MedStar Health

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June 1, 2018

Kevin McDonald
Chief, Certificate of Need
4160 Patterson Avenue
Baltimore, Maryland 21215

Re: MedStar Franklin Square Kidney Transplant Service- Matter # 17-03-2405

Mr. McDonald:

Attached please find our response to your letter dated May 3, 2018. Should you have any questions regarding this matter, feel free to contact me at (410) 772-6689.

Sincerely,

Patricia G. Cameron
Director, Regulatory Affairs - Maryland

cc: Paul Parker
Gregory Branch, MD, Health Officer, Baltimore County

PART I – PROJECT IDENTIFICATION AND GENERAL INFORMATION

1. Regarding your response to **Question #3**, the links provided as sources responding to **questions 3(c) and 3(d)** were not specific enough to enable a reviewer to find the data. More exact, extended links should be provided.

MFSMC Response:

The MFSMC response to question 3(c), now with extended links to the sources:

> ***Nationally, there are 141 centers performing liver transplant that are CMS certified and approved by UNOS; only two (2) liver transplant centers nationally do not have a kidney transplant program. These are small liver transplant programs, averaging 23 transplant procedures annually. Since 1988, 8019 combined liver-kidney transplants have been performed nationally.***
>
> *Source* :LIVER PROGRAMS W/O KIDNEY PROGRAMS: https://optn.transplant.hrsa.gov/data/view-data-reports/build-advanced/ Data filtered by: 1.Transplant, Transplant Year = 2018, 2.Organ, 3.Transplant Center
>
> *Source:* SLK VOLUME: https://optn.transplant.hrsa.gov/data/view-data-reports/build-advanced/ Data filtered by: 1. Multiple Organ Transplant, Multiple Organ = Liver-Kidney, 2.Any, 3.Transplant Year

MFSMC's response to questions 3(d), with extended links to the sources:

> ***MGTI outcomes reflect an appropriate degree of aggressiveness and innovation that is rarely seen in programs with an Observed: Expected ratio (O/E) < 1.0. MGTI's additional strengths (and complements to these data) are the points made elsewhere regarding- imports, minority transplants, use of high KDPI organs and KPD. The tables in Figure 2 show the most recently reported comparative outcome data.***
>
> *Sources:* KIDNEY VOLUME (aggregate KIDNEY and Simultaneous Pancreas Kidney (SPK) volume*):*
>
> *https://optn.transplant.hrsa.gov/data/view-data-reports/build-advanced/ Data filtered by 1. Transplant, Organ = Kidney, Year = 2016, 2.Any, 3.Transplant Center. Aggregate with filters by 1. Transplant, Organ = Kidney /Pancreas, Year = 2016, 2.Any, 3.Transplant Center.*

Source: SUPERIOR OUTCOMES: SRTR Program-Specific Reports (PSR) - CITED ON THE TABLES

Source: STATUS 7 PERCENTAGE: UNOS Benchmark report Figure 2. Available privately to centers via secure website (portal.unos.org). DCGU-TX1 Report released April 2017

2. Regarding your response to **Question #5**, please provide details as to what is included in Figure 4 under the $59,189 (67.9%) of cost identified as for "Organ."

MFSMC Response:

This number, $59,189, refers to the estimated average charge associated with the costs for the organ acquisition, provided either through a living donor or from a deceased donor organ through the organ procurement organization (OPO). Associated costs underlying the charge include registration with UNOS, all pre-testing, transplant evaluation, consultants where needed, and HLA laboratory studies.

PART IV – CRITERIA

Charity Care Policy

3. Regarding MFSMC's charity care policy, specifically the section relating to determination of probable eligibility, please provide a copy of the "initial financial assistance application" that must be completed in order to receive the determination.

MFSMC Response:

See Attachment A for the requested financial assistance application.

Quality of Care

4. Staff notes that the review of MFSMC's Quality of Measures on April 3, 2018 indicates that a number of quality of care measure were reported as "Below Average." Please provide details on how the applicant is correcting or will correct the following quality measures:[1]

Results of Care	Rating	Risk-Adjusted Rates
How often did nurses always communicate well with patients?	Below Average	74%
How often did doctors always communicate well with patients?	Below Average	76%
How often did staff always explain about medicines before giving them to patients?	Below Average	58%
Were patients always given information about what to do during their recovery at home?	Below Average	86%
How well do patients understand their care when they leave the hospital?	Below Average	41%
How often were the patients' rooms and bathrooms always kept clean?	Below Average	58%
How often did patients always receive help quickly from hospital staff?	Below Average	55%
How often was patients' pain always well-controlled?	Below Average	62%
How often was the area around patients' rooms always kept quiet at night?	Below Average	54%
How do patients rate the hospital overall?	Below Average	63%
How long patients spent in the emergency department before leaving for their hospital room	Below Average	452 minutes
How long patients spent in the emergency department before being sent home	Below Average	291 minutes
How long patients spent in the emergency department before they were seen by a healthcare professional	Below Average	55 minutes

[1] Note: CMS provides an update on these quality measures on a quarterly basis (last update was April 1, 2018), though not all of the measures are updated at the same time. Staff requests that the applicant review the status of its quality of care measures during the course of the project's CON review and provide any updates with the course of correction if the status of these measures should change and receive a rating of "below average."

How long patients who came to the emergency department with broken bones had to wait before receiving pain medication	Below Average	71 minutes
Patients who left the emergency department without being seen	Below Average	4%
How long patients who come to the hospital with chest pain or possible heart attack waited to get a test that detects heart damage after a heart attack	Below Average	12 minutes
Patients who had a low-risk surgery and received a heart-related test, such as an MRI, at least 30 days prior to their surgery though they do not have a heart condition	Below Average	6%

MFSMC Response:

Results of Care	Rating	Risk-Adjusted Rates	Corrective Action
How often did nurses always communicate well with patients?	Below Average	74%	bedside shift report and inviting patient and families to attend daily IMOC (interdisciplinary Model of Care) Rounds
How often did doctors always communicate well with patients?	Below Average	76%	5-minute Physician sit-down at bedside
How often did staff always explain about medicines before giving them to patients?	Below Average	58%	information sheets for nursing with common medication indication information and Pharmacy rounding on select patients
Were patients always given information about what to do during their recovery at home?	Below Average	86%	pilot discharge folder on 1T to address info such as discharge medications, follow-up appointments, etc.
How well do patients understand their care when they leave the hospital?	Below Average	41%	pilot discharge folder on 1T to address info such as discharge medications, follow-up appointments, etc.
How often were the patients' rooms and bathrooms always kept clean?	Below Average	58%	EVS leaving high-touch area cards in patient rooms of the areas that have been cleaned, such as the bathroom and bedside table, with a contact number if additional housekeeping was needed
How often did patients always	Below	55%	a "No pass zone" to respond to call bells

receive help quickly from hospital staff?	Average		in a more timely manner and purposeful hourly rounding to proactively address patient needs
How often was patients' pain always well-controlled?	Below Average	62%	Dimension discontinued in Jan 2018, focus on new Communication about Pain questions
Results of Care	**Rating**	**Risk-Adjusted Rates**	**Corrective Action**
How often was patients' pain always well-controlled?	Below Average	62%	Dimension discontinued in Jan 2018, focus on new Communication about Pain questions
How often was the area around patients' rooms always kept quiet at night?	Below Average	54%	using white noise machines on specific units at night to promote sleep and silence ambient noise on the unit
How do patients rate the hospital overall?	Below Average	63%	Key drivers are Communication with Doctors and Communication with Nurses, continue to monitor efforts being made to improve those dimension scores. Efforts are focused on daily meetings with patient, physician and nurse (and family member if desired) to discuss daily treatment plans, etc.
How long patients spent in the emergency department before leaving for their hospital room	Below Average	452 minutes	full-capacity protocol in place when criteria met and patients meeting criteria are transferred to the floors in a hallway location to begin their inpatient care
How long patients spent in the emergency department before being sent home	Below Average	291 minutes	FastER which focuses on evaluating patients in FlexCare locations or transferring appropriate post-MSE patients to appropriate care setting
How long patients spent in the emergency department before they were seen by a healthcare professional	Below Average	55 minutes	FastER which focuses on evaluating patients in FlexCare locations or transferring appropriate post-MSE patients to appropriate care setting
How long patients who came to the emergency department with broken bones had to wait before receiving pain medication	Below Average	71 minutes	FastER which focuses on evaluating patients in FlexCare locations
Patients who left the emergency department without being seen	Below Average	4%	Evaluating reasons why patients leave the ED and when during their ED visit they leave (pre-triage, between triage and evaluation, post-eval pre-treatment etc.). Focus is on shorter wait-times to treatment and patient triage at time of check in.

How long patients who come to the hospital with chest pain or possible heart attack waited to get a test that detects heart damage after a heart attack	Below Average	12 minutes	FastER which focuses on evaluating patients in FlexCare locations with the intention of reserving the main ER for more acute patients with lower ESI scores
Results of Care	**Rating**	**Risk-Adjusted Rates**	**Corrective Action**
Patients who had a low-risk surgery and received a heart-related test, such as an MRI, at least 30 days prior to their surgery though they do not have a heart condition	Below Average	6%	Cardiac CT angiography service for patients presenting to the ED with chest pain. This exam can rule out coronary artery stenosis as cause of chest pain much faster than traditional stress testing. 3 hours vs. 8 – 12 hours

Project Review Standards – State Health Plan

Need and Access

5. Regarding your response to **Question #14**, please elaborate on your statement that "certain regulatory issues and leadership changes" impacted kidney transplant volumes (24% decline) between CY 15 and CY 16.

