



Government of the District of Columbia
Department of Health



Center for Policy, Planning and Evaluation

State Health Planning and
Development Agency
March 30, 2017

Kimberly Russo
Chief Executive Officer
District Hospital Partners, L.P.
George Washington University Hospital
900 23rd Street NW
Washington, DC 20037



**Re: Modification of the Certificate of Need for the Establishment of Kidney and
Pancreas Transplant Services - Certificate of Need Registration No. 12-2-8**

Dear Ms. Russo:

The D.C. State Health Planning and Development Agency (SHPDA) has issued a modified Certificate of Need (CON) as referenced above. A statement of findings is enclosed.

Please note that any person may request reconsideration of the review decision within 30 days of this decision. The SHPDA may grant a reconsideration request upon demonstration of "good cause", as defined in D.C. Official Code § 44-412 (b) and Certificate of Need Regulations, 22 DCMR Section 4312.

Thank you very much for your cooperation during the review period. If you have questions concerning this matter, please do not hesitate to contact me.

Sincerely,

Amha W. Selassie
Director

AS:dlm

Enclosures

cc: Sharon Lewis, DHA
Claudia Schlosberg
John Brennan
Guy Collier
Edward Rich, Esq.



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Development Agency**

**DISTRICT OF COLUMBIA
STATE HEALTH PLANNING AND DEVELOPMENT AGENCY
Notice of Official Action
Certificate of Need
Number 12-2-8
(Modification)**

On April 11, 2014, the State Health Planning and Development Agency (SHPDA) as ordered by the District of Columbia Office of Administrative Hearings (OAH) issued a Certificate of Need (CON) to District Hospital Partners (DHP) for the establishment of kidney and pancreas transplant services at George Washington University Hospital (GWUH). On September 15, 2016, the District of Columbia Court of Appeals reversed the order of OAH directing SHPDA to issue DHP a CON. Recognizing that a substantial amount of time has passed since SHPDA issued the CON and with the understanding that DHP is currently operating its transplant services, the Court remanded the matter to SHPDA in order to determine whether to allow the CON to remain in place, to modify or retract the CON that SHPDA issued to DHP.


Accordingly, the SHPDA held a public hearing to receive testimony from all interested/affected parties and received pre and post hearing filings from DHP and MedStar Health, Inc. before making a determination in accordance with the direction of the D.C. Court of Appeals.

Based on its review and assessment of the current circumstances, the SHPDA hereby modifies the current CON issued on April 11, 2014 to DHP for the establishment of kidney and pancreas transplant services as follows:

- A. SHPDA reaffirms the decision authorizing DHP to establish kidney transplant services at George Washington University Hospital; and
- B. SHPDA rescinds the decision authorizing DHP to establish pancreas transplant services at George Washington University Hospital.

Signed this 30th day of March, 2017.

Sincerely,

A handwritten signature in black ink, appearing to read 'Amha W. Selassie', with a stylized flourish at the end.

Amha W. Selassie
Director

AS:dlm



**Government of the District of Columbia
Department of Health**



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Development Agency

**DISTRICT OF COLUMBIA
STATE HEALTH PLANNING AND DEVELOPMENT AGENCY**

**STATEMENT OF FINDINGS AND CONCLUSION
DISTRICT HOSPITAL PARTNERS, L.P.
GEORGE WASHINGTON UNIVERSITY HOSPITAL
CERTIFICATE OF NEED REGISTRATION NO. 12-2-8 (Modification)**

INTRODUCTION

This matter comes back before the District of Columbia State Health Planning and Development Agency (SHPDA) as the result of a remand by the District of Columbia Office of Administrative Hearings (OAH).¹ The remand was ordered by the District of Columbia Court of Appeals,² which determined that the OAH had erred in ordering SHPDA to issue a Certificate of Need (CON) to District Hospital Partners, L.P. (DHP) and ordered OAH to remand the matter to the SHPDA. SHPDA had originally denied DHP's application, filed in 2012, for a CON to establish kidney and pancreas transplant services at George Washington University Hospital (GWUH), determining that DHP had not established a need for the services. OAH had reversed SHPDA's decision and had ordered SHPDA to issue DHP a CON, which SHPDA did on April 11, 2014.

