

MEMORANDUM

- TO: Michael J. O'Grady, Ph.D., Commissioner/Reviewer, MHCC Wynee Hawk, Chief, Certificate of Need Division, MHCC Moira Lawson, Program Manager, Certificate of Need Division, MHCC
- **FROM:** Katie Wunderlich, Executive Director, HSCRC Jerry Schmith, Director, Revenue & Regulation Compliance, HSCRC Bob Gallion, Associate Director III, Revenue & Regulation Compliance, HSCRC
- DATE: November 16, 2021
- RE: MedStar Franklin Square Medical Center ("Franklin Square") CON Application to Establish Kidney Transplant Services Docket No. 17-03-2405

This memo is in response to your request dated October 13, 2021. Franklin Square filed a Certificate of Need ("CON") application August 14, 2017, proposing the introduction of a kidney transplantation program. You have requested that the staff of HSCRC provide its opinion on the general financial feasibility and viability of the proposed kidney transplant services and provide insight regarding certain assumptions made.

BACKGROUND

There are currently two kidney transplantation programs in Baltimore, one at Johns Hopkins Hospital ("JHH") and one at University of Maryland Medical Center ("UMMC"). Both programs are now averaging over 200 kidney transplants per year. In addition, there are two kidney transplantation programs in Washington, D.C., one at MedStar Georgetown University Hospital ("Georgetown"), which is also averaging over 200 kidney transplants per year, and one at George Washington University Hospital ("George Washington"), which is averaging over 50 kidney transplants per year. JHH and UMMC are recognized as interested parties in this review.

THE PROJECT

There are no capital costs for the project. Franklin Square anticipates that it will do 12 transplants in the 1st year of operation (FY 2019), 24 in the 2nd year (FY 2020), and 44 in the 3rd year (FY 2021), resulting in net losses of \$1,082,000 and \$641,000, respectively, in the first two years of operation, with a net income of \$433,000 in year three.

Franklin Square estimates that referrals of MedStar patients to the existing Baltimore programs will decline from about fifteen (15) per year (collectively) to about five (5).

ANALYSIS

The State Health Plan requires the applicant to address whether its proposed program is cost effective as compared to the existing programs in its service area. Franklin Square contends that its cost structure is significantly lower than that of either JHH or UMMC. To make that case, Franklin Square used the following methodology. Franklin Square compared its general cost structure as measured by charge per ECMAD of \$13,099 to that of JHH (\$16,640) and UMMC (\$19,544) using data from the 9 months ending March 2017. Then, extrapolating from those general cost structures, Franklin Square calculated and compared the per case kidney transplant costs of its proposed program of \$87,203 with those of JHH (\$148,500) and UMMC (\$116,270) for kidney transplants, using data from the 6 months ending March 2016.

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QUESTIONS from MHCC to HSCRC

- HSCRC staff is asked to review the financial projections provided by the applicant, as well as the assumptions (revenue, expenses, staffing, and utilization) upon which these projections are based, as provided in the CON application and subsequent filings, and comment on the financial feasibility of the project and the reasonableness of the assumptions. In addition, HSCRC staff is asked to comment on the viability of the project (a criterion that encompasses the availability of resources to implement the proposed project and the sustainability of the proposed new kidney transplant service over time).
- 2) Franklin Square states that because it is a community hospital, its charges for kidney transplants would be significantly less than those at the existing programs in large academic medical centers such as JHH or UMMC. Does HSCRC staff believe that a new kidney transplantation program at Franklin Square would be expected to have lower charges and therefore be more cost effective than the programs at JHH and UMMC as projected by Franklin Square?
- 3) How will a shift in kidney transplant cases from Georgetown to Franklin Square impact the spending and savings targets HSCRC must meet under the Medicare Total Cost of Care model?

HSCRC REVIEW, DISCUSSION, and OPINION:

HSCRC staff ("staff") has reviewed the following: 1) the CON application dated August 14, 2017; 2) the subsequent Franklin Square Completeness Responses dated March 1, 2018 and June 1, 2018; 3) Franklin Square Additional Information dated August 23, 2018; 4) Franklin Square Motion Responses dated November 5, 2018, November 12, 2019, and December 30, 2019; 5) Franklin Square Interested Party Responses dated November 20, 2018; and 6) Franklin Square Reviewer's Responses dated July 9, 2021 and October 1, 2021.

Upon review of the statistical and financial information provided in the CON and subsequent completeness responses, it was noted that such information was most recently updated as submitted March 1, 2018, reflecting actual data through fiscal 2017 and projected data beginning with fiscal 2018. The three (3) years of operations for the transplant services were projected to be fiscal 2019 through fiscal 2021. Given that at this time fiscal 2021 has come to pass, and it is very likely that the operation if approved, would not begin in earnest before fiscal 2023 or perhaps fiscal 2024, staff is acknowledging that the projections are likely at least four (4) years old, and perhaps five (5). MHCC has notified HSCRC staff that we are not to expect responses to our inquiries previously submitted, and that we are not to expect to receive updated projections. Therefore, we have based our opinion upon what we have reviewed. Accordingly, our opinion does not incorporate any material changes that may have been made to the information previously reviewed. What follows are HSCRC staff responses to the questions raised by MHCC:

 Consistent with the assumptions presented in the CON, all of Maryland's facilities (inclusive of Franklin Square) would continue to achieve kidney transplant volumes more than the minimums required, even after Franklin Square's kidney transplant service matured and volumes grew. The minimum annual case volume for adult kidney transplant programs is thirty (30) cases per year.