MFSMC Response:

During CY15 and CY16 the University of Maryland was reviewed by the Organ Procurement and Transplant Network's (OPTN's) Membership and Professional Standards Committee (MPSC) for not meeting expected outcomes thresholds for patient and graft survival. Both published and experiential data have demonstrated that while programs are currently under MPSC review with continued Root Cause Analysis (RCA) expected for previous and ongoing graft losses, or patient deaths, many programs become more risk averse and adopt more conservative acceptance patterns in listing candidates for transplantation, i.e. recipient screening, as well as in their acceptance of donor organs that may not be "perfect". The University of Maryland continues to have less than expected reported outcomes per the SRTR website.[2]

Johns Hopkins Hospital (JHH) underwent significant leadership changes during this same time period, with the director of its Transplant Institute leaving the institution to become the director of the program at New York University. With his departure several other senior individuals exited the program as well. With these key departures and lack of leadership, this program became more risk averse as well, particularly in the context of a past Systems Improvement Agreement (SIA) imposed on the JHH liver program by

[2] See: https://www.srtr.org/document/pdf?fileName=\012018_release\pdfPSR\MDUMTX1KI201711PNEW.pdf); MDUM Program Specific Report Released January 2018. Graft survival: Table C6, p25. Patient survival: Table C12, p43

CMS (see Attachment B) related to patient and graft losses above what had been expected.

Cost Effectiveness

6. Regarding your response to **Question #25**, please provide evidence that supports your statement that "MedStar Health maintains the 11th largest organ transplant program in the nation." Using this same scale, where would Johns Hopkins Hospital's and UMMS' kidney transplant programs rank in this narrative?

MFSMC Response:

Table 1. U.S. Transplant Center Rankings, by Volume

US Transplant Center Rankings by Volume		2016
Rank	Center	Abdominal Organs
0	All Centers	28,856
1	FLJM-TX1 Jackson Memorial Hospital	536
2	CAUC-TX1 UCLA Medical Center	527
3	WIUW-TX1 Univ of Wisconsin Hosp and Clinics	527
4	CASF-TX1 Univ of CA San Francisco Med Ctr	520
5	AZMC-TX1 Mayo Clinic Hospital	477
6	GAEM-TX1 Emory University Hospital	444
7	INIM-TX1 Indiana University Health	442
8	TXHS-TX1 Methodist Specialty & Transplant Hosp	440
9	MDUM-TX1 Univ of Maryland Med System	407
10	CASM-TX1 UC Davis Medical Center	403
11	DCGU-TX1 Georgetown Univ Med Ctr	398
12	NYMS-TX1 Mount Sinai Med Center	373
13	LAOF-TX1 Ochsner Foundation Hospital	373
14	ALUA-TX1 Univ of Alabama Hospital	366
15	MNMC-TX1 Rochester Methodist Hosp- Mayo Clinic	359
16	TXMH-TX1 Houston Methodist Hospital	358
17	FLTG-TX1 Tampa General Hospital	355
18	TNVU-TX1 Vanderbilt Univ Med Ctr	353
19	ILNM-TX1 Northwestern Memorial Hospital	347
20	OHCC-TX1 Cleveland Clinic Foundation	342
21	MDJH-TX1 Johns Hopkins Hospital	342

Figure 1 in our CON application for a liver transplant program, shown as Table 1 above, shows the 2016 "Rankings by Volume" for the top 21 transplant centers in the U.S. As shown, on the basis of the total number of transplants performed (all organs), Georgetown/MGTI ranks 11th in the nation, UMMS ranks 9th, and Hopkins ranks 21st.

Table 2. Kidney Transplant Volume by Center, CY 2016

Aggregate Kidney Volume CY 2016

RANK	CENTER	KIDNEY VOLUME
0	All Centers	19858
1	CASM-TX1 UC Davis Medical Center	402
2	TXHS-TX1 Methodist Specialty & Transplant Hosp	367
3	CAUC-TX1 UCLA Medical Center	357
4	WIUW-TX1 Univ of Wisconsin Hosp and Clinics	355
5	CASF-TX1 Univ of CA San Francisco Med Ctr	329
6	FLJM-TX1 Jackson Memorial Hospital	329
7	AZMC-TX1 Mayo Clinic Hospital	327
8	NJSB-TX1 St Barnabas Medical Center	304
9	GAEM-TX1 Emory University Hospital	280
10	FLTG-TX1 Tampa General Hospital	271
11	ILNM-TX1 Northwestern Memorial Hospital	236
12	NYNY-TX1 New York-Presbyterian/Weill Cornell	230
13	CAPM-TX1 California Pacific Med Ctr	227
14	TXMH-TX1 Houston Methodist Hospital	226
15	OHOU-TX1 Ohio State Univ Med Ctr	226
16	DCGU-TX1 Georgetown Univ Med Ctr	226
17	CACS-TX1 Cedars-Sinai Med Center	225
18	MDUM-TX1 Univ of Maryland Med System	223
19	MNUM-TX1 Univ. of Minnesota Medical Center	223
20	MOBH-TX1 Barnes-Jewish Hospital	220
21	INIM-TX1 Indiana University Health	217
22	MNMC-TX1 Rochester Methodist Hosp- Mayo Clinic	216
23	MDJH-TX1 Johns Hopkins Hospital	212
24	NYMS-TX1 Mount Sinai Med Center	212
25	ALUA-TX1 Univ of Alabama Hospital	210

Regarding kidney transplant volume alone , Table 2, "Aggregate Kidney Volume CY 2016" shows that MGTI/Georgetown University Hospital program ranks 16th in the nation, while UMMS' program ranks 18th, and Hopkins ranks 23rd. These kidney rankings changed somewhat in CY 2017, as shown in Table 3, although the relative positional rankings persist. These tables show clearly that Georgetown/MGTI is among the top transplant programs by volume in the entire country. In this high performance by volume context, Georgetown/MGTI also maintains superior patient and graft outcome statistics, as had been shown in the original application and subsequent responses to completeness questions.

Table 3. Transplant Volume by Center, CY 2016

Total Kidney Volume CY 2017

RANK	CENTER	KIDNEY VOLUME
0	All Centers	20,639
1	CAUC-TX1 UCLA Medical Center	366
2	FLJM-TX1 Jackson Memorial Hospital	366
3	CASF-TX1 Univ of CA San Francisco Med Ctr	353
4	NJSB-TX1 St Barnabas Medical Center	340
5	AZMC-TX1 Mayo Clinic Hospital	327
6	WIUW-TX1 Univ of Wisconsin Hosp and Clinics	319
7	TXHS-TX1 Methodist Specialty & Transplant Hosp	289
8	ALUA-TX1 Univ of Alabama Hospital	286
9	CASM-TX1 UC Davis Medical Center	277
10	SCMU-TX1 Medical Univ of SC	276
11	MDUM-TX1 Univ of Maryland Med System	273
12	OHOU-TX1 Ohio State Univ Med Ctr	265
13	MOBH-TX1 Barnes-Jewish Hospital	254
14	GAEM-TX1 Emory University Hospital	250
15	ILNM-TX1 Northwestern Memorial Hospital	248
16	FLTG-TX1 Tampa General Hospital	244
17	TXMH-TX1 Houston Methodist Hospital	243
18	COUC-TX1 University of Colorado Hospital/HSC	238
19	INIM-TX1 Indiana University Health	221
20	DCGU-TX1 Georgetown Univ Med Ctr	218
21	MNUM-TX1 Univ. of Minnesota Medical Center	212
22	CACS-TX1 Cedars-Sinai Med Center	209
23	MNMC-TX1 Rochester Methodist Hosp- Mayo Clinic	204
24	NYMS-TX1 Mount Sinai Med Center	203
25	NYCP-TX1 New York-Presbyterian/Columbia	198
26	PAPT-TX1 Univ of Pittsburgh Med Ctr	198
27	TNVU-TX1 Vanderbilt Univ Med Ctr	198
28	MDJH-TX1 Johns Hopkins Hospital	196
29	CALL-TX1 Loma Linda Univ Med Ctr	195
30	PAUP-TX1 The Hosp of the Univ of PA	195

Impact

7. **Question 27** was: *"Given the applicant's estimate that only a small number of its prospective cases will be drawn from existing providers, please discuss whether the patients projected to be served are patients who are currently leaving the area, patients who are not currently receiving transplants, etc.?"* The response did not provide a clear answer.

MFSMC Response:

In its application, MFSMC represented that there will be a small shift of volume from the LLF OPO's two existing transplant centers to the proposed MFSMC program. MFSMC projects a net shift of 10 cases by FY21 (application, p.60-61). This represents a decline of about 2% in the volume of the current providers. MFSMC considers this a small impact on the existing programs.

The table below summarizes the nature of the patients projected to be served by the proposed MFSMC program. As the table indicates, 24 of MFSMC's projected patients are those not currently receiving transplants, 10 are patients evaluated for transplant through the MFSMC program and transferred to MGTI for transplantation, and 10 are cases that will migrate from the two LLF OPO transplant centers.

Table 4. Projected Kidney Transplant Cases by Patient Origin

New Cases	24
Currently performed at GUH	10
Currently performed in LLF region	10
Currently performed outside either region	0
Total Projected Transplant Volume	44

Health Promotion and Disease Prevention

8. **Question 28** – on the health promotion and disease prevention standard – said: *This standard is about prevention of end stage organ disease and increasing the availability of donor organs. The applicant responded with a discussion of its efforts to educate the public about transplantation as an option. Please describe the applicant's efforts or plans to "actively... engage in health promotion and disease prevention activities aimed at reducing the prevalence of end stage organ disease" and toward "...increasing the availability of donor organs," especially those "...designed to address those at greatest risk for end stage organ failure."* The response did not add much to what was in the initial application. Please provide more **specificity** regarding these prevention and organ donation educational efforts.

MFSMC Response:

MedStar Health's Community Health Needs Assessment targets chronic disease prevention and management as one its priority areas, and therefore all hospitals have specific disease prevention and self management programs. System-wide we offer the Living Well Chronic Disease Self Management Program, which is based on the Stanford University Chronic Disease Self Management Program model. The Living Well Chronic Disease Management Program for chronic disease self management includes components targeting prevention and lifestyle modification. See Attachment C. It is a seven week program, offered in community settings such as churches, libraries and community centers, at no charge. Patients with one or more chronic conditions are identified through the electronic health record, and referred to the program by their physician, or through fliers available in various clinic and community locations. Some hospitals also implement the CDC's National Diabetes Prevention Program, a one year intervention specifically targeting diabetes. This program has around 2,000 enrollees nationally. Another initiative at MedStar is the Diabetes Self Management Education Program that is aimed at managing diabetes effectively, and prevention is part of the program. It is done through individual or group classes at the patients' choice. It's an ongoing program offering a two hour session with a dietician and a nurse, covered by

insurance, including Medicaid, currently with over 3,000 enrolled. In addition, when severe cases are identified, physicians can refer patients to the Diabetes Boot Camp, a 12 week program concerning glucose control. See Attachment D. Diabetes patients may also be referred to Davita's Kidney Smart program to slow the progression of kidney disease. Patients are referred to classes, and Kidney Smart comes to speak to staff members. Lastly, hospitals conduct Speaker Bureaus across the District where physicians go out into the community to provide seminars and education related to diabetes prevention, management and care.