The Court of Appeals did not grant the relief sought by the Appellant, Medstar Health, Inc. (Medstar), which was to revoke the CON. Rather, the Court deferred to SHPDA and ordered that SHPDA determine, "in light of current circumstances"³ whether to allow the CON to remain in place. The Court further clarified its decision as follows:

¹ Remand Order, *District Hospital Partners, LP v. District of Columbia Department of Health State Health Planning and Development Agency*, No. 2013-DOH-00014 (Oct. 27, 2016).

² *Medstar Health, Inc. v. District of Columbia Department of Health State Health Planning and Development Agency et al*; No. 14-AA-328 (D.C. Sept. 15, 2016).

³ *Medstar Health, Inc.*; No. 14-AA-328 at 4.

Ordinarily, if an agency fails to employ the proper standard of review, as OAH did in this case, we remand to the agency to conduct its review anew under the correct standard. But recognizing that a substantial amount of time has passed since SHPDA, at the direction of OAH, issued the certificate of need, and with the understanding that DHP is currently operating its transplant facility, we remand to OAH with instructions to remand this matter to SHPDA to determine whether to modify or retract the certificate of need that it issued to DHP.⁴

Therefore, consistent with the decision of the Court of Appeals, and at its direction, SHPDA is required to determine whether to uphold its previous decision, modify the CON or allow the CON to remain in place “in light of current circumstances,” recognizing “that a substantial time has passed” since the CON was issued, and “with the understanding that DHP is currently operating the transplant facility.”⁵

OVERVIEW

On May 31, 2013, SHPDA denied the certificate of need application of DHP for the establishment of a kidney and pancreas transplant services at GWUH.^{6 7} On August 8, 2013, DHP filed a Notice of Appeal with the OAH appealing the denial of the application. On January 27, 2014, the OAH reversed SHPDA’s decision and ordered SHPDA to issue a CON to DHP to establish the proposed services. After the CON was issued, MedStar filed a petition with the D.C. Court of Appeals challenging OAH’s decision to approve the CON. On September 15, 2016, the Court of Appeals reversed OAH’s decision and remanded the matter to SHPDA so that it may determine, in light of current

⁴ *Id.* at 33-34.

⁵ *Medstar Health, Inc.*; No. 14-AA-328 at 3-4.

⁶ District of Columbia State Health Planning and Development Agency Certificate of Need Review Findings in the Matter of: District Hospital Partners, L.P., George Washington University Hospital Certificate of Need Registration No. 12-2-8, May 31, 2013.

⁷ DHP and GWUH will be used interchangeably in this document to refer to the hospital.

circumstances, whether it should adhere to its prior denial by revoking the CON, modify the CON or allow the CON to remain in place. The Court also concluded “that OAH is not empowered to do what it did in this case, i.e. conduct an evidentiary do-over and effectively assume *de novo* decision-making authority over the issuance of certificates of need.”⁸

After the matter was remanded, on February 6, 2017, the SHPDA held a public hearing to receive testimony from all interested/affected parties before making a determination on “whether to modify or retract the certificate of need that it issued to DHP.” At the public hearing, DHP and MedStar were given a period of up to one hour each in which to make their presentations. Members of the public, whether scheduled or unscheduled, were also given the opportunity to provide testimony.

PRESENTATION BY DHP

Kidney Transplant Services

In written submissions before and after the public hearing, DHP argued that “SHPDA should affirm GWUH’s validly issued CON, in light of the clear demonstration of public need for this critical service over the thirty-two months since its issuance.” GWUH also stated that it welcomes the opportunity for SHPDA to review the transplant program “[b]ecause SHPDA is assessing existing transplant services... rather than the establishment of a ‘new institutional health service’.” GWUH further argues that rescinding the CON “would result in significant turmoil among George Washington Transplant Institute (GWTI’s) transplant patients and candidates, negatively impacting the availability of needed services for the District’s sickest and most vulnerable patients.” It further states that patients “would be left with a single provider of adult, non-military services at MedStar.”

