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March 12, 2021

VIA EMAIL DPH.DON@State.MA.US

Lara Szent-Gyorgyi
Director, Determination of Need Program
Massachusetts Department of Public Health
250 Washington Street, 6th Floor
Boston, MA 02108

RE: Determination of Need ("DoN") Application Project #21012113-AS (the "Application") – Proposed $223,724,658 Multi-Site DoN for Three New Ambulatory Sites located in Westborough, Westwood & Woburn, each including a Freestanding Ambulatory Surgery Center with Four Operating Rooms, Physician Services and Imaging Services (CTs and MRIs) (the "proposed projects") – Additional Comments of UMass Memorial TTG

Dear Ms. Szent-Gyorgyi:

On behalf of the UMass Memorial TTG, this letter supplements the comments included in the TTG registration filing dated February 12, 2021 regarding the proposed projects.

The purpose of these additional comments is twofold: (i) to emphasize that the intent of the proposed projects would operate to subvert the goals of the DoN program, and (ii) to further address important technical noncompliance issues raised by the Application. From a gating perspective, the technical review is essential as we believe the Application is noncompliant and should be withdrawn. In light of the fact that the technical issues relate directly to the health care policy implications of the proposed project, however, it is important that the Department consider both types of arguments in tandem at the outset of its review.

Contrary to Applicant's assertion, the compliance of the Westborough project siting with 105 CMR 100.715(B)(2), has not been established by the Applicant[1]. As further described below, the

[1] 105 CMR 100.715(B)(2) provides: "For any Application for Notice of Determination of Need made pursuant to 105 CMR 100.715(B)(2)(a) 1. 2. or 3. which includes a Proposed Project within the Primary Service Area of an existing Hospital that is: 1. designated as an independent community disproportionate share or nondisproportionate share Hospital as defined by HPC's Massachusetts Hospital Cohort Designation and Affiliation Status, and 2. not an existing joint venture or Affiliate of the Applicant: a. The Proposed Project must constitute a joint venture with the independent community disproportionate share or non-disproportionate share Hospital; or b. The Applicant must

primary service area ("PSA") definition under the DoN regulation, which is a necessary component for analyzing the appropriate placement of a freestanding ambulatory surgery center ("ASC") near an independent community hospital ("ICH") identified by the Massachusetts Health Policy Commission ("HPC"), remains to be finalized. Since the proposed Westborough site is arguably within the PSA of an ICH (Milford Regional Medical Center "Milford"), and Applicant has failed to establish either of the permitted ways of demonstrating the local ICH's consent to permit placement within the PSA, the appropriate delineation of the applicable PSA for analyzing the proposed project siting in Westborough must be determined by the Department in accordance with the DoN regulation.

Under the DoN Regulation[2] "Primary Service Area" is defined by the Department as "the geographic area in which a majority of patients who receive care at a Health Care Facility reside. The percentage of patients who are counted in determining the Primary Service Area will be set out in Guideline." In addition, "Guideline" is defined in the DoN Regulation as an "enforceable sub-regulatory requirement that has been issued by the Commissioner pursuant to 105 CMR 100.000, but not promulgated as regulation. The Commissioner shall ensure that prior to issuance, all Guidelines have been put forth for public comment. The Commissioner shall notify the Public Health Council of any Guideline issued by the Department within 60 days of issuance." In the absence of the proper issuance of the Guideline regarding the PSA, an ASC is unable to confirm the siting of an ASC in proximity to an ICH unless the proposed project already constitutes a joint venture with the ICH or has obtained a letter of support signed by ICH's chief executive officer and board chair.

The DoN staff's intent when this regulatory provision was enacted in 2018 was to align the Department's PSA definition with the HPC's, consistent with the alignment between the goals of the DoN program and the HPC regarding cost containment, as described in our prior comments. The HPC uses a flexible and tailored approach when calculating a PSA to ensure the formula used matches the facts and circumstances of the scenario to which it is being applied. The HPC's technical bulletin[3] on this topic provides that the HPC may make certain fact-specific

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obtain a letter of support signed by the independent community disproportionate share or non-disproportionate share Hospital's chief executive officer and board chair."

