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Kevin McDonald
Chief, Certificate of Need
MARYLAND HEALTH CARE COMMISSION
4160 Patterson Avenue
Baltimore, Maryland 21215

February 15, 2018

Re: Suburban Hospital Liver Transplant Application - Matter No. 17-15-2400

Dear Mr. McDonald:

We are responding to the Commission staff's request for additional information related to a second set of completeness questions posed by letter dated February 2, 2018. We first restate the question followed by Applicant's response.

Quality of Care

1. **Regarding the response to Question #8, please address the following:**

   a. **For the metrics under consumer ratings for communication, Suburban Hospital was below average and explained that over the past three years Suburban Hospital has worked on its electronic medical record system to improve the discharge instructions and process for communicating with patients. However, it is not clear what impact this has had. Please further explain what evidence exists that the changes implemented have led to improvements.**

A multi-disciplinary team consisting of representatives from across the Johns Hopkins Health System worked to enhance Suburban's electronic discharge instructions. These instructions are known as the "After Visit Summary" (AVS). The team redesigned the AVS to create a more readable and patient-friendly document that highlights important discharge information. This information includes instructions for home and follow-up appointments. Prior to discharge, a nurse reviews the AVS with each patient discharge.

Suburban begins discussing a safe discharge with the patient upon admission. The patient's care plan is reviewed during bedside shift report and during multi-disciplinary team rounds. To support the nurse's communication with the patient about discharge, each unit has a dedicated social worker or case manager to facilitate the discharge plan and answer questions.

Follow-up appointments can be made for patients while still in the hospital. The Administrative Service Representative (ASR) is able to make appointments with the patient's primary care physician or an appropriate specialist.

Also, while in the hospital, a patient designates a Care Partner to provide support during their hospital stay and to help them manage health care needs after leaving the hospital. A Care Partner can be a spouse, partner, family member, neighbor, or trusted friend. The designated Care Partner completes a HIPAA release form and is documented in the electronic health record. The Care Partner is encouraged to participate in the review of discharge instructions to further support the patient in understanding the instructions.

Suburban Hospital's transition guide nurses meet or call high-risk patients to answer any questions related to discharge or follow-up appointments. These nurses also make themselves available to answer any post-acute medical-related questions. All inpatient units conduct discharge phone calls within 24 to 48 hours of a patient's discharge. The nurse can answer specific questions related to the patient's medications, highlight symptoms to watch for, and review discharge instructions. In addition, beginning in February 2017, all inpatients are now assigned an educational video on the discharge process and the importance of understanding discharge instructions.

The current data posted on Hospital Compare shows an improvement in Suburban's performance related to discharge information. We expect additional improvement as a result of the changes implemented since February 2017 (the educational video concerning discharge), near the end of the last data collection period for which measures are available, and other changes that occurred during the last data collection period, the effect of which was not fully reflected in the measure for the period. We will continue to assess the impact of the most recent changes and identify effective communication strategies for our patients.

Measure indentifier	Technical measure title	Measure as posted on Hospital Compare	Data collection periods		Suburban Hospital
			From	To	
H-COMP-6-Y-P	Discharge information (composite measure	Patients who reported that YES, they were given information about what to do during their recovery at home	7/1/2015	3/31/2016	83%
			10/1/2015	6/30/2016	83%
			1/1/2016	12/31/2016	84%
			4/1/2016	3/31/2017	84%

b. Under heart failure for results of care, Suburban Hospital was below average and explained that its performance is reflective of its elderly population. Suburban Hospital stated that it follows readmissions very closely and have not identified related trends. Please further explain why Suburban is convinced that no steps need to be taken to improve performance on this metric. It may be useful to explain the process for reviewing readmissions for heart failure patients.

Our analysis has shown that the results of this metric for Suburban are affected by the relatively older average age of our Heart Failure patients. We are not convinced, however, that this metric cannot be improved. Suburban has introduced the following initiatives to improve Heart Failure (HF) 30-day mortality:

To optimize treatment, Suburban screens HF patients during hospitalization for impaired Left Ventricular Ejection Fraction (LVEF). We have instituted multidisciplinary rounds to better focus their care and ensure communication of the care plan among all team members, the patient and their family. Our EPIC EMR has a hard stop in the Discharge Order Set for HF patients requiring the evaluation ACE1/ ARB at time of discharge. In addition, Case Managers assess these patients during admission for the need for assistance at discharge from Suburban's Transition Guide RNs.