GWUH states that the Hospital as of December 8, 2016 has performed 82 kidney transplants and had 126 patients on its transplant waiting list. Of the 82 transplants, 31

⁸ *Medstar Health, Inc.*; No. 14-AA-328 at 3-4.

were performed in 2015 and 51 in 2016. The transplants included 20 living donor kidney donations. According to GWUH, all transplant patients have survived the procedure and only one patient has experienced graft loss (transplant failure). GWUH further states that the Hospital "has performed numerous high risk transplants that other hospitals frequently decline to perform due to the complexity of the procedure." Additionally, GWUH maintains that of the 82 transplant recipients, more than half, 45 patients, faced high transplant risks because they had HIV or Hepatitis C, or their blood types were incompatible with their donors. It is also reported that GWUH has implemented a paired exchange program under which recipients and living donors who are not compatible can enter into an exchange with other incompatible pairs. Through this arrangement, the program completed a three-way paired exchange in 2015 and two-way paired exchange in 2016.

DHP states that it works closely with the Minority Organ and Tissue Transplant Education Program (MOTTEP), an organization that aims to increase the number of organ donors and improve awareness of the causes and behaviors that lead to the need for transplants in the first place. GWUH maintains that it has conducted 120 outreach events in the D.C. Metro area. The services were provided at health fairs, festivals, churches, grocery stores, work places and senior centers, and GWUH estimates that it has reached 150,000 individuals since 2015.

GWUH states that District residents have been positively impacted by the increased access to transplant opportunities. Out of the 82 transplants performed at GWUH in 2015 and 2016, 36 recipients were District residents.

Pancreas Transplant Services

GWUH states that it has not started providing pancreas transplant services. While the kidney transplant program has received approval from the United Network for Organ Sharing (UNOS) in June 2015 and from the Centers for Medicare and Medicaid (CMS) in January 2016, GWUH has not received approvals for the pancreas transplant

program from either UNOS or CMS. GWUH stated that it could not apply for the pancreas program until it hired additional physicians. It also stated that it has hired physicians and will submit applications for approval.

Impact on the Medstar Kidney Transplant Program

GWUH maintains that while MedStar has consistently argued that the addition of a new program in the District would negatively impact kidney transplant services at MedStar, the transplant volumes at MedStar Georgetown University Hospital have increased since GWUH began its kidney transplant program. GWUH states that its entrance into the market appears to have triggered an increase in MedStar's kidney transplant patients. According to GWUH, during the two years GWUH's program has been operational, the number of transplants at MedStar has grown from 163 transplants in 2013 and 150 transplants in 2014 to 201 transplants in 2015 and a projected 206 transplants in 2016. GWUH goes on to say that, given the volume of transplants at MedStar in the five years prior to the establishment of services at GWUH, it is unlikely that the transplants performed at GWUH would have been done at MedStar. GWUH states that if all the "transplants had been performed at MedStar, this would have reflected a 150% increase in transplant volumes between 2014 and 2016 at MedStar Georgetown University Hospital." GWUH also states that in response to the introduction of the program at GWUH, MedStar appears to have increased marketing of its transplant program. "This *beneficial* competition and ongoing outreach by both hospitals", GWUH maintains, "will lead to continued increases in transplants" at both facilities and enhance the accessibility and quality of services available to residents.

PRESENTATION BY MEDSTAR

MedStar maintains that "The Court of Appeals agreed with the SHPDA that the CON should never have been issued because the SHPDA's decision of May 31, 2013 denying the CON was adequately supported by the evidence in the record before the agency." MedStar states that withdrawing the CON "will also preserve and safeguard

for the future the SHPDA's authority, and dignify its important role in health planning." Failing to affirm the decision to deny the CON "would create a pathway for others to avoid complying with SHPDA's decisions in the future by providing a clear incentive to proceed with the project even where the matter remains subject to appeal." MedStar maintains "that the improperly issued CON be retracted and the GWUH transplant program be closed." MedStar goes on to say that although "the Court of Appeals proposed modification as a potential remedy, it is one that is legally impossible." Retraction, it is stated, is the only proper and legal remedy. According to MedStar, "DHP ought to be instructed to 'start over' in the CON process and to close its service. At this time, the SHPDA should and must honor and adhere to the rule of law by abiding by the Court Order and revoking the Certificate of Need, as invited to by the Court of Appeals. Permitting DHP to benefit from its risky decision to ignore the CON appeals process would reduce the District of Columbia's health planning laws and the SHPDA's authority and integrity to a shambles."