[2] 105 CMR 100.100. https://www.mass.gov/doc/105-cmr-100-determination-of-need/download

[3] See, Mass. Health Policy Comm'n, Technical Bulletin for 958 CMR 7.00: Notices of Material Change and Cost and Market Impact Reviews, p.1 (Aug. 27, 2017): "This Technical Bulletin is a sub-regulatory document containing methodological explanations and examples to facilitate understanding of and compliance with the provisions contained in 958 CMR 7.00, including measurement of Primary Service Areas… A Primary Service Area should be calculated by service line, based on the best available data, as described in 958 CMR 7.02. …the Commission may make certain fact-specific determinations regarding a Primary Service Area. The following is an exemplar calculation of the Primary Service Area for inpatient general acute care services. The methodology for calculating Primary Service Areas for specialty acute care services, outpatient/ambulatory services, primary care services, and other service lines may be described by the Commission in a future Technical Bulletin" (emphasis added)". https://www.mass.gov/doc/final-958-cmr-700-technical-bulletin-0

determinations regarding a particular PSA. The HPC states that flexibility in determination of the PSA ensures coherent results for many different types of hospitals (e.g. quaternary/tertiary, community, urban, rural, high volume, low volume), whose service areas can be expected to be shaped by the hospital's unique characteristics[4]. The HPC also states that it anticipates promulgating additional technical bulletins to address specific provider types or services.

In developing its own PSA Guideline, as informed by the HPC, the Department may choose to consider various factors, just as hospitals and ASCs, like MGB, self-define their own PSAs. Some factors DPH could consider in customizing a PSA in evaluating a project such as the Applicant's include a project's proposed service area being particularly inclusive of the ICH's

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[4] See FN 118, Mass. Health Policy Comm'n Final Report, "Review of Partners HealthCare System's Proposed Acquisition of South Shore Hospital (HPC-CMIR-2013-1) and Harbor Medical Associates (HPC-CMIR-2013-2) (Feb. 19, 2014). https://www.mass.gov/doc/final-cmir-report-partners-south-shore-harbor/download
"Chapter 224 requires the HPC to promulgate a standard methodology for calculating PSAs in the Massachusetts health care market. MASS. GEN. LAWS ch. 6D, § 13(j) (2012). We have surveyed (and continue to survey) how different providers in Massachusetts determine their service areas, and the latest empirical methods used by leading health care researchers. Our review has uncovered some modest differences in the various ways Massachusetts providers define their service areas (usually driven by unique characteristics of a provider or specific knowledge of the surrounding market), but similarities in approach far exceeded the differences. All methods in use assessed a hospital's PSA based on the volume of discharges sent to the hospital from different towns or zip codes, and sought to identify a compact, contiguous area that is responsible for a significant proportion of the hospital's discharges (and for which the hospital is an important provider). Some of the methods reviewed by the HPC explicitly considered the proximity of a given town or zip code to the hospital, while others did not. In seeking to identify a compact area that is responsible for a significant proportion of the hospital's discharges, most methodologies resulted in a PSA comprising about 75% of the hospital's discharges, which mirrors federal FTC/DOJ ACO guidelines. FTC & DOJ ACO Final Policy Statement, supra note 116. Based on this exhaustive review, and on extensive modeling of variations in methodologies across a spectrum of Massachusetts hospitals, the HPC has developed a working definition of PSA that yields coherent results for many different types of hospitals (e.g., quaternary/tertiary, community, urban, rural, high volume, low volume), whose service areas can be expected to be shaped by the hospital's unique characteristics. The HPC's methodology yields more consistently reliable results for a range of hospitals than other methods that may be used by individual hospitals to define their service area for business purposes. This methodology generally defines a PSA by focusing on the contiguous zip codes closest to a hospital by drive time, from which the hospital draws 75% of its commercial discharges, and for which the hospital represents a minimum proportion of the zip code's total discharges. Specifically, we measured the drive time from the centroid (or approximate center) of a zip code to the hospital. Although we reviewed some methods for defining a service area that do not explicitly consider geographic proximity, both the leading economic research and recent decisions by agencies that monitor health care markets have emphasized the importance of patient travel time in assessing a hospital's market. See, e.g., In the Matter of ProMedica Health System, Inc., FED. TRADE COMM'N, Docket no. 9346, at 26 (June 25, 2012); Katherine Ho, The Welfare Effects of Restricted Hospital Choice in the US Medical Care Market, 21 J. Applied Econ. 1039, 1051 (Nov. 7, 2006); Cory Capps et al., Competition and Market Power in Option Demand Markets, 34 RAND J. OF ECON. 737, 752 (2003); Robert Town & Gregory Vistnes, Hospital Competition in HMO Networks, 20 J. HEALTH ECON. 733, 746-47 (2001). We included both methodologies to ensure that our findings are robust, but we observe two limitations with SSH's methodology for the purpose of assessing competitive impact. First, it appears that SSH uses all discharges, and does not examine commercial discharges separately. For the purpose of assessing competitive impact, it is more relevant to focus on commercially insured patients, as hospitals negotiate with private payers, not government payers. Second, SSH's methodology does not assess geographic proximity of hospitals to patients, because it does not consider drive times. While their approach may be appropriate for internal business assessments, the HPC's methodology is more appropriate in these dimensions for the purpose of assessing competitive impact."

self-defined PSA, drive times, a community's dependency on a particular hospital, including for emergency room services, and consideration of MassHealth and Medicare patients (i.e. in addition to the HPC's emphasis on commercially insured patients).