Post-discharge, HF patients are remotely monitored for blood pressure, weight, and pulse oximetry. They are also followed by HF Transition Guides and post-discharge phone calls to ensure they are taking medications, monitoring weight and have scheduled their follow-up appointments.

Suburban will continue to seek the most effective ways to address the needs of HF patients during their admission and after discharge.

c. Under imaging, Suburban Hospital was below average on the rate of patients who came to the hospital for a scan of their brain and also got a scan of their sinuses. For this measure, when a patient gets both a scan of their brain and sinuses on the same day for a headache, it is generally considered inappropriate. The explanation provided, suggesting that patients may have been undercounted, does not fit with the expectations for this measure. Please explain why Suburban Hospital is convinced that no steps need to be taken to improve its performance on this metric.

Suburban Hospital has instituted new guidelines for the utilization of Head and Sinus CT evaluation of patients with headache to provide better instruction to our ordering physicians. On

the most recently published Hospital Compare results, there was a significant decrease, from 7.0% to 2.3%, which is less than the Maryland state average.

d. Under patient safety, regarding blood clots in patients that could have been prevented, Suburban was below average and explained that it cares for some high risk populations who are at higher risk for blood clots. Suburban Hospital stated that it has not observed any unusual trends in its hospitalized patients. Please further explain why Suburban Hospital is convinced that no steps need to be taken to improve performance on this metric.

With Suburban Hospital's conversion to Computerized Physician Order Entry (CPOE) in July of 2014, every Suburban admission order set contains venous thromboembolism (VTE) orders for chemical and mechanical prophylaxis. The provider "Admission Navigator" contains decision support for medical and surgical patients with risk factors and contraindications to therapy. If the provider does not complete this assessment, the software challenges the provider to complete it before selecting VTE prophylaxis. VTE prophylaxis spans both pharmacological and mechanical components, and both are hard stops. In other words, these steps must be completed in order to sign the orders.

To assess VTE risk from immobility, in the "Nursing Admission Navigator" patients are screened for difficulty walking and climbing stairs. This is required documentation in the Epic electronic medical record platform. Early mobility is a key component of patient care. In the "Daily Care/Safety" template, patients are assessed daily via the nurse mobility assessment, documentation of AM-PAC daily functional activities score, and Highest Level of Mobility (HLM), including level of assistance needed.

The most recent data from Hospital Compare shows a 0% Potentially Preventable VTE rate for Suburban from the time period between 03/31/2016 and 04/01/2017.

Access & Need

2. Regarding the response to Question #13, please explain what evidence exists that the number of ICU beds available in the WRTC DSA limits access to liver transplant candidates who reside in the WRTC.

There is no dispute that the availability of intensive care unit ("ICU") beds is necessary for a transplant center. Patients with high MELD scores routinely require ICU care, and so the ability to perform liver transplants on those patients depends on ICU bed availability. On occasion, a transplant center may be unable to perform a liver transplant because an ICU bed is not available. That is less likely to occur in a hospital with a higher number of ICU beds. It is also less likely to occur in a DSA with more than one center.

University of Maryland Medical System ("UMMS"), for instance, has 266 ICU beds. UMMS was able to perform 53 transplants on patients with MELD scores of 35 and above in 2016. Georgetown, by contrast, has only 57 ICU beds. During this same time frame, Georgetown performed only 8 transplants on patients with MELD scores of 35 and above. We cannot know for sure if the lack of an available ICU bed at a critical time contributed to this low number, but it likely did.

The addition of a liver transplant program at Suburban will add 42 ICU beds at a liver transplant center to accommodate patients with advanced liver disease in the WRTC DSA. The presence of a second center in the DSA can alleviate the impact on patients of an ICU bed shortage in a DSA with only one center.

3. **Regarding the response to Question #16 (and #37), please explain how the capacity of a center to conduct the candidate evaluation should be measured and what level of capacity should be deemed acceptable.**

One measure of whether the capacity to conduct candidate evaluations in a DSA is acceptable is the number of patients who are added to the waitlist. While there is no benchmark for waitlist length, or the rate at which patients are added to the waitlist, the disparity between the WRTC waitlist and the LLF waitlist may result, in part, because the single center in the WRTC DSA lacks the capacity to conduct a sufficient number of candidate evaluations.

A second liver transplant center in the WRTC DSA will result in greater candidate evaluation capacity and more patients added to the waitlist. The best measure of success, though, will be additional patients transplanted.

