidentiary support for all of GMSC's procedures will thus be provided not only from studies like those we submitted, but from Medicare's list of approved ASC surgical procedures as well.

V. The Board Should Permit GMSC To Comply With Condition 21 In A Manner That Protects Physician Privacy.

At present, the information required by Condition (B)(21) will reveal each GMSC provider's procedure volume and associated financial productivity. This is private and competitively sensitive personal financial information, which the providers keep confidential, and the GMSC will not disclose other than as required by the GMCB. Public disclosure of this information on the GMSC's website, in implementation reports, or in response to a public records request to the GMCB, could disadvantage physicians in negotiating future offers of employment with hospitals or other potential employers. That is because a physician's record of procedure volumes and where s/he performs procedures is not typically available for review by prospective employers unless the physician voluntarily and confidentially provides it. It may also harm individual physicians in several other respects, as we explained in our letter to the Board on January 10, 2019.

As we explained at the hearing, we believe CON Condition (B)(21) will serve its intended purpose just as well if information is reported by specialty rather than by individual provider. This condition is intended to aid the GMCB and the GMSC in identifying potential violations of the "anti-steering" policy the GMSC has adopted under CON Condition (A)(3), which prohibits providers from accepting a patient or determining whether to perform a patient's procedure at the GMSC based upon the patient's insurance status or ability to pay for services. An individual provider's violation of this policy would of course impact aggregated data reported by specialty, and a concerning trend in the aggregated data would alert the GMCB and the GMSC to the need for further inquiry into anti-steering policy compliance.

Given the very limited number of cases that some providers will be performing at the center (for some, only a handful per quarter), and Condition 21's requirement to list reasons each patient was referred to the ASC or the hospital, we are further concerned that there will be circumstances in which disclosure of the information to be reported under Condition (B)(21)(d) for each provider will violate the Health Insurance Portability and Accountability Act (HIPAA)

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[10] https://www.cms.gov/regulations-and-guidance/guidance/manuals/internet-only-manuals-ioms-items/cms018912.html.

Privacy Rule. The HIPAA Privacy Rule protects the confidentiality of "protected health information" (PHI). PHI is defined to include information, including demographic information collected from an individual, "with respect to which there is a reasonable basis to believe the information can be used to identify the individual," which relates to his or her health, provision of healthcare to him or her, or payment for healthcare services provided to him or her. 45 C.F.R. § 160.103. Given the size of the community and the personal nature of the information involved, we believe we should steer well clear of the risk that it might be possible to identify the person whose procedure occurred at the hospital because of an underlying health condition or the like. Aggregating the data by specialty limits the identifiability of patients and protects the privacy of doctors without impairing the Board's policy aims at all.

CONCLUSION

This has been a long and complex process for us—not just as a nascent business but as individuals—and we are very eager to end our work as amateur regulatory attorneys and get down to the business of providing lower-cost and higher-quality medical care to Vermont. At times, we have found this process a bit inscrutable: For example, we still do not know whether the purpose of the April 17th hearing was solely to demonstrate compliance with the conditions of our CON (as we had thought) or to begin—or perhaps consider whether to begin—some kind of CON amendment process or the like (as VAHHS evidently believes). At other times, we have confronted CON conditions and Board rules that were logically impossible to meet or difficult to understand. And at every turn, the incentive of the entrenched economic interests has been to make this process all the more long, complex, and inscrutable, so as to delay or foreclose the downward price pressures we are hoping to create. That has made it unnecessarily difficult for us to work with the Board to achieve what we believe to be our common aims.

Nonetheless, for the foregoing reasons, we believe that we have shown complete compliance with our CON conditions and a full willingness to work with the Board to meet its conditions and policy priorities going forward. But even above and beyond that conclusion, the Board should recognize that the complexity of this process *itself* adds costs to the Vermont healthcare system and discourages investments that could bring real benefit to patients and payors alike. Conversely, it should be clear that this system can be abused by those who have the strongest pecuniary interest in limiting competition. The result is that people who have both a business model and a personal ethical commitment tied to making better and more affordable health care available in this state are faced with a cautionary tale suggesting that there might be a better way to spend their time. Or to put it a little more personally, I wish that it was easier for someone who wanted to provide something of value to Vermont's healthcare system to do so.

It is also important to underscore here, that while we represent an alternative to the large academic medical center in the state, we also understand that we are their partner and have already starting working with them to arrange for care delivery that is in the best interest of the local patients who will receive care both at the surgery center and at hospitals. We have a

transfer agreement in place with UVMMC. We also have toured the laboratory services department at UVMMC and worked with the physicians and administrators there to devise the best protocols for sending specimens that may need lab work out from the surgery center to the UVMMC lab. We have also coordinated with the hospital in numerous other areas including the possibility of training surgical residents from the medical school at the surgery center. We are looking forward to even deeper and more meaningful collaboration with other parts of the healthcare system in the future.

As further evidence of that, we have worked diligently with leadership at OneCare, Vermont's single accountable care organization (ACO), to devise the best ways that we, together, can ensure that GMSC meet's the Board's requirements for meaningful participation in the ACO payment reform model. These discussions resulted initially in our binding Memorandum of Understanding, which was accepted by the Board in April 2018 before we began construction. We have since that time signed OneCare's letter of interest for participating as a contracted provider of the ACO for the contract year that begins in 2020. We look forward to becoming part of the ACO structure and excited about how new payment arrangements for our services that are value-based, and provide more transparency and predictability of costs, may evolve in the coming years.

We appreciate the consideration the Board has shown towards our project and the evidence we have marshalled to support it to this point, and we hope very much that we have provided what the Board needs to finally approve GMSC's operations. If there is any other information we can provide, please let us know.

Sincerely,

Amy Cooper

Manager
Green Mountain Surgery Center