Finally, in examining the PSA, the Department also should consider carefully whether an Applicant has attempted to circumvent the intent of the DoN Regulations by gerrymandering the location of a proposed project[5]. MGB was highly surgical in its decision to locate the proposed project in Westborough, bordering localities that abut Milford's self –identified PSA[6] and included by Milford within its own PSA. MGB also selected a location that was already well-served[7] with the apparent intention of steering patients to its facility to cherry-pick[8] the

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[5] "Any action taken by a provider to circumvent the purpose and object of the program is a violation of the DoN Regulations." 105 CMR 100.001.

[6] Berlin, Bolton, Grafton, Northborough, North Grafton, Shrewsbury, Upton, Westborough, Framingham, Ashland, Hopkinton, Hudson, Marlborough, Milford, and Southborough.

[7] There are approximately 24 facilities within a ten minute drive of the proposed Westborough location, which provide the same services as the proposed projects, fourteen of which are specialty care facilities. Nearly 200 facilities are within twenty minute drive of the proposed Westborough location, including three hospitals and an ambulatory surgery center.

[8] There is a body of economic literature demonstrating the harm that results from health system conduct that has the purpose and/or effect of cherry-picking (also known as cream-skimming) commercial patients from full service hospitals to ASCs and other limited-service hospitals. See, e.g., "An Economic Model of Competition Between General Hospitals and Physician-Owned Specialty Facilities," The Antitrust Bulletin, vol. 52 Fall-Winter 2007; Chakravarty, S., "Much ado about nothing? The financial impact of physician-owned specialty hospitals," Int J Health Econ Management (2016) 16:103–131 (summarizing empirical analysis finding adverse impact of specialty hospital entry on general hospital financial performance after incorporating cherry-picking selection behavior, and underlining the importance of the payment reforms aimed at correcting distortions in the reimbursement system that generate incentives for risk selection among provider groups. "As hospitals start to come under increasing financial pressure due to such [distortions], the need to ensure a level playing field between physician-owned and general hospitals assume further importance."); *see also* the HPC Community Hospital Study referenced at note 10,below. Hospitals must receive enough revenue to allow them to cover their costs and earn a competitive return. The competitive return allows them to continue to invest in the facility to provide less profitable services. As a general matter, commercially insured patients generate more net revenue for hospitals than do Medicare and Medicaid. Essentially, none of a hospital's Medicaid or self-pay patients yield enough revenue to cover the full cost of services, and revenue from many Medicare patients also does not cover fully allocated costs. Consequently, hospitals subsidize government-insured and self-pay patients with revenue from commercial patients. Through the operation of an ASC with other integrated ambulatory services, MGB can avoid the cost of providing the full range of services, including ER/trauma care offered by a full service hospital. MGB-affiliated physicians associated with the ambulatory site have the ability to steer the most profitable patients away from Milford, Marlborough (a community DSH) and UMass Memorial and toward its Westborough location. See also notes 10 and 11 with respect to the particular harm caused by ASCs.

Based on CHIA data, this dynamic already appears to be playing out in the service area of MGB's Foxborough location, as Sturdy Memorial Hospital had forewarned in testimony and public comments submitted to the Department, Based on FY16 to FY19 CHIA Inpatient Case Mix data results for the 18 different towns in and around the Foxborough location, the overall Commercial and Medicaid market grew by 149 and 31 discharges respectively. MGB was able to increase its commercial inpatient referrals from these town by 498 discharges while lowering their Medicaid referrals by 242 discharges. In contrast, Sturdy Memorial and Steward Norwood Hospital

commercially insured patients residing in the surrounding area. This is evident because the proposed project in Westborough is (i) sited in a higher income area with a high percentage of commercial insurance coverage and low percentage of residents who are uninsured, insured by MassHealth, or living in poverty[9]; (ii) sited in a location that is not well served by public transportation making the services essentially inaccessible to residents without access to a personal vehicle and especially so to the residents in the more outlying, lower income communities MGB has chosen to include within its self-defined PSA (i.e. Framingham, Milford and Marlborough); and thus (iii) is designed to attract more mobile, higher income, commercial pay patients. Of significant concern, the Proposed Project in Westborough is also located in a community with a low percentage of Black and Latino residents which will only increase existing racial and ethnic disparities in access to care. In sum, the Westborough project represents a focused investment in an already well-resourced predominantly white community in lieu of investing in lower income, predominantly Black and/or Latino communities which lack such access.