In summary, MedStar states that:

1. There is no public need for the kidney and pancreas transplant services at GWUH and that GWUH has yet to provide a single pancreas transplant;
2. While GWUH has shown acceptable one-year outcomes in a very small number of kidney transplant patients, it is premature to extrapolate these data as a measure of the quality of the program overall;
3. MedStar's transplant staffing and other resources far exceed those at GWUH and could absorb the current kidney transplant volume at GWUH without any additional recruitment of surgeons;
4. MedStar's transplant services are largely accessible, particularly to D.C. residents. The facility performed kidney transplants on 31 D.C. residents in 2015 and 42 residents in 2016;

5. The provision of transplant services to D.C. residents will not be negatively affected by the closure of the transplant program at GWUH. Patients on GWUH's waiting list can be immediately transitioned, without jeopardizing waiting time, to a larger program with proven efficiency in accommodating patients; and
6. GWUH took a business and clinical gamble in prematurely opening a kidney transplant service that may not be sustainable.

MedStar further asserts the following:

- "'Modification' of the improperly issued CON would not give appropriate weight to the SHPDA's original decision;
- The only remaining alternative for SHPDA, and the only properly actionable alternative, both legally and equitably, is for the SHPDA to "retract" the improperly issued CON;
- Following retraction, the SHPDA should order and supervise the closing of the unapproved DHP transplant service, as it is authorized to do;
- Upon closure, DHP remains free to file a new CON application and demonstrate current 'need' for its program; and
- Following the steps of retraction, closure, and re-filing is the only process that will serve the legal requirements and achieve a responsible result in this case."

PUBLIC HEARING

At the February 6, 2017 public hearing that was held to receive testimony from all interested/affected parties before the SHPDA makes a determination on whether to reaffirm, modify or retract the certificate of need, representatives of GWUH and MedStar as well as members of the general public have provided testimony.

GWUH stated that the transplant program has been extraordinarily successful and that the number of transplants has been much greater than expected. GWUH also argued that the program has been not only good for GWUH and the community but also for MedStar. Representatives of GWUH emphasized their community outreach activities, reaching roughly 150,000 people in D.C., particularly in those parts of the city that are most affected by the devastating disease. It was further stated that GWUH has committed significant resources to providing high quality kidney transplant services and a full continuum of kidney disease care. The Transplant Institute has 20 full time staff members and is supported by many divisions in the hospital. Over two-thirds of the patients receiving kidney transplants at GWUH are said to have public rather than private insurance, and that the hospital is a participating provider with all four D.C. Medicaid managed care plans.

The representatives of GWUH pointed out that there are currently two adult kidney transplant programs in the District and that without GWUH's program there would be a monopoly. They argued that the data so far shows that competition has been great for the citizens. GWUH stated that since the prevalence of kidney disease in the District is the highest in the nation, there is a need for a second transplant program to enhance access for the services, particularly by those who reside in the most affected parts of the city. It further stated that 78% of its transplant recipients have been African-American and another 11% other minorities.

The representatives also stated that GWUH has performed transplants on high risk patients and that the outcomes were better than those of Inova, Georgetown, Johns

Hopkins, or University of Maryland hospitals. In other words, while they have transplanted the highest risk patients, they have had better outcomes. The representatives also noted that while GWUH performed 31 transplants the first year and 51 transplants the second year of operation, there was no negative impact on the competition. On the contrary, the number of kidney transplants at MedStar have also increased.

The representatives of GWUH also stated that the hospital is focused on increasing community outreach and engagement of kidney disease, kidney donation, and kidney transplantation. GWUH works with MOTTEP to educate the public about conditions that lead to kidney disease, and in many cases kidney transplantation. They said that since beginning services in 2015, the GWUH transplant program has conducted outreach events in the D.C. metro area, with particular emphasis on Wards 5, 7, and 8.