MGTI hosts an annual conference to educate physicians and other professionals. The conference includes information on disease prevention. For example, the 2018 symposium included a tract on liver disease treatment. In addition, through continuing medical education, community-based primary care and specialist physicians receive education to treat and to educate their patients through grand rounds and case conferences. These occur weekly, bi-weekly or monthly, totaling about 200 events per year system wide.

MedStar's in-house continuing education program for all MedStar associates provides on-line education on various topics of chronic disease prevention and management. For example, over 450 nurses at MFSMC enrolled in an online course on how to teach survival skills to diabetic patients, including signs, symptoms, and prevention of hypoglycemia; guidelines for meal planning; and situations when they should contact their physician. Additionally, the MedStar has created MedStar Health InFocus, a patient education website that provides patients with information on managing Type II diabetes, reducing the risk of heart failure, and performing cardiac rehab exercises.

These are a few examples of the numerous activities around the MedStar Health System targeting education, prevention and management of the conditions that can lead to end stage organ failure if not managed effectively.

As described in our application, the ability to increase the availability of donor organs depends on increasing the number of living donors and expanding clinical expertise toward expanding the utilization of the existing organ pool (e.g., desensitizing ABO incompatible patients, judicious matching of imperfect organs to acceptable recipients). Toward these objectives, MGTI works continuously in making connections with the referral, dialysis and patient communities toward supporting patients with advanced kidney disease who may benefit from transplant. MGTI's mission in this regard is to educate patients about the advantages of organ transplantation in terms of avoidance of future complications from the disease processes and improvement in quality of life.

MGTI staff works closely with the National Kidney Foundation (NKF) and other non-profits whose mission is public education in this area NKF in collaborative efforts. For example, Dr. Matthew Cooper, MD; Director, Kidney and Pancreas Transplantation; MedStar Georgetown Transplant Institute received NKF's first Arthur P. Pasquarella Leadership in Action Award in the National Capital Area. As stated by NKF, "This award recognizes the outstanding accomplishments of a National Kidney Foundation volunteer who has demonstrated significant dedication and commitment to the overall mission through fundraising, program development and advocacy." As had been noted previously, Dr. Cooper also chairs a consensus conference aimed at improving organ utilization, with participants from CMS, UNOS, NKF and others

Provided below is a specific list of MGTI's recent outreach and educational activities related to both living donation and health promotion including kidney disease, patient support and kidney transplant, providing an 18 month snapshot of some of these

efforts. Many educational materials, devoted to living donation specifically, are available through seminars, personal education for potential candidates at dialysis centers and physicians' offices, mailings about living donation, television spots and printed materials.

Similar activities will be extended to the MFSMC service area population. All of these items reflect community outreach to the renal community and providers as well as to patients. The Kidney Support Group, which meets regularly, includes an educational component; this forum is open to the community.

Kidney Outreach Activities Jan. 2017- June 2018

January 2017

4 (Wed): Dialysis Patient Transplant Education-FMC Hyattsville, MD
5 (Thr): Dialysis Patient Transplant Education-FMC Hyattsville, MD
9 (Mon): Dialysis Patient Transplant Education-Davita Franconia, VA
10 (Wed): Dialysis Patient Transplant Education- Davita Franconia, VA
12 (Thr): Kidney Transplant Support Group-Washington DC (Open to Community)

February 2017

1 (Wed): Dialysis Patient Transplant Education-Davita Annapolis, MD
2 (Thurs): Dialysis Patient Transplant Education-Davita Annapolis, MD
6 (Mon): Dialysis Patient Transplant Education- Davita 25th Street, Baltimore, MD
9 (Thr): Dialysis Patient Transplant Education-Davita 25th Street, Baltimore MD
9 (Thr): Kidney Transplant Support Group, Washington DC (Open to Community)
15 (Wed): Dialysis Patient Transplant Education-Charing Cross, Baltimore/Catonsville, MD
16 (Thr): Dialysis Patient Transplant Education-Charing Cross, Baltimore/Catonsville, MD
21 (Tues): Dialysis Patient Transplant Education-FMC Annapolis, MD
22 (Wed): Dialysis Patient Transplant Education-FMC Annapolis, MD
27 (Mon): Dialysis Patient Transplant Education-FMC Essex, Balt. MD
28 (Tues): Dialysis Patient Transplant Education-FMC Essex, Balt. MD

March 2017

7 (Tues): Dialysis Patient Transplant Education- Davita White Square-Baltimore, MD

15 (Wed): Dialysis Patient Transplant Education- Davita White Square-Baltimore, MD
17 (Thr): Kidney Transplant Support Group, Washington DC (Open to Community)
27 (Mon): Dialysis Patient Transplant Education-FMC Rosedale, MD
30 (Thr): Dialysis Patient Transplant Education-FMC Rosedale, MD
30 (Thr): Staff Update on Transplant- Davita At Home- Rosedale MD

April 2017

4 (Tues): Dialysis Patient Transplant Education-Davita Arlington, VA
5 (Wed): Dialysis Patient Transplant Education-Davita Arlington, VA
8 (Sat): "Living Donor Workshop"- MGUH, Washington DC
10 (Mon): Dialysis Patient Transplant Education-Catonsville North, Baltimore MD
11 (Tues): Dialysis Patient Transplant Education-Catonsville North, Baltimore MD
13 (Thr): Kidney Transplant Support Group-Washington DC (Open to Community)
18 (Tues): Dialysis Patient Transplant Education-HUH, DC
19 (Wed): Dialysis Patient Transplant Education-HUH, DC
25 (Tues): Dialysis Patient Transplant Education-Kidney Care Laurel, MD
26 (Wed): Dialysis Patient Transplant Education-Kidney Care Laurel, MD

May 2017

5 (Fri): Dialysis Patient Transplant Education-Lexington Park, MD
9 (Tues): Dialysis Patient Transplant Education-FMC White Marsh, Baltimore, MD
10 (Wed): Dialysis Patient Transplant Education-FMC White Marsh, Baltimore, MD
11 (Thr): KidneyTransplant Support Group- Washington DC (Open to Community)
17 (Wed): Dialysis Patient Transplant Education- Davita, Hagerstown MD
22 (Mon): Dialysis Patient Transplant Education-Davita Wheaton, MD
23 (Tues): Dialysis Patient Transplant Education-Davita Wheaton, MD

June 2017

1 (Thr): Community Lecture: "Transplant and LD" - MFSMC, Baltimore, MD
6 (Tues): Dialysis Patient Transplant Education-US Renal Oxon Hill, MD
7 (Wed): Dialysis Patient Transplant Education-US Renal Oxon Hill, MD
8 (Thr): Kidney Transplant Support Group- Washington DC (Open to Community)

July 2017

10 (Mon): Dialysis Patient Transplant Education- FMC Towson, MD
11 (Tues): Dialysis Patient Transplant Education- FMC Towson, MD
13 (Thr): Kidney Transplant Support Group-Washington DC (Open to Community)

16 (Sun): Nat. Assoc. Of Nephrology Technicians- CME Seminar "What to Know About Renal Transplant", MGSH, Baltimore, MD

August 2017

8 (Tuesday): Dialysis Patient Transplant Education-Davita Varnum- Washington DC
9 (Wed): Dialysis Patient Transplant Education—Davita Varnum, Washington DC
10 (Thr): Kidney Transplant Support Group- Washington DC (Open to Community)

September 2017

5 (Tues): Grand Rounds/Academic Conference Internal Medicine/Nephr. MFSMC, Baltimore, MD
10 (Tues): Dialysis Patient Transplant Education-Davita Bel Air, Bel Air, MD
11 (Wed): Dialysis Patient Transplant Education-Davita Bel Air, Bel Air, MD
11 (Wed): "Lunch and Learn about Kidney Transplant"–Transplant Training/Education Dialysis Staff, Bel Air, MD
14 (Thr): Kidney Transplant Support Group- Washington DC (Open to Community)
26 (Tues): Kidney/Pancreas Patient Group Kick-Off- MGUH, Washington DC
27 (Wed): Grand Rounds/Academic Conference- Hospitalists, MGSMC, Baltimore, MD

October 2017

1 (Sat): Health Fair: Capitol Dialysis, Washington D.C
4 (Wed): Dialysis Patient Transplant Education-Davita Greenspring, Baltimore MD
5 (Thr): Dialysis Patient Transplant Education-Davita Greenspring, Baltimore MD
7 (Sat): MGTI Kidney Transplant "Current Issues in Transplant" Seminar /CME-Washington DC
12 (Thr): Kidney Transplant Support Group- Washington DC (Open to Community)
13 (Fri): Nephrology Practice Update on Transplant with 'Maryland Kidney Group' - Baltimore, MD
14 (Sat): NKF Kidney Walk, Washington DC
24 (Tues): Update visits: Davita Alexandria (Virginia); US Renal Arlington; FMC Alexandria;

November 2017

2 (Thr): "Living Donor Workshop"- MGUH, Washington DC
9 (Thr): KidneyTransplant Support Group-Washington DC (Open to Community)

14 (Tues): Nephrology Practice Visit-Transplant Update - Hecht, Bass, Schwartz, Hila and Mahajan, Rockville
14 (Tues): Rockville Jewish Community Center Community Lecture, "Transplant and Donation" - Rockville, MD
15 (Wed): Dialysis Patient Transplant Education-American Renal, Ellicott City, MD
16 (Tues): Dialysis Patient Transplant Education-American Renal, Ellicott City, MD
16 (Tues): Baltimore Staff Update Visit: Davita Middleriver, Baltimore

December 2017

6 (Wed): Dialysis Patient Transplant Education-US Renal Ft. Washington, Ft. Washington MD
14 (Thr) Kidney Transplant Support Group-Washington DC (Open to Community)

January 2018

11 (Thr) Kidney Transplant Support Group
18 (Thr) "MGTI Update on Transplant" for Southern MD providers, Oxon Hill MD