MGB's actions not only do nothing to increase access for lower income, poor and Black and Latino residents but will effectively undermine and reduce such access through the adverse impact to vulnerable critical access providers. As the HPC, CHIA and the Massachusetts Office of Attorney General have observed[10], safety net and disproportionate share hospital ("DSH") providers rely on the modest positive margin from commercial pay patients to subsidize the significant negative margins on services provided to MassHealth patients and other important but loss generating service lines. Even a modest shift in commercial volume from local safety net and DSH providers to MGB (including both ambulatory services at the new location and associated secondary, tertiary and quaternary referral volume MGB will capture at its network hospital locations) will jeopardize operating margins and balance sheets for the local providers leaving fewer resources to care for the remaining patients dependent on these institutions. As a result of the loss of commercial volume and lower or negative operating margins, the safety net and DSH providers will have less capital (and less access to debt and bond financing) to continue to invest in facilities and programs. This in turn will make them even less competitive in the

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both experienced increases in Medicaid discharges of 171 and 87 respectively, with Steward Norwood Hospital significantly affected by lower commercial discharges of 218.

[9] The proposed Westborough facility would expand MGB's service area to many new communities which are in the top quintile of income in the Commonwealth ($139,428 - $373,970), and thus with high rates of commercial insurance. As noted above, all but three of the thirteen towns in Westborough area exceeds the Median household income level at more than 130% of the statewide average. In addition, poverty levels within each town are well below the statewide, Boston, Worcester and two neighboring counties, and have a lower 65+ population than the statewide and Worcester County average. According to US census 2019 information results:

- Median Income: MA ($81,215) v. Westborough ($112,153)
- Persons in Poverty: MA & Worcester County (9.4%) v. Westborough (4.6%)

[10] For an in-depth analysis reflecting important work conducted by all three agencies and covering all of the health policy considerations detailed in these comments, please see the HPC's report entitled "*Community Hospitals at a CrossRoads: Findings from an Examination of the Massachusetts Health Care System*" (March 2016) (the "Community Hospital Study").

commercial pay market and with less to offer their remaining patient population. In order to remain financially viable, safety net and DSH providers must either seek financial support from the State or close loss generating services – many of which primarily serve low income and MassHealth patients. Over time this cycle will only intensify existing disparities in access to care and destabilize the Commonwealth's health care delivery system.

Consistent with its sister agencies, the Department has seen fit to mitigate, through the DoN Regulation, what it identified as one of the most the significant risks to ICHs -- the loss of patients due to the siting of ASCs in close proximity to the very hospitals to which they will send their patients in need of emergency care[11]. The importance of this concern to the Department is illustrated by the fact that the Department further clarified its ASC/ICH regulation through the 2018 amendment to ensure a more in-depth review of PSA in that context. In enacting that amendment, the Department determined that without sub regulatory guidance, there would not be clear direction as to the siting of an ASC in proximity to an ICH. Thus, without an advance agreement from the local ICH, an ASC project may not be sited in its proximity without evidence of compliance with an appropriately promulgated DPH PSA Guideline.

We submit that now is the time, before MGH attempts to refashion the Commonwealth's health care landscape singlehandedly, for the Department to take a step back from the Application review process and undertake the called-for public sub regulatory guidance process. A thorough consideration of PSA may help alleviate the additional concern caused by fact that the DoN Program does not yet have the legislatively required state health plan to help guide its analyses.[12]

Finally, Application is also incomplete due to Applicant's failure to complete section 12.5 of the Application. This provision asks that the Applicant state the total proposed construction costs, specifically related to a proposed project which will be contracted out to local or minority, women, or veteran-owned businesses expressed in estimated total dollars.

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[11] See the Community Hospital Study, page 60. Interestingly, this risk of ASCs being sited in close proximity to full service hospitals has also been recognized by the Applicant itself as reflected in its own public financing disclosure documents. According to MGB, ASCs "may attract away significant commercial outpatient services traditional performed at hospitals. Commercial outpatient services, currently among the most profitable for hospitals, may be lost to competitors… Full service hospitals rely upon the revenues generated from commercial outpatient services to fund other less profitable services, and the decline of such business may result in a decline in operating income… Consequently, hospitals are vulnerable to competition from ambulatory surgery centers." See page 8 of the Official Statement for the $385,885,000 Massachusetts Development Finance Agency Revenue Bonds, Mass General Brigham Issue, Series A (2020) at https://emma.msrb.org/ER1305791-ER1017935-ER1423610.pdf. See also note 8.

[12] The Applicant itself has stated in its Official Statement at pg.28: "DoN regulations effective in December 2018 implement the legislative requirements that the DoN Program be guided by the state health plan in furtherance of the plan's goals of ensuring appropriate allocation of healthcare resources, increased access and lower cost."

For all the reasons stated herein, we submit that the Application is incomplete and should be withdrawn.

Sincerely,

Douglas S. Brown
President of Community Hospitals and CAO
UMass Memorial TTG Representative

Cc: Katharine Eshghi
Jennifer Gallop

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