In addition, many transplant recipients provided testimony at the hearing. They testified that they are satisfied with the services at GWUH, that the facility is accessible, that Dr. Melancon, the transplant surgeon, is very helpful, and that the transplant team is supportive. Many of them stated that they were on the waiting list of MedStar Georgetown University Hospital or Johns Hopkins Hospital but have had little opportunity for interaction with the Hospitals concerning their transplant. They said that GWUH is providing transplants to patients who would not have been eligible in the past. Several patients talked about having difficulty accessing services at MedStar facilities. They said that calls were not returned and questions were not readily answered. It was also stated that MedStar does not accept patients that are covered by all Medicaid managed care organizations in the District. They maintained that the kidney transplant program at GWUH is an asset to the community and that the hospital should be allowed to continue the transplantation services. They emphasized the need for having options and choices for those in need of a lifesaving procedure.

On the other hand, a representative of MedStar said that MedStar is interested in preserving the integrity of the certificate of need process. He said that GWUH "jumped

the gun and moved forward with their project” while the case was pending in court. He then said that if an applicant is allowed to open a facility or service while the case is on appeal, the certificate of need process will become worthless and that anybody could do whatever they want. GWUH made a decision to start the services at its own risk and that the Court of Appeals did not allow them to continue the services. Instead, MedStar maintains, the Court remanded the case to SHPDA to consider current circumstances and to modify or retract the certificate of need. MedStar then argued that the SHPDA does not have the mechanism for modification and that retraction is the only option. MedStar maintains that if GWUH wants to provide the services it should submit a new certificate of need application. GWUH should be treated like any other applicant, and that it should not be treated favorably because it had the temerity to go forward and start providing services.

With regard to quality of care, MedStar said that it has no problems with the quality of services that are provided at GWUH.

MedStar also confirmed that the kidney transplant program at MedStar Washington Hospital Center has been discontinued and that kidney transplants are now performed at MedStar Georgetown University Hospital. It was also stated that transplant evaluations and post-transplant care are provided at MedStar Washington Hospital Center.

SUMMARY

GWUH states that much has changed since SHPDA’s denial of GWUH’s CON application in May of 2013. Although SHPDA denied the application based on its determination of the then-existing circumstances, GWUH maintains that current conditions address the concerns that were raised at the time.

First, GWUH states that changes in the regulations of the Organ Procurement and Transplantation Network (OPTN) have improved the ability of transplantable organs to

be imported from other regions into the District. As a result, GWUH states, the number of transplantable kidneys imported to the region has quadrupled since 2014. It maintains that the fact that GWUH and MedStar have increased kidney transplants should allay the original concerns of SHPDA about the availability of organs.

Second, GWUH argues that, as stated by patients at the public hearing, several patients encountered barriers to receiving services from other transplant providers. On the other hand, since becoming operational, GWUH has been accessible and that over half of GWUH's kidney transplant patients were "high risk", including those with HIV or Hepatitis C.

Third, since GWUH's program became operational, the number of living donor transplants in the District has increased.

Fourth, GWUH has actively worked to promote awareness of the options of living donor transplants in the District.

Fifth, kidney transplants are no longer performed at MedStar Washington Hospital Center, thereby limiting the options for patients.

Sixth, GWUH has exceeded its projected number of kidney transplants. GWUH reports that, it has performed 31 transplants during the first year and 55 transplants during the second year of operation.

Seventh, GWUH is increasing living donor transplant opportunities for African American patients.

Eighth, any disruption of the services would cause mass confusion among District residents and patients, resulting in immediate harm for prospective transplant candidates.

GWUH further maintains that:

- SHPDA clearly has the discretion to affirm and preserve the CON for kidney and pancreas transplant services at GWUH;
- SHPDA can and should review the status of the transplant services at GWUH;
- Increased transplant volumes since 2015 demonstrate that there was an unmet need and support GWUH's transplant program;
- GWUH provides a more accessible option both financially and geographically. GWUH participates with all four District Medicaid managed care plans, while MedStar Georgetown University Hospital does not have a contract with two of those plans;
- GWUH had a beneficial competitive impact and MedStar's overall kidney transplant volume has increased;
- "GWUH fully recognizes that it proceeded with its program at risk" and that its "calculated risk" has led to over 80 kidney transplants; and
- "Shutting down such a successful program would do nothing but harm District residents."