After netting out the revenue projected for the kidney transplant services, the projected gross patient service revenues for the entire facility, with inflation, as presented on Table H, appear reasonable through fiscal year 2021 compared to the approved Global Budgeted Revenue (GBR) for Franklin Square. The average annual growth rate projected on such revenue beyond fiscal 2017 is 2.1%, which is reasonable compared to Franklin Square's average annual GBR growth rate of approximately 3.9%.

The average annual operating profit margin for the entire facility, as per the audited financial statements for the five (5) years ended fiscal 2019 (pre-COVID), was 4.0%. The average annual operating profit margin for the entire facility with inflation as presented on Table H for the three (3) years ending fiscal 2021 is projected to be 2.1%. If the three (3) years ending fiscal 2021 were presented without the profits assumed on the kidney transplant services, such average

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operating margin would measure approximately 2.2%. Holding all else equal, this would imply a conservative projection of operating expenses and resulting margins, save for any impact of the current COVID pandemic.

Based upon staff's review of the information presented and subject to any material changes to that information, which may have been brought to light, the HSCRC believes that the kidney transplant services project appears to be financially feasible. However, staff has not received a response to the questions that were forwarded to MHCC, nor has the staff been afforded an opportunity to discuss how Franklin Square calculated the projected revenue assumed in Table H and the additional revenue assumed in Table K. While staff realizes that Franklin Square would receive some increase to its GBR revenue if the program is approved, staff is not certain whether the revenue assumed in the projections is reasonable.

Further, staff understands that the primary resource challenge and limiting factor of any organ transplant program, is not so much in the number of organs to be used, but rather in the number of organs to be supplied. Effective March 15, 2021, the allocation of available kidneys follows a new national policy model, whereby a donated kidney is first made available to compatible candidates within a 250 nautical mile radius around the donor hospital. This policy is significantly different from the former allocation policy, which was based upon donation service areas, in which the Living Legacy Foundation (LLF) and the Washington Regional Transplant Community (WRTC) operated as Organ Procurement Organizations, with WRTC serving the DC metro area, and LLF serving the balance of Maryland, including the Baltimore metro area. The statistical volume projections and the financial projections have not been amended since first submitted in March 2018, and therefore do not account for the effects, if any, of the new allocation policy. Staff is not currently able to judge the potentially material impact of this organ allocation change; however, such uncertainty does put into question the ongoing viability of the proposed program.

2) Generally, the organ acquisition and direct transplant costs should be relatively uniform across the hospitals. If all the programs are operating with approximately the same number of physicians, cost of supplies, length of stay, and other direct costs, etc., then the main difference would be overhead cost, indirect cost, and capital costs at Franklin Square versus JHH or UMMC. The indirect costs will be lower at a community hospital when compared to an Academic Medical Center.

In general, Academic Medical Centers have higher overhead and indirect costs than community hospitals. They are included in a separate peer group to help account for these differences. Holding all else equal, the overhead, indirect, and capital costs at Franklin Square will be less than that of JHH and UMMC, and likely result in a lower overall rate structure that reflects the lower cost of a non-Academic Medical Center. Additionally, Franklin Square is not a relatively inefficient provider as measured in the Inter-hospital Cost Comparison (ICC) compared to other community hospitals. Again, if the direct costs are comparable, then the overhead and indirect costs would be more in line with a community hospital and most likely result in a lower set of unit rates than at an Academic Medical Center.

3) In general, this proposal to add kidney transplants to Franklin Square, to the extent that volume shifts from Georgetown and pertains to out-of-state residents, aligns with staff's belief that border, or regional/national hospitals have a built-in advantage in our Model in that they can lower their cost per case, while at the same time not negatively affect total cost of care performance. This is because these hospitals can export a service to a non-Maryland resident, thereby spreading fixed costs over more patients, which has no bearing on Maryland resident Total Cost of Care (TCOC.)

In terms of the impact on the Maryland Medicare TCOC model, kidney transplants are currently carved out of the market shift policy. So Franklin Square would only be subject to a market shift adjustment for Maryland residents currently being provided these services at another Maryland hospital if transplants become part of a service line that is assessed in the market shift algorithm. If the charges at Franklin Square are less than at the Academic Medical Centers, as Franklin Square has estimated, then the impact would be positive.

For volumes currently being provided outside of Maryland, there exists a methodology that was previously used for JHH that staff believes could be employed for Franklin Square as well. Staff suggests that Franklin Square may be allowed a charge per case that would consider the full cost of the organ plus a 50% variable cost factor applied to all

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other costs. If this is the final methodology used, then the impact would depend on how much the patient is currently being charged at Georgetown compared to the new GBR allowed revenue for Franklin Square.