February 2018

8 (Thr) Kidney Transplant Support Group- Washington DC (Open to Community)
20 (Tues) Dialysis Patient Transplant Education-Davita Annapolis, Annapolis MD
21 (Wed) Dialysis Patient Transplant Education-Davita Annapolis, Annapolis MD

March 2018

8 (Thr): Kidney Transplant Support Group- Washington DC (Open to Community)
15 (Thr): Community Lecture, "Transplant and Donation" –Annapolis, MD
20 (Tues): Dialysis Patient Transplant Education-Davita Arlington, VA
21 (Wed): Dialysis Patient Transplant Education-Davita Arlington, VA
22 (Thr): Dialysis Patient Transplant Education- US Renal Arlington, VA
23 (Fri): Dialysis Patient Transplant Education-US Renal Arlington, VA
25 (Sun): NKF Patient Education Seminar- Columbia, MD
26 (Mon): Dialysis Patient Transplant Education-Davita Tyson's, VA
27 (Tues): Dialysis Patient Transplant Education-Davita Tyson's VA
28 (Wed): Dialysis Patient Transplant Education- Davita Duke St, Alexandria VA
29 (Thr): Dialysis Patient Transplant Education-Davita Duke St Alexandria VA

April 2018

9 (Mon): Dialysis Patient Transplant Education-US Renal Fairfax, VA
10 (Tues): Dialysis Patient Transplant Education-US Renal Fairfax, VA
12 (Thr): Kidney Transplant Support Group- Washington DC (Open to Community)
16 (Mon): Dialysis Patient Transplant Education- Davita Herndon, VA
17 (Tues): Dialysis Patient Transplant Education-Davita Herndon, VA
25 (Wed): Dialysis Patient Transplant Education- Davita Springfield, VA
26 (Thr): Dialysis Patient Transplant Education-Davita Springfield, VA
30 (Mon): Dialysis Patient Transplant Education-Davita Rivertown, Oxon Hill, MD

May 2018

1 (Tue): Dialysis Patient Transplant Education-Davita Rivertown, Oxon Hill, MD
2 (Wed): Dialysis Patient Transplant Education-Davita Frederick, MD
9 (Wed): Dialysis Patient Transplant Education-Davita Lee St. Washington DC
10 (Thr): Dialysis Patient Transplant Education-Davita Lee St. Washington DC
10 (Thr): Kidney Transplant Support Group-Washington DC (Open to Community)
16 (Wed): Dialysis Patient Transplant Education –Davita Franconia, VA
17 (Thr): "Living Donor Workshop"- Annapolis
17 (Thr): Dialysis Patient Transplant Education-Davita Franconia, VA
19 (Sat): MGTI Transplant Seminar: CME, Bethesda MD
21 (Mon): Dialysis Patient Transplant Education –Davita CDC, Alexandria
22 (Mon): Dialysis Patient Transplant Education-Davita CDC, Alexandria

June 2018 (Scheduled)

2 (Sat): Church Health Expo- First Baptist Church of Glen Arden, Landover MD
5 (Tue): Dialysis Patient Transplant Education- Howard Univ., Washington DC
6 (Wed) Dialysis Patient Transplant Education-Howard Univ., Washington DC
13 (Wed): Dialysis Patient Transplant Education- Davita Glen Burnie, MD
14 (Thr): Dialysis Patient Transplant Education-Davita Glen Burnie, MD
14 (Thr): Kidney Transplant Support Group-Washington DC (Open to Community)
18 (Mon) Dialysis Patient Transplant Education- Davita Howard Co. MD
19 (Tues) Dialysis Patient Transplant Education- Davita Howard Co., MD

NEED

9. Your response to **question 29(b),** which asked for *"...an analysis of need for the project that is population-based, applying utilization rates based on historic trends and expected future changes to those trends,"* provided national statistics on the number of patients on dialysis and the number of transplants. Our question was seeking a translation of these statistics – and/or other relevant incidence rate statistics – to the local population. Please provide utilization rates based on historic trends and expected future changes to those trends that are specific for the service area population indicated in your response to #29(a) of this completeness response, or else explain why this is not possible.

MFSMC Response:

Kidney failure, which requires dialysis intervention to maintain kidney function, is a primary indicator of the need for kidney transplant. Using national rates of dialysis utilization applied to the LLF OPO population, and assuming 100% of dialysis patients could eventually need transplant, MFSMC provides in the table below a historical and projected future volume of kidney transplants needed in this geography.

Table 5. Kidney Transplant Need in the LLF OPO Geography Historical Trends & Projection

	Historic				Forecast	
Metric	**CY2010**	**CY2015**	**CY2016**	**CY2017**	**CY2021**	**CY2025**
Population[1]	3,791,804	3,890,944	3,914,075	3,937,205	4,031,891	4,133,066
Renal Dialysis Use Rate/1000 Pop.[2]	1.458	1.458	1.458	1.458	1.458	1.458
Transplant Need	5,528	5,673	5,707	5,740	5,878	6,026

[1]Source: LLF OPO population (All Maryland excluding Charles, Montgomery and Prince Georges County): 2017 Total Population Projections for Non-Hispanic White, Non-Hispanic Black, Non-Hispanic Other and Hispanic by Age and Gender (August 2017), Prepared by the Maryland Department of Planning, Projections and State Data Center

[2]Source: U.S. Population: https://www.census.gov/quickfacts/fact/table/US/PST045216; National Kidney Dialysis Utilization: https://www.niddk.nih.gov/health-information/health-statistics/kidney-disease.

This level of transplant need far exceeds the number of donor organs available for transplantation in the LLF OPO. This estimate is also in line with national and Maryland data that indicate a large shortfall between the supply of donor organs and the demand

for donor organs. This data was previously referenced by MFSMC in its Figure 11: Organ Supply vs. Demand (National), and Figure 12: Organ Supply vs. Demand (Maryland) in its response to staff's first set of completion questions, p.26-27.

It is this shortfall of donor organs, and MGTI's demonstrated ability to increase the supply of donor organs, that forms the basis of MFSMC's case for its proposed kidney transplant program.

Table 6 below summarizes MGTI's CY2016 success in applying innovations and initiatives that increase the supply of donor kidneys. It also projects the volume, by type of transplant, of the application of these innovations and initiatives at the proposed MFSMC program in CY2021.

Table 6. Kidney Transplants by Type, MGTI Experience and MFSMC Projected

	MGTI Experience[1] (CY2016 – Total n = 205)		Projected MFSMC Impact (CY2021 – Total n =44)	
	Cases	% Total	Cases	% Total
High (>85) KDPI Donors[1]	27	13.2%	5	11.4%
Living Donor	66	32.2%	11	25.0%
Paired-Kidney Exchanges	20	9.8%	3	6.8%
"Routine" HLA matched donor-recipient pairs	92	44.9%	25	56.8%
Total	**205**	**100.0%**	**44**	**100.0%**

[1]Source: Internal data

AVAILABILITY OF MORE COST-EFFECTIVE ALTERNATIVES

10. **Question 32** asked MFSMC to *"articulate very plainly [the project's] goals and objectives."* The response spoke to the reputation of its transplant program at MGTI, abilities to meet needs of a minority population, and the enthusiasm of individual patients and their doctors for establishment of such a program at MFSMC. That is not a" clear articulation of goals and objectives."

MFSMC Response:

Specific goals and objectives related to the proposed combined liver/kidney transplant program are listed below:

- *Provide a combined kidney and liver transplant service, and thereby support those liver transplant patients that will require a simultaneous liver kidney (SLK) transplant, the standard of care for patients with co-existing disease, since ≈15% of individuals with advanced liver disease also develop kidney failure, and outcomes are far better when the transplants are performed simultaneously;*
- *Reduce the cost of transplantation services by developing a high quality transplant program in a community hospital setting;*
- *Increase the availability of organs through the application of advanced surgical techniques, such as split liver transplantation, where one organ is utilized for more than one recipient, paired kidney exchanges, and living donors; encouraging more living donation, judiciously matching "marginal" donors to recipients by their individual characteristics (age, coexisting disease, size etc), and desensitization protocols that permit matching donors and recipients with ostensible ABO incompatibility.*
- *Better serve referring gastroenterologists and internists in the community who have expressed a need for assistance with the long-term management of these complex patients;*
- *Offer the Baltimore community MGTI's deep experience with transplanting complicated patients – with improved clinical outcomes;*

- *Obviate redundancy and duplication through strict utilization management, effective transitions in care, risk and illness stratification and care coordination overall; and*
- *Build on MFSMC's strong teaching mission, its robust digestive disease center and strong relationship with local dialysis centers.*

11. **Question 32** asked MFSMC to *"articulate very plainly [the project's] goals and objectives."* The response spoke to the reputation of its transplant program at MGTI, abilities to meet needs of a minority population, and the enthusiasm of individual patients and their doctors for establishment of such a program at MFSMC. That is not a" clear articulation of goals and objectives."

MFSMC Response:

See response to Question #10.

12. **Question 33** was: "With kidney transplant programs available in DC and Baltimore, please explain the 'clinical and geographic gaps' in terms of community need rather than MedStar system needs, which seems to be the crux of the applicant's response." The response spoke of:

"MGTI's philosophy of care....continuous research of new diagnostic options...specific areas of innovation...novel surgical approaches...judicious consideration of higher risk donors for transplantation...population health management involve[ing] the integration of all facets of an individual's health...[and the need for a] 'home base' for all aspects of individual healthcare [that] provides a number of tangible benefits [such as]...a familiar environment of care; an habitual cadre of providers; available family and other supportive "human" resources and relief from the anxiety of the cost and effort involved in travel superimposed on an already stressful situation."

This information did not directly answer the question posed.

MFSMC Response:

By clinical gaps, MFSMC was referring to the expansion of clinical expertise, including advanced surgical techniques in liver transplantation, targeted toward increasing the supply of donor kidneys and livers in the Baltimore community. Because MGTI is a leader in transplant surgery, performing a higher percentage of cases that increase the utilization of single organs in multiple recipients, applying desensitization techniques that allow matching in ABO incompatible patients, judiciously matching donor and recipient characteristics in order to efficiently transplant the available organs to awaiting candidates, MFSMC described a "clinical gap" in the available options for those awaiting transplantation in the LLF OPO DSA.