On the other hand, MedStar argues that, for both legal and factual reasons, the CON must be revoked and the services closed. MedStar states that:

- GWUH has failed to demonstrate that it has met a need for kidney transplant services for D.C. residents, providing only about one transplant per month to D.C. residents over two years, and only twenty in the past six months, or less than one a week;

- GWUH has failed to establish a kidney and pancreas transplant service as authorized and that, as a result of this failure alone, the CON should be revoked;
- Given the lack of long-term data regarding GWUH's transplant program, SHPDA can make no findings on the record as to the quality of services provided at GWUH;
- GWUH's kidney transplant program represents an unnecessary duplication of services;
- MedStar's transplant services are largely accessible and that MedStar treats patients from all payor services, including Medicaid;
- The provision of transplant services in the District will not be negatively affected by the closure of the transplant services at GWUH. All patients who received transplants at GWUH could have been accommodated at MedStar; and
- The CON law requires that an applicant demonstrate a "public need" for its proposed services.

SHPDA'S CONCLUSION

After a review of the information, the SHPDA has determined that circumstances have changed since SHPDA, at the direction of OAH, issued the certificate of need for the establishment of kidney and pancreas transplant services.

The first major change is the fact that kidney transplant services at MedStar Washington Hospital Center have been discontinued and that apart from GWUH, there is now only one other non-military adult kidney transplant program in operation in the District.

Second, GWUH has been able to perform over 80 kidney transplants in the last two years, demonstrating a need for the services.

Third, the number of transplants performed at MedStar Georgetown Hospital has not been negatively affected. In fact, the number of transplants performed at Medstar over the last two years has increased and not decreased.

Fourth, a number of transplant patients have expressed strong support for having a choice of more than one hospital when it comes to life-saving transplant services.

Fifth, the number of kidneys available for transplantation in the District has increased in the last couple of years.

On the other hand, while GWUH states that there is a compelling public need for kidney and pancreas transplant services in the District, it has not performed any pancreas transplants. In fact, GWUH has not applied for and received approval from either the United Network for Organ Sharing (UNOS) or by the Centers for Medicare and Medicaid Services (CMS). GWUH has not provided information to show that it has a waiting list for pancreas transplants or that it is ready to offer the services soon. It is also not clear why GWUH has not as yet established the pancreas transplant services. Nor did GWUH provide information on 1) the projected need for pancreas transplants, 2) when it plans to receive UNOS and CMS approval, or 3) when it plans to start the provision of pancreas transplant services. While GWUH states that "Current circumstances demonstrate that GWUH's kidney transplant program should remain open", it did not provide detailed information on pancreas transplants or justification for establishing the services at this time.

DECISION

In accordance with the decision by the Court of Appeals, the SHPDA considered whether to rescind, modify or leave in place the certificate of need that was issued to DHP for the establishment of kidney and pancreas transplant services. In reaching its decision, and consistent with the directive of the Court of Appeals, the SHPDA has taken into account the fact that substantial time has passed and circumstances have

changed since the CON was issued, and that the kidney transplant program has been operational.

Kidney Transplant

Based on the information in the record, the SHPDA has determined that District Hospital Partners/George Washington University Hospital has provided justification for the kidney transplant program. The services will help address the needs of patients who suffer from end stage renal disease. Kidney transplants provide significant life-saving and quality of life benefits and it is important that patients have access to the services. Given the fact that GWUH is the one adult kidney transplant program in the District that has contracts with all D.C. Medicaid Managed Care Organizations, continuation of GWUH's kidney transplant services will allow for greater access by patients. It therefore makes health planning sense to ensure that patients have a choice of access to the lifesaving services. As a result, SHPDA has determined that GWUH continue to provide kidney transplant services for adult patients.

Pancreas Transplant

On the other hand, the SHPDA has determined that DHP has not implemented the pancreas transplant services since the CON was issued and has not demonstrated a need for the program. Therefore, SHPDA has decided to modify the original CON by rescinding the approval for the establishment of pancreas transplant services at GWUH.

3/30/2017
Date


Amha W. Selassie
Director