4. **Regarding the response to Question #18, please address the following:**

   a. **Please explain under what circumstances a patient can get a liver transplant without ever listing, other than a living donor transplant. Please provide the number of transplants in this category for each of the three most recent years, for transplant centers in the WRTC DSA and LLF DSA.**

A patient cannot get a deceased donor liver transplant, or a living donor liver transplant, without listing. All liver transplant patients must be listed in order to go to transplant.

   b. **Please explain why Suburban Hospital concludes that WRTC DSA residents with higher MELD scores have insufficient access to transplant services contrary to national policy, in spite of a national policy implemented in June 2013 (Share**

35) that dictates regional sharing of livers for candidates with MELD scores higher than 35.

In response to Completeness Question number 11, we cited a publication by Massie and others that quantifies the impact of Share 35 on organ sharing and recipient allocation. UNOS designed Share 35 to benefit patients with end stage liver disease. In our response, we stated:

> Nationally, in the first year of Share 35 the proportion of deceased donor liver transplants ("DDLT") allocated to recipients with a MELD of 35 or greater increased from 23.1% to 30.1%. The proportion of regional liver shares increased from 18.9% to 30.4%. This means that sicker patients were accessing liver transplants at a higher rate and more livers were being shared between DSAs within a given Region.

In short, at a national level, the policy appears to be doing what it was intended to do. However, comparing the LLF DSA and WRTC DSA paints a different picture. In response to completeness question number 36, we quantified the number of deceased donor liver transplants performed on patients with varying MELD scores in the LLF DSA and in the WRTC DSA in 2016, two and a half years after Share 35 was implemented. The table below includes from that response the number of transplanted patients with MELD scores of 35 and above in 2016, and we have added transplant numbers for 2015.

MELD ≥ 35	LLF Centers	WRTC Center
2015	75	7
2016	75	8

This data shows that while Share 35 succeeded in getting more patients with higher MELD scores transplanted nationally, very few transplants for higher MELD patients were performed in the WRTC DSA. As a result, residents of the WRTC DSA with higher MELD scores continue to experience insufficient access.

c. Staff also notes that the national policy for liver distribution changed again in December 2017 to reduce disparities in access to liver transplants, increasing regional sharing of organs and giving greater preference to liver transplant candidates with the greatest immediate need for a liver. Please explain how you anticipate this change in policy will alter access of WRTC DSA residents to liver transplants and affect the need for an additional transplant program in the WRTC DSA.

The change in national policy for liver distribution made in December 2017 is in many ways an extension of Share 35. Chiefly, the policy broadens the pool of patients for whom sharing is required for those at or above a sharing threshold of MELD 32.

It is likely that implementation of the new policy will result in patients with MELD scores of 32 and above composing a higher proportion of the total number of patients transplanted nationally. Further, the proportion of livers that are shared between DSAs will be greater nationally.

Given that Share 35 did not have the intended beneficial impact for sicker patients in the WRTC DSA, it cannot be assumed that the new policy will increase transplants for sicker patients in the WRTC DSA either. Even if the policy does result in more high MELD patients getting transplanted, it does not address the other issues that may be contributing to insufficient access in the WRTC DSA, such as ICU bed availability, evaluation capacity, and waitlist additions. A second center is needed in the WRTC DSA to improve overall access to liver transplantation.

5. **Regarding the response to Question #22, it is speculative to say that the waitlist policies of the transplant center in the WRTC DSA are hurting residents of the WRTC, without knowing the waitlist policies. The information on MELD scores for patients added to the liver transplant programs in the LLF DSA and WRTC DSA available through the OPTN web site (https://optn.transplant.hrsa.gov/data/view-data-reports/center-data/) does not suggest any obvious differences in the waitlist practices of Johns Hopkins University and MedStar Georgetown University Hospital, with respect to patient acuity at the time of listing. If you disagree with this assessment, please explain.**

The data available for patient acuity at time of listing for JHH and MGUH, may not, in fact, suggest any obvious differences in the waitlist practices of the two centers. There are, however, obvious differences in the number of high MELD patients transplanted in the WRTC DSA compared to the LLF DSA. As referenced in 4b above, 75 MELD 35 and above patients were transplanted in the LLF DSA in 2016, while only 8 were transplanted in the WRTC DSA. To evaluate the ability of high MELD patients to access transplant services, "MELD at time of transplant" is a more meaningful metric, and it shows obvious differences between the two DSAs.

6. **Regarding the response to Question #29, please provide information on the reasons why livers were exported from the WRTC and transplanted by Johns Hopkins Hospital, when the reason was not attributed to the Share 35 policy for years 2014-2016.**

Livers that were exported by the WRTC to Johns Hopkins for years 2014 to 2016 that were not the result of the Share 35 policy are livers that were rejected by Georgetown. We do not know why Georgetown passed on those livers. But those same livers were accepted and transplanted by Johns Hopkins.