By geographic gaps, MFSMC was referring to the distance that Baltimore area residents must travel to access these advanced clinical techniques. Though technically within the 3-hour drive time suggested by the State Health Plan, MedStar Health believes that Baltimore area residents will be advantaged through the presence of a full array of treatment and follow up options closer to home.

13. **Question 34** asked you to *"explain why utilizing the existing programs in Baltimore results in 'critical components in the delivery of high quality care (being) compromised or lost altogether,'"* a statement made on p. 81 when you were addressing the availability of more cost-effective alternatives. The response listed a number of features presented as elements or characteristics of the MGTI program, but again did not directly answer the question posed.

MFSMC Response:

In our response to this question, MedStar Health has sought to highlight the benefits of patients remaining within their own MedStar Health System under the care of our physicians. Advantages include maintaining continuity among providers familiar with all elements of their care and the full array of services within the system of care. Additionally, the benefits of comprehensive, ongoing communication through one Electronic Medical Record (EMR) within the MedStar Health System cannot be understated. The existing integrated health information exchange system[3], established to link distinct local health care systems, is limited in that it only includes certain defined elements and lacks clinical detail, obviating its effectiveness in communicating clinical data essential to the continuity of care for the most complex and severely ill patients. Finally, specific comments from referring providers have noted that the transition in care from existing centers is less than adequate, which can result in patients being returned to their primary provider prematurely without sufficient follow-up from the transplant center. Lack of fully integrated communication is inherently inefficient in terms of redundant testing and lost time, critical components of patient care. These risks are mitigated when the patient remains within the MedStar System.

Notwithstanding the above paragraph, MFSMC wishes to reiterate that although we consider the benefits of patients remaining in the MedStar Health System for transplant surgery to be very significant, this is not the impetus behind its proposed program. As

[3] Chesapeake Regional Information System for our Patients (CRISP), a regional health information exchange serving Maryland and the District of Columbia.

stated elsewhere, the central impetus of the proposed MFSMC program is to increase the supply of available organs for transplantation, thus offering this life-saving surgery to more residents of the LLF OPO. The improvement in patient care that results from receiving all available options in transplant care within one integrated system is a substantial benefit that the proposed program brings Maryland patients.

VIABILITY OF THE PROPOSAL

14. **Question 35 stated**: *"The discussion of volume assumptions states that 'Kidney transplant volumes were estimated based on patients under dialysis treatment in MFSMC immediate vicinity,"* and asked you to *"explain the empirical numerical relationship between patients under dialysis treatment and the number of kidney transplants."* In response MFSMC cited what it characterized as a "standard methodology" attributed to Medicare showing national statistics of patients on dialysis and patients receiving transplants. Please summarize the meaning of those statistics, and explain the conclusions you draw from it concerning local need/demand for kidney transplants.

MFSMC Response:

National data indicates that approximately 4% of renal dialysis patients receive kidney transplants per year. The calculations that MFSMC performed to create volume assumptions for its proposed kidney transplant program are detailed below.

1) MedStar Health provides outpatient dialysis at two of its Baltimore hospitals. These include the DaVita Good Samaritan Dialysis Center on the campus of MedStar Good Samaritan Hospital, and the DaVita Union Memorial Hospital Dialysis Center on the campus of MedStar Union Memorial Hospital. Combined, these programs administer renal dialysis to about 550 patients/year. At the national rate of 4% of dialysis patients receiving kidney transplants/year, MFSMC projects that these programs will produce about 22 transplant cases/year.

2) Double listing of patients: MGTI Transplant candidates will be listed on both the WRTC Waiting List and the LLF Waiting List. MFSMC projects that 5 patients/year from the MGTI program will receive transplants at MFSMC.

3) MFSMC also included referrals from its own nephrology program, associates of Mid-Atlantic Nephrology Associates, Maryland Kidney Group, and Fresenius Kidney Care Porter Dialysis, a large renal dialysis service with seven centers in

eastern Baltimore County. The hospital projected 17 cases from these sources by FY21. This projection was not made using the above-mentioned methodology as patient counts for these non-MedStar entities were not available to MFSMC. The projection was developed through discussions with representatives of these organizations.

IMPACT

15. The response to **question 38**, which requested that you respond to the INSTRUCTIONS under the Impact criterion and "provide a summary description of the impact of the proposed project on costs and charges of the applicant hospital, consistent with the information provided in the application tables package," simply referred staff to the "tables provided as an attachment to this document." Those referenced tables were the standard application tables, and offer no information regarding the impact of the proposed project on costs and charges of the applicant hospital.

MFSMC Response:

For the initial year, MFSMC expects operating revenues of $1.2 million with matching expenses of $2.3 million, resulting in an operating loss of $1.1 million in the first year of operation. The program is expected to be profitable by year three.

TABLES

16. Please explain the nature of the "non-transplant discharges" listed in Table I.

MFSMC Response:

Non-transplant discharges were calculated by assessing preoperative and postoperative admissions related directly to the actual transplant procedures performed at MGUH in 2016. In addition to these admissions, patients with progressive disease, who might not proceed to transplantation but were admitted for medical management and interventional procedural treatments, were incorporated; this latter group was included under the proviso that patients with advanced disease will seek the expertise of a center experienced in advanced disease management and transplantation.

17. Regarding Tables J and K, please provide:

a. The assumptions used to calculate allowance for bad debt, contractual allowance, and charity care;
b. The basis for "Other Expenses" and "Purchased Services."

MFSMC Response:

Allowances for bad debt, contractuals and charity care are based on historical trend data for MFSMC.

Purchased Services are related to payment for organ acquisition services through the OPO as well as additional organ transport services (i.e., jet transport for distantly-located organs) when indicated.

Other Expenses refers to miscellaneous costs incurred for the courier of materials between OPOs, middle-of-the-night transportation (patients who cannot get to the hospital independently), and organ "packaging" for transport. These are costs that are not included routinely in the organ cost for individual patients.

18. Regarding Table L, please clarify the discrepancy between the reduction of 18.5 FTEs at a cost of about $2.2 million in the table with the assumptions in Attachment 11 under Expense Reductions and Saving Initiatives, Item B that the project will result in the reduction of 20 FTEs at a cost of $2 million.

MFSMC Response:

The FTE changes reported in Table L are correct. Attachment 11, item B under '*Expense Reductions and Savings Initiatives*' refers to a separate project, a part of overall FTE savings to MFSMC, but not directly related to the liver or kidney transplantation proposals.

Attachment A

MedStar Health Uniform Financial Assistance Application

Patient Account Number(s):_____

Information About You

Name _____
First Middle Last

Social Security Number ____-____-____ Marital Status: Single Married Separated
US Citizen: Yes No Permanent Resident: Yes No

Home Address _____ Phone _____

_____

_____ _____
City State Zip code Country

Employer Name _____ Phone _____

Work Address _____

_____
City State Zip code

Household members:

Name	Age	Relationship

Have you applied for Medical Assistance Yes No
If yes, what was the date you applied? _____
If yes, what was the determination? _____
Do you receive any type of state or county assistance? Yes No
Advocate that completed or mailed F/A Application:_____ Date:_____

I. Family Income

List the amount of your monthly income from all sources. You may be required to supply proof of income, assets, and expenses. If you have no income, please provide a letter of support from the person providing your housing and meals.

	Monthly Amount
Employment	
Retirement/pension benefits	
Social security benefits	
Public assistance benefits	
Disability benefits	
Unemployment benefits	
Veterans benefits	
Alimony	
Rental property income	
Strike benefits	
Military allotment	
Farm or self employment	
Other income source	
Total	

II. Liquid Assets

	Current Balance
Checking account	
Savings account	
Stocks, bonds, CD, or money market	
Other accounts	
Total	

III. Other Assets

If you own any of the following items, please list the type and approximate value.

Home	Loan Balance _____	Approximate value _____
Automobile	Make __N/A__ Year __N/A__	Approximate value _____N/A_____
Additional vehicle	Make __N/A__ Year _N/A____	Approximate value ____ N/A_____
Additional vehicle	Make __N/A____ Year __N/A__	Approximate value _____N/A_____
Other property		Approximate value _____N/A_____
	Total	_____

IV. Monthly Expenses

	Amount
Rent or Mortgage	____N/A_____
Utilities	____N/A_____
Car payment(s)	____N/A_____
Credit card(s)	____N/A_____
Car insurance	____N/A_____
Health insurance	____N/A_____
Other medical expenses	_____
Other expenses	____N/A_____
Total	_____

Do you have any other unpaid medical bills? Yes No

For what service? _____

If you have arranged a payment plan, what is the monthly payment? _____

If you request that the hospital extend additional financial assistance, the hospital may request additional information in order to make a supplemental determination. By signing this form, you certify that the information provided is true and agree to notify the hospital of any changes to the information provided within ten days of the change.

_____ _____

Applicant signature Date

_____

Relationship to Patient

Attachment B

Published Jan. 3, 2014 at 10:37AM / Updated January 8, 2014 at 05:58AM

Transplant centers pull back to avoid sanctions

PART 2: High-risk patients can put programs in jeopardy

(Dr. Andrew Cameron, pictured far left, the surgical director for Johns Hopkins' liver transplant program, say: "All the programs have done the math and have determined that if your outcomes are trending low into a gray zone, the best way to get out of the gray zone is to go conservative. Whether we want to say that that is an appropriate correction ... or whether we see this as the problem, governmental scrutiny is resulting in fewer transplants and more conservative centers." Submitted photo)

In 2009, Brigitte Sullivan, transplant coordinator at Johns Hopkins Medical Center, knew she had a problem on her hands. Three of the venerable institution's most high-profile transplant programs — kidney, lung and liver — had survival rates that lagged below new benchmarks required by the Medicare program.

Over a two-year period, the liver transplant program, for example, had survival rates of 77 percent to 79 percent, while the Centers for Medicare & Medicaid Services expected them to reach rates of 87 percent to 90 percent.

Three-part Bulletin series.

Part 1: (http://www.bendbulletin.com/health/organtransplants/1389220-151/patients-denied-transplants-as-donor-organs-are-discarded) With the focus on survival rates, patients are being denied transplants.

Part 2: Transplant centers react to tough regulations.

Part 3: (http://www.bendbulletin.com/health/organtransplants/1375026-151/transplantable-organs-go-to-waste) Why viable organs are being thrown out.

"We sort of justified that internally by saying we've got really sick patients here," Sullivan said. "We didn't know how serious CMS would be taking it. We're Hopkins, we're supposed to be doing this. Is CMS really going to shut us down?"

The Hopkins transplant teams would learn that CMS was adopting a much more hardline stance toward transplant programs. Where in the past, transplant centers with serious quality issues were often cited multiple times for poor outcomes and ethical violations, few were ever closed. Prior to 2007, the regulatory oversight of transplant centers was widely seen as having no teeth.

Now, after six years of experience with a new regulatory approach, many centers believe the CMS regulations are too punitive in nature, and that centers striving to expand access to lifesaving transplantation are being caught up in the same net as poor-quality programs.

Regulatory pressure

The new regulations, known as the Medicare Conditions of Participation, or COPs, were finalized in 2005 after a series of highly public transplant scandals. Reports of wait-list irregularities, diversions of organs and major medical errors spurred CMS officials to step in and establish regulations for what primarily had been a self-regulated field.

CMS, the largest purchaser of transplants in the world (with the possible exception of China), adopted metrics originally developed by the transplant industry itself. Years earlier, the United Network for Organ Sharing's Organ Procurement and Transplant Network had set up a flagging system to help identify and improve programs with subpar results.

But while that flagging system relied on peer review and public disclosure, the CMS regulations threaten to shut down centers that don't improve.

Centers whose number of patient deaths or organ failures exceed 150 percent of what would be expected for their mix of patients are flagged. Multiple flags within a 2½-year period trigger CMS action.

Centers then have 210 days in which to explain the mitigating factors that led to their low survival rates. If programs can improve by the end of that period, they are allowed to continue operating as usual. In other cases, CMS will acknowledge the mitigating circumstances and grant exceptions.

The centers that can't improve quickly or convince CMS to grant an exception are given three options: shut down voluntarily, shut down involuntarily, or enter into a systems improvement agreement, or SIA. Through August 2012, 127 of the nation's 330 transplant centers were flagged twice and investigated by CMS, including the programs at Hopkins.

Pulling back

The Hopkins surgeons saw themselves as a program of last resort for patients no one else would take, an innovator that would pioneer new strategies and techniques in transplantation.

"In Maryland, we have a high proportion of patients on the waiting list and low proportion of organs that are available," Sullivan said. "So we were also being very aggressive about accepting organs that other transplant centers thought were marginal organs."

Hopkins was able to convince CMS to grant mitigating-factor exceptions in 2009 for its kidney and lung programs but not for liver. Instead, the liver program entered into a systems improvement agreement with CMS, forcing an intense review of policies and procedures.

Immediately, Hopkins cut the number of liver transplants they would do that year from their previous annual average of 50 to only 27. They would no longer transplant patients with acute liver failure, who had a 60 percent chance of surviving for one year, well below the overall survival rate of 86 percent. They declined to transplant patients co-infected with HIV and hepatitis C, and took the sickest liver patients off their transplant list.

They also became more selective in the types of donor organs they would accept, declining organs from donors whose hearts had stopped before the organs were removed or those older than 60.

During Hopkins' probation, 41 out of 43 patients survived liver transplant, a survival rate of 95 percent. Patients stayed an average of three days in the intensive care unit and 17 days in the hospital post-transplant, about half the time of patients in previous years. While Hopkins had achieved one of the highest liver transplant success rates in the country during that time, it was clear they were transplanting much healthier patients. And they were using higher quality organs, cutting their use of suboptimal livers from 35 to 25 percent of transplants.

Patients who no longer met the criteria for transplant were offered a second opinion at another transplant center. Of the 10 patients who were referred elsewhere, only two were successfully transplanted.

"That group that we were considering transplanting ultimately had a 20 percent one-year successful survival," said Dr. Andrew Cameron, surgical director for the liver transplant program. "And in fact, if we had transplanted those patients, we would have been closed down."

Cameron and Sullivan believe the Hopkins program emerged from the experience stronger, although the process took a toll. Competing transplant centers in the area publicized Hopkins' troubles, and the program lost a significant amount of its referral base and private insurance business.

They have since resumed transplanting riskier patients, and were on pace to perform 70 liver transplants in 2013. Sullivan prints out their survival rates monthly, so the surgeons know exactly where the programs stand.

"If we know we're getting close here, we've got to pull back," she said. "We've got to dial back the risk-o-meter."

That means a patient's chance of getting a transplant at Hopkins could depend on the success of the previous transplant cases. If the program has a good run, it can take on a riskier patient. A few bad outcomes and that same patient might not get transplanted.

"Our philosophy before all this happened was we would rather give a patient a 50 percent chance of surviving with a liver transplant versus a 100 percent chance of death," she said. "And after all this was implemented, we say we can't use this liver on someone who only has a 50 percent chance of survival."

Under probation

Although Hopkins was among the first programs to go through the remedial process, studies suggest many centers are resorting to similar risk aversion. In a study published last year, researchers found that kidney transplant centers that had been flagged at least once during the period from January 2007 to July 2009 reduced the volume of transplants significantly, while those centers that weren't flagged continued to grow the number of transplants along their same pre-2007 rates.

"We can't infer a direct cause-and-effect relationship," said Jesse Schold, an epidemiologist with the Cleveland Clinic and lead author of the study. "But there's a lot of anecdotal evidence and a lot of intuition that this is likely to happen, simply because transplant centers have to keep their own survival in the decision-making of their everyday function."

Other studies have shown that centers that were flagged in the first years of the new metrics had ramped up their use of marginal kidneys in the previous years. Such kidneys have a lower overall success rate for transplant, yet still offer patients a significant benefit over staying on dialysis. Once centers were flagged, however, their use of such marginal organs quickly dropped again.

"It's very clear that all the programs have done the math and have determined that if your outcomes are trending low into a gray zone, the best way to get out of the gray zone is to go conservative," Cameron said. "Whether we want to say that that is an appropriate correction on the part of a center that had competency problems or was overly aggressive, or whether we see this as the problem, governmental scrutiny is resulting in fewer transplants and more conservative centers."

In 2011, Hopkins was once again flagged for subpar outcomes, this time in its heart transplant program.

"In an effort to meet the needs of our high-risk, extremely sick population, we were taking hearts that were not pristine," explained Dr. Glenn Whitman, a heart transplant surgeon at Hopkins. "If you wait only for absolutely perfect hearts ... you're not going to have many hearts."

The program tightened its criteria, cutting the distance they were willing to travel for a heart and limiting transplant candidates to those who had no other health problems. Like the other centers, their volumes dropped and their survival rates went up. But Whitman wonders whether the program is playing it too safe.

"I think it's what CMS wants, in a way," Whitman said. "But maybe if you're not having some people die, maybe you're being too risk averse. Maybe we should be taking a few more risks."

CMS officials declined to comment on the record but said the drop in volumes at flagged centers was appropriate. The agency wants to see programs step back, reassess their policies and procedures, before reintroducing risk and increasing volumes again. Some programs, they said, had ramped up volumes or risk prior to 2007, and overstretched their capabilities.

Of the 127 transplant centers flagged by CMS through August, 52 were granted exemptions, and another 24 came into compliance before the 210-day review period expired. Of the remaining, 16 shut down their transplant programs and 35 entered into improvement agreements.

Dr. Peter Stock, a transplant surgeon at the University of California, San Francisco and former chair of the United Network of Organ Sharing kidney transplant committee, agreed that centers have a disincentive to transplant higher risk patients. But he also says that given the limited supply of organs, the system must keep centers accountable.

"When centers are flagged, there's usually a reason for it," he said. "I know we're trying to push the envelope but you've got to push it in a judicious way."

Dr. Alan Langnas, chief of transplant surgery at the University of Nebraska Medical Center and president of the American Society of Transplant Surgeons, said CMS is using a system that was initially designed to improve performance, not be a measure of program quality.

"Unfortunately, the flagging of programs has become more punitive in nature, and I think people have gotten a little gun-shy," he said. "The worst thing that can happen to you is you get flagged."

Burden to patients

Many in the transplant community are concerned that the harsh penalties for falling below the survival benchmark push centers to take drastic steps to avoid getting flagged.

"You don't need to be under threat of getting shut down, because then you have to respond in a much more extreme way, and that extreme way is risk aversion," said Dr. Dorry Segev, a Hopkins kidney transplant surgeon. "And then you're not doing anybody any favors."

And when centers pull back on risk, patients often have a harder time getting a transplant.

Stephanie Rath, 44, was diagnosed with cystic fibrosis when she was 19. Living in the suburbs of Indianapolis, she had always been cared for by doctors at Indiana University Health. In 2010, she turned to IU Health to be evaluated for a lung transplant only to find the transplant center was no longer in her health plan's network.

Unbeknownst to her, IU Health had been flagged by CMS for poor outcomes in May of 2010. Such flags often spur private insurers to pull their patients out of those centers as well.

After a two-year delay while she was treated for rectal cancer, she launched a college tour of sorts, being evaluated at the University of Pittsburgh Medical Center, University of Kentucky Transplant Center, Duke University Medical Center and Indiana University Health, which had since come back into her plan's network. In the end, the latter two centers considered her too high-risk to transplant. She and her husband had to pack up and relocate to Pittsburgh, where she was successfully transplanted last year.

Rath understands that centers have to draw lines in terms of who they can transplant, but expressed concern they might be relying too heavily on statistics and not considering the individual.

"I'm a cystic who's been sick all my life, and worked for 20 plus years to stay healthy and survived a really (poor) lung capacity, survived a cancer, and had multiple surgeries, monthlong hospitalizations in the ICU. I'm the overachiever. I'm the patient you want to have," she said. "I would have been disappointed if somebody didn't give me a chance for as hard as I've worked."

Cystic fibrosis patients often get caught up in predetermined limits as centers try to maximize their survival rates. Dr. Cynthia Gries, Director of Outcomes Research in the Division of Pulmonary, Allergy and Critical Care Medicine at the University of Pittsburgh Medical Center, said many centers will not transplant patients with CF whose body mass index is under 17, yet those patients have an 80 percent one-year survival rate. Although this survival rate is lower than patients with CF and normal BMIs, it is higher than many other patients who are considered for transplant.