7. **Regarding the response to Question #36, please explain why Suburban attributes competition as the reason for transplant programs in the LLF prioritizing sicker patients, rather than changes to national policy. The number of liver transplant programs in the WRTC and LLF DSAs has not changed in the past decade, and difference in adult deceased donor transplant rates for residents of each DSA (at any transplant center, not just within the same DSA) has only clearly diverged recently based on the information as provided in the table on page 17 of your response to Question #14.**

There are clear, significant, growing disparities between the WRTC center and the LLF centers in the number of transplants performed, the number of residents receiving transplants, the number of transplants for sicker patients, the use of organs, and the number of patients added to waitlists. These disparities date back at least to 2011, and have worsened over time. On the particular measure of transplants performed for patients with higher MELD scores, the WRTC center numbers are especially low, and did not improve with the implementation of Share 35. The LLF numbers, on the other hand, are high and increased with the implementation of Share 35.

Suburban's goal is to improve these measures in the WRTC DSA and decrease access disparities between the LLF and the WRTC DSAs. Our belief that competition is an important and powerful tool for improving these measures is rooted in our own experience at the Johns Hopkins Comprehensive Transplant Center and is supported by an extensive body of peer-reviewed medical literature, cited beginning on page 49 of our application.

That is not to say that a lack of competition in the WRTC DSA is the only cause of the observed disparities. But we can say based on our experience and on the literature that competition created by a second transplant center in the WRTC DSA will have a positive impact, increasing the number of transplants performed, the number performed locally, the number of organs used, and the number of patients placed on the waitlist.

8. **Regarding the response to Question #37, does the Johns Hopkins Hospital track how often factors such as insurance, transportation, and caregiver support result in turning a potential liver transplant candidate away from its transplant program or not referring for evaluation? Is there another organization that would be tracking this type of information?**

Johns Hopkins collects the reasons associated with a change in patient status when the change discontinues or defers a patient from the referral, evaluation or waitlist phase. This information is typically recorded in the narrative notes in the patient's chart by the social worker or transplant nurse coordinator. It is not tracked in a way that allows us to identify trends. We are not aware of any other organization that tracks this type of information.

9. **Regarding response to Question #62, Suburban Hospital stated that it expects equivalent growth can be achieved in the WRTC DSA as compared to the LLF DSA. Has this assessment changed as a result of the national change in liver transplant policy?**

No. We expect that the latest national policy change will have the intended effect of increasing access to organs for sicker patients through greater sharing, just as Share 35 did. Unfortunately, Share 35 did not have the desired effect for sicker patients specifically in the WRTC DSA. Even if the new policy does result in more high MELD patients in the WRTC DSA receiving a transplant, as we hope it does, other improvements in access will be realized by the addition of a liver transplant program at Suburban. A second center will improve ICU bed availability, evaluation capacity, and waitlist additions, and ultimately more transplants will be performed in the WRTC DSA.

10. **Regarding response to Question #63, please explain why the percentage of the population below the poverty line in only select counties from each DSA is compared, rather than for the whole population of each DSA.**

We compared D.C. and the three Maryland counties in the WRTC DSA to Baltimore City and the three surrounding central Maryland counties to show that the prevalence of poverty is similar in the area immediately surrounding these metro areas where the liver transplant centers are located. For the population living below poverty, travel to another city or another region for medical care is difficult if not impossible.

Thank you for the opportunity to provide additional information. We look forward to moving to the next phase of review.

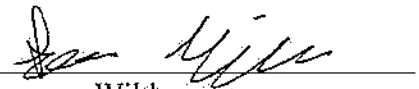
Sincerely,

Anne Langley

cc: Uma S. Ahluwalia, Montgomery County Health Department
Jacqueline Schultz, CEO, Suburban Hospital

AFFIRMATION

I hereby declare and affirm under the penalties of perjury that the facts stated in this application and its attachments are true and correct to the best of my knowledge, information, and belief.

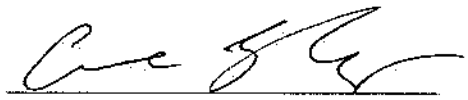


Spencer Wildonger
Director of Health Planning
Health Care Transformation and Strategic Planning
Johns Hopkins Health System

02/15/2018
Date

AFFIRMATION

I hereby declare and affirm under the penalties of perjury that the facts stated in this application and its attachments are true and correct to the best of my knowledge, information, and belief.



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