"Although statistically sound research is extremely important in the lung transplant field, I think it is important to step back from number crunching and consider whether our allocation decisions make clinical sense as well," she said.

The easy transplants

The need to achieve certain survival rates has also made transplant research difficult. Researchers know their survival rates won't be as high when they first try out new techniques. That learning curve, however, has become a liability under the new regulations.

"Some of the biggest transplant programs in this country that were moving the field forward just stopped doing clinical trials," said Dr. Michael Abecassis, director of the transplant center at Northwestern University in Chicago.

Transplant surgeons have called on CMS to allow for a high-risk carve-out of anywhere from 5 to 20 percent of cases that could be designated as research and not counted in the survival rates. CMS could still measure the quality of transplant programs based on standard cases, but not get in the way of medical progress.

Otherwise, innovative transplant programs like those at Johns Hopkins run into regulatory problems. Hopkins pioneered the use of paired kidney donations, when a living kidney donor is incompatible with the recipient and so exchanges kidneys with another incompatible donor-and-recipient pair. They've also developed techniques for giving people incompatible kidneys and transplanting patients with a high level of antibodies that make finding a suitable kidney much more difficult.

Two years ago, Hopkins surgeons published research in the New England Journal showing that people who undergo desensitization for live donor kidney transplant have twice the survival benefit at eight years than those who wait for a compatible organ from a deceased donor.

"If that were a chemotherapy agent, they would be lining up across the Atlantic," Segev said. "What happened to us performing this service? We almost got shut down by CMS."

It took nine months of often-tense negotiations to convince CMS to exempt those transplant patients from Hopkins' survival rate calculations. CMS officials now point to the Hopkins kidney example as proof of the flexibility in the system.

"We on the ground, having gone through that, consider it a huge side effect," Segev said. "A lot of programs doing incompatible transplants stopped or drastically reduced their incompatible volume because of what was happening."

Dr. Nicole Turgeon, a transplant surgeon at Emory University, found that when programs are flagged, waiting times for patients go up.

Her research suggests that centers seem to be picking and choosing which patients to transplant based on how those patients would affect the centers' expected survival rates. Centers moved faster to transplant candidates with conditions like diabetes, hypertension, peripheral vascular disease or prior transplants, which receive extra points in the formula used to derive each center's expected survival rates. But they were slower in transplanting older and heavier patients for whom they got no risk adjustment.

"I think the COPs have made us look a lot closer at what we're doing, for better or for worse," Turgeon said. "It's allowing us to scrutinize our outcomes and maybe do better for our patients."

It may be that programs were transplanting patients who had too low a chance of survival, putting the patient through a needless procedure and denying better transplant candidates the organ.

"On the other side of the coin, if we are doing fewer transplants or we are increasing patients' waiting times, they could get sicker, they could no longer be transplant candidates, they could die on the waiting list," Turgeon said.

As much as transplant surgeons bemoan the regulatory pressure, they acknowledge that the Medicare regulations have brought much-needed stability to the field. In addition to the survival metrics, the regulations require programs to have multidisciplinary teams in place to maximize patient outcomes. They require centers to engage in systematic quality improvement efforts, and to have the basic infrastructure in place for successful transplants.

"It's supposed to level the playing field in terms of infrastructure and process," said Dr. Janet Tuttle-Newhall, a transplant surgeon at St. Louis University Medical Center. "It's a high-risk endeavor. You can't do it on the cheap."

Newhall experienced the flagging process firsthand when the SLU liver program was cited in 2012. Center officials had already recognized their outcomes had dropped below expected levels and had begun the process of reassessing their program.

Her hospital serves many of the poorer residents of St. Louis. Its patients are predominantly African-American, indigent, uninsured. They often arrive at the hospital in worse shape than their more affluent suburban neighbors, and carry many of the risk factors associated with poorer post-transplant survival.

"We call them the statistical double whammies, because they have such bad outcomes but you get no risk adjustment for not having a family member, or not having a phone, or having your insurance applied for when you get admitted with liver disease," Newhall said. "But if we were to close, these people would not have access to transplants."

They standardized protocols for evaluating transplant candidates and tightened criteria for the types of organs they'd accept. The number of liver transplants at the center dropped, but their survival rates rose to exceed the threshold and the program quickly came back into compliance

Still, Newhall is not convinced higher survival rates are necessarily a sign of improvement. "When I started this in 1996, the one-year survival in liver transplant was 85 percent. (In 2012), it was 92 percent. Why do you think that is?" she asked, before answering her own question.

"We're doing easier patients."

—Reporter: 541-617-7814, mhawryluk@bendbulletin.com

Attachment C

MedStar Health

Helping Patients Live Well with Chronic Disease Self- Management Programs at MedStar Health

Living Well is a seven-week program that can help your patients take charge of their health and their life.

This program is designed for adults living with a chronic condition, such as heart disease, diabetes, cancer, depression, chronic pain, lung disease or any chronic health concern.

The program covers:

- Problem solving
- Managing emotions
- Exercise
- Managing medications
- Cognitive symptom management
- Communication skills
- Goal setting
- Developing patient/physician partnerships
- Advanced directives
- Health eating and much more

Community Health at MedStar Health is providing these workshops at **no cost** to participants. Classes are highly interactive.

The program was developed by Stanford University. It has been tested and evaluated with the following results.

- Showed significant improvements in exercise, cognitive symptom management, communication with physicians
- Spent fewer days in the hospital
- Had fewer outpatient visits and hospitalizations

Referring a Patient is Easy

Simply complete a referral order in MedConnect by clicking on the "Orders" tab and select "Community Health Program Referral." Once the referral is sent, a member from our team will follow up with your patient for program intake and enrollment.

Patients can visit **MedStarHealth.org/LivingWell** for specific dates and locations. Hospital calendars are updated regularly.

For more information about Living Well, contact your local hospital's Community Health department, or email **communityhealth@medstar.net** or call **877-367-5864**.

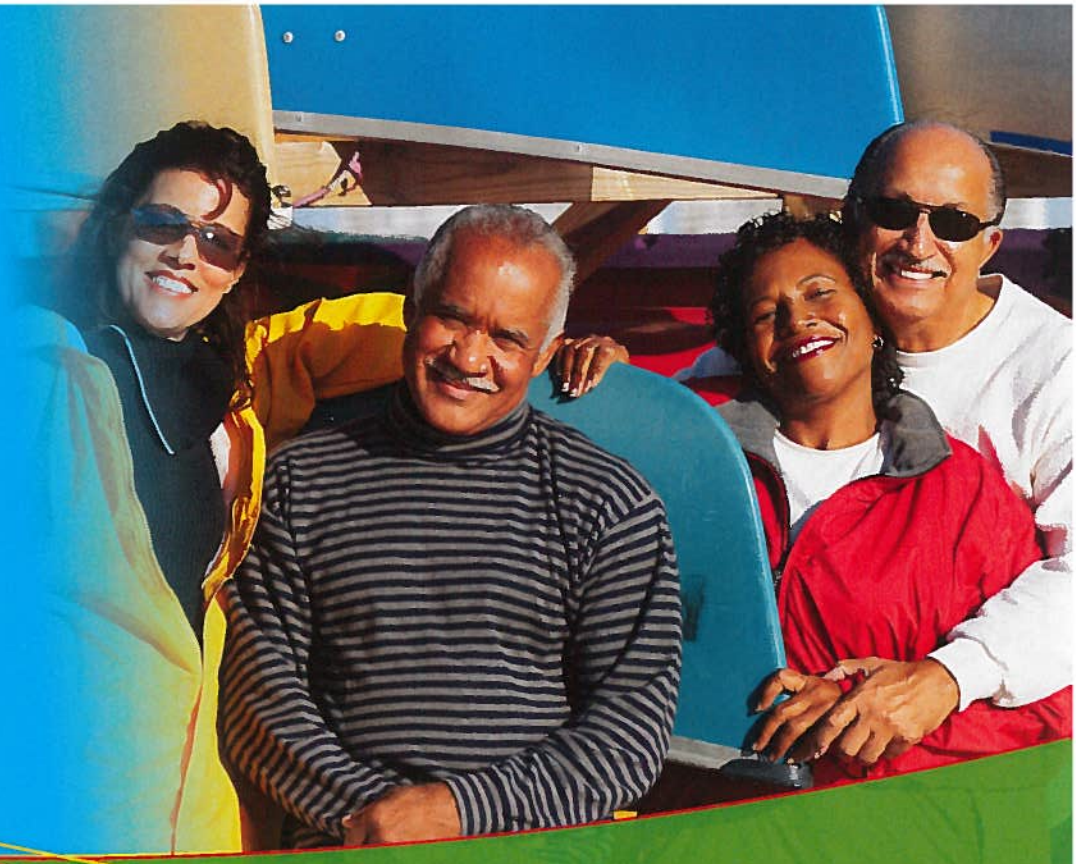
Knowledge and Compassion
Focused on You

17-MSH-1231.052017

Living Well

Take Charge of Your Health.

A FREE Workshop for People Living with a Chronic Disease or Condition



Living Well is a seven-week program that can help you take charge of your health and your life!

- The program is designed for adults living with a chronic condition, such as heart disease, diabetes, cancer, depression, chronic pain, arthritis, lung disease or any chronic health concern.
- Learn how to manage symptoms, organize medications, cope with emotions, eat healthy, manage weight, and communicate with family, friends and healthcare professionals. Receive help problem solving and setting goals to improve the quality of your life.
- Classes are taught by trained leaders.
- Make new friends and have FUN!

Cost: **Free**, includes program materials and convenient parking

Registration required • Class size is limited.

Visit **MedStarHealth.org/LivingWell** for specific dates and locations. Hospital calendars updated regularly. To register or to request additional information call **877-367-5864** or email at **communityhealth@medstar.net**.

Starting spring 2017, the Living Well Program is offered across the health system:

Washington Region:

- MedStar Georgetown University Hospital
- MedStar Montgomery Medical Center
- MedStar Southern Maryland Hospital Center
- MedStar St. Mary's Hospital
- MedStar Washington Hospital Center

Baltimore Region:

- MedStar Franklin Square Medical Center
- MedStar Good Samaritan Hospital
- MedStar Harbor Hospital
- MedStar Union Memorial Hospital

MedStar Health

Knowledge and Compassion
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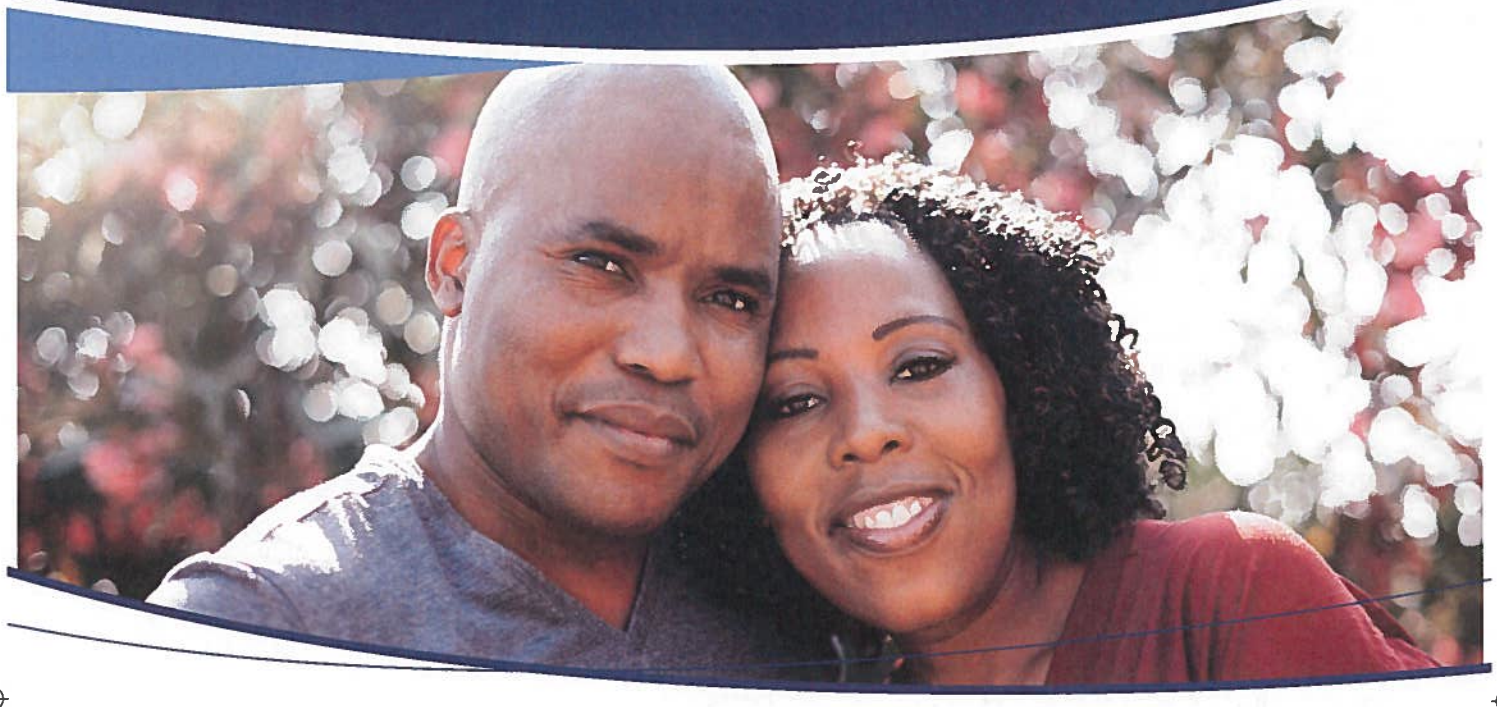
17-MSH-1701.042017

Attachment D

MedStar Diabetes Institute: Helping to Shape the Future of Diabetes Care

The MedStar Diabetes Pathway – "Diabetes Boot Camp"



Your doctor has referred you to the **MedStar Diabetes Boot Camp** to help you better manage your diabetes. As you know, diabetes can be challenging to live with, and most people with diabetes need to get extra support to stay on track. You will work with the MedStar Health Diabetes Team for a total of 12 weeks, to help you determine which lifestyle changes and medications work best for YOU! We will provide you with the support that is needed, to help you meet your goals and feel better. It is important that you understand that this is a "Boot Camp," and that you will be asked to work hard to learn how to live well with diabetes. **You should only "sign up" to do the MedStar Diabetes Boot Camp if you are ready for change!**

What can I expect as a patient in the MedStar Diabetes Boot Camp?

You will meet in-person with the diabetes educator two times during a two week period. You should allow 2 hours for the first visit and 1 hour for the second. These visits will be at a **MedStar Diabetes Center**.

You will then "graduate" to our **Diabetes Virtual Call Center**. A Boot Camp team member will reach out to you one or more times a week during the next 10 weeks, for virtual visits by phone, text or email. We will make changes in your diabetes medications as needed. We will also work with you on lifestyle changes that may help to improve your blood sugar control.

MedStar Diabetes Institute

You will learn how to use a **Telcare Blood Sugar Meter**. Each time you check your blood sugar, the blood sugar test result will be sent over a telephone network to the MedStar Diabetes Pathway Team computer dashboard. This allows us to check every weekday to see how your sugars are doing. If there is a concern such as a high or low blood sugar we will contact you to see what changes may be needed in your medication or lifestyle. **We cannot watch this dashboard 24/7**, *so if at any time you have sugars that you are worried about, you should call your own doctor, your Boot Camp team member or go to the Emergency Room for help.*

You will learn how to make better food choices that are good for your blood sugar control, and overall health.

You will work with our team to find a diabetes medication plan that fits your special needs.

After 12 weeks, you will return to your doctor, who will continue to care for your diabetes.

How do I get started?

Your doctor will contact the Boot Camp diabetes educator to refer you to the program. Please contact the diabetes center at the MedStar Facility of your choice, to schedule your first appointment. We look forward to working with you and doctor in helping you to improve your diabetes control and feel better!

MedStar Franklin Square Hospital
9000 Franklin Square Dr.,
Baltimore, MD 21237
443-534-7484

MedStar Good Samaritan Hospital
Good Health Center
5601 Loch Raven Blvd.,
Baltimore, MD 21225
443-444-4193

MedStar Union Memorial Hospital
Diabetes Center
201 E. University Pkwy. #526,
Baltimore, MD 21218
410-554-4511

MedStar Washington Hospital Center
Diabetes Pathway Center
110 Irving St., NW,
Washington, DC 20010
202-877-2384

MedStar Georgetown University Hospital
4000 Reservoir Rd., NW,
Washington, DC 20007
202-444-5528

MedStar Diabetes Institute

MedStar Diabetes Institute: Helping to Shape the Future of Diabetes Care

The MedStar Diabetes Pathway – "Diabetes Boot Camp"

What is the MedStar "Diabetes Boot Camp"

- An evidence-based, technology-enabled program to support our MMG Providers and their patients with uncontrolled type 2 diabetes (A1C > 9%) in achieving targeted glycemic control and reduction in health resources utilization.
- 12 week intensive program focused on diabetes medications management and diabetes survival skills education.
- Medication initiation and adjustments driven by active monitoring of blood glucose using a cellular enabled blood glucose monitoring system. Visits are initially 1:1 with an Endocrinologist-supervised MedStar Certified Diabetes Educator and then progress to a virtual call center with Nurse Practitioners to facilitate frequent communication with the patient.

Boot Camp Results -The Evidence

- First 98 patients had an absolute A1C reduction of 3.1% (mean A1C 11.4% to 8.3%, $p<.001$)
- Risk for ED visits and hospital admits was reduced by 27% at 30 days, by 65% at 3 months and by 43% at 6 months.
- Patients and Providers expressed satisfaction with the program.

Who is eligible?

- Adults with Type 2 Diabetes and A1C ≥ 9%
- Patient expresses readiness to change and willingness to participate

Who is ineligible?

- Type 1 Diabetics
- Active severe mental illness
- Pregnant patients
- Patients on high dose glucocorticoid therapy
- Patients with severe heart failure or receiving treatment for cancer.
- Patients planning bariatric surgery

MedStar Diabetes Institute

What can I tell my patient to expect?

- The Boot Camp team will reach out to your patient to discuss the program and schedule a first visit.
- There will be two in-person visits with the diabetes educator at a **MedStar Diabetes Pathway Center**.
- The patient then "graduates" to the **MedStar Diabetes Virtual Call Center** and is engaged for 10 more weeks by a Boot Camp NP. Blood glucose values are reviewed near-daily and patients are contacted, at minimum, weekly to discuss blood glucose results and make adjustments to diabetes medications, adherence strategies, and lifestyle changes, until BG targets are reached.
- All patients receive an FDA cleared cellular-enabled blood glucose (BG) monitoring system (Telcare BGM®) that auto- transmits blood glucose values to a provider dashboard. Upon completing Boot Camp, the patient is transitioned back to the referring provider with ongoing diabetes management recommendations.
- For patients who have not reached glycemic goals by 12 weeks, Diabetes Virtual Call Center services may be extended at the referring provider's request.

How do I refer a patient in Cerner?

1. Place an order for ***"MedStar Diabetes Pathway,"*** which will trigger a referral for:
   - Patient enrollment in the 12 week Boot Camp
   - Algorithm-guided diabetes medication management, including prescriptions as needed
   - Diabetes Education and Medical Nutrition Therapy
   - A1C orders
     - -Baseline A1C if last A1C in EMR is dated >1 month prior
     - -12 week A1C at program completion.
2. Flag the MedStar Site Educator
   - MedStar Franklin Square Hospital Center – Kristin Bartel
   - MedStar Good Samaritan Hospital – Kristin Bartel
   - MedStar Georgetown University Hospital – Jennifer Sapolsky
   - MedStar Union Memorial Hospital – Lynne Brecker
   - MedStar Washington Hospital Center – Debra Thayer and Carine Nassar

MedStar Diabetes Institute

Affirmations

Affirmation

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

Anne P. Weiland
Vice President - Surgery, Orthopaedics and
Neurosciences, MedStar Health

June 1, 2018

Affirmation

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

Eric Slechter
Director of Planning
MedStar Franklin Square Medical Center
MedStar Harbor Hospital

6/1/18
(date)

Affirmation

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

30 May 2018

Patricia G. Cameron
Director, Regulatory Affairs - Maryland

(date)