BEFORE THE MARYLAND HEALTH CARE COMMISSION

IN THE MATTER OF THE APPLICATION OF MEDSTAR FRANKLIN SQUARE MEDICAL CENTER FOR A CON TO ESTABLISH A LIVER TRANSPLANT PROGRAM AT FRANKLIN SQUARE CAMPUS IN ROSEDALE	Docket No. 17–03–2406 October 15, 2018

INTERESTED PARTY COMMENTS OF THE JOHNS HOPKINS HOSPITAL IN OPPOSITION TO MEDSTAR FRANKLIN SQUARE MEDICAL CENTER'S APPLICATION FOR A CERTIFICATE OF NEED TO OPEN A THIRD LIVER TRANSPLANT PROGRAM IN THE LIVING LEGACY FOUNDATION DONOR SERVICE AREA

In accordance with COMAR 10.24.01.08F(1)(a)&(b), The Johns Hopkins Hospital requests interested party status in this matter and submits these comments in opposition to the application by MedStar Franklin Square Medical Center and MedStar, Inc. (collectively "MedStar") for a certificate of need to open a new liver transplant program in Baltimore County.[1]

Introduction

The University of Maryland Medical System and The Johns Hopkins Hospital both operate liver transplant programs in the donor service area known as the Living Legacy Foundation ("LLF DSA"). These competitive programs make optimal use of marginal organs and perform a high volume of liver transplants in the LLF DSA. MedStar, which operates the sole liver transplant program in the Washington Regional Transplant Center DSA ("WRTC DSA") at Georgetown University

[1] The Johns Hopkins Hospital incorporates its response to the University of Maryland Medical Center's motion to stay as set forth in its interested party comments at MHCC Docket No. 17-03-2405.

Hospital, has applied to open a third liver transplant program within the LLF DSA at Franklin Square in Rosedale, Maryland.

MedStar bases its application on its claims that it can improve the highly functioning LLF DSA by reducing demand for liver transplants and by increasing the supply of livers. MedStar proposes to reduce demand by better managing liver disease in the region. And it proposes to increase the supply of organs through rare procedures such as split liver transplants and living donor transplants. But MedStar does not require a certificate of need to better manage liver disease; it can do that already. And the extraordinary and complex medical procedures it discusses at length in its application already are being performed in the LLF DSA—indeed, at a greater volume on adult patients than in the WRTC DSA. Furthermore, MedStar's own projections show that its proposal to perform isolated instances of these procedures—several years down the road—will have zero effect on the supply of organs in the LLF DSA.

Even if MedStar were capable of improving functions in the LLF DSA, MedStar has not even tried to a show a need for a third program. COMAR 10.24.15(B)(1) & COMAR 10.24.01.08G(3)(b). Nor has it identified barriers to access or fully analyzed the impact that a third program would have on the existing programs. COMAR 10.24.15(B)(3)(b). Because MedStar has failed to demonstrate the need for a third liver transplant program in the LLF DSA, has not shown the existence of any barriers to access, and has not addressed the impact, COMAR 10.24.15(B)(5)(d) &

10.24.01.08G(3)(f), of a new low-volume liver transplant program, MedStar's application should be denied.

Background

Maryland is split into two DSAs: the WRTC DSA and the LLF DSA. MedStar proposes to open a new liver transplant program in the LLF DSA, which includes all Maryland counties except Prince George's County, Montgomery County, and Charles County. Those three Maryland counties, along with Washington D.C. and 14 counties in northern Virginia, make up the WRTC DSA.

I. The Two Liver Transplant Programs in the LLF DSA.

The LLF DSA contains a population of approximately 3.9 million people. The University of Maryland and Johns Hopkins maintain liver transplant programs in the LLF DSA that in 2016 performed a combined 291 liver transplants. Application 56, 57.[2] MedStar acknowledges that there were stable volume levels of liver transplants in the LLF DSA between 2006 and 2011, followed by a period of "significant growth in the number of adult liver transplants performed by these two centers." Application 58.

Johns Hopkins operates four solid-organ transplant programs: liver, kidney–pancreas, lung, and heart. It has, for many years, performed multi-organ transplantation, including heart–lung, heart–kidney, heart–liver, lung–kidney, kidney–pancreas, and liver–kidney. The simultaneous liver–kidney transplant

[2] "Application" refers to MedStar's August 14, 2017 application, followed by the page number. "CQ.I" refers to MedStar's responses to the Commission's first round of completeness questions and "CQ.II" refers to MedStar's responses to the Commission's second round of completeness questions.

(referred to as an "SLK" transplant) is Johns Hopkins' most common form of multi-organ transplant. The two programs in the LLF DSA perform an average of 24 SLK transplants annually. (MedStar does not disclose Georgetown's annual averages.)

Simultaneous Liver Kidney Volume

CY	2013	2014	2015	2016	2017	Avg
JHH	13	12	15	18	15	**14.6**
UMMS	10	5	10	12	14	**10.2**
LLF TOTAL	23	17	25	30	29	**24.8**

Sources: JHH and UMMS internal data.

In sum, residents of the LLF DSA have access to both liver transplants and SLK transplants at two high volume centers in their DSA, and access those transplants at rates higher than neighboring DSAs and DSAs with comparable population size.

II. The Sole Transplant Program in the WRTC DSA.

The WRTC DSA is larger than the LLF DSA; it covers 5.5 million people, including 2.1 million Maryland residents. But the WRTC DSA is served by only a single liver transplant center, and is the only single-center DSA in the region. MedStar operates that lone transplant program in the WRTC DSA. As MedStar acknowledges, some MedStar patients choose the programs in the LLF DSA over MedStar's program at Georgetown. Application 75.

The single center in the WRTC DSA performs far fewer transplants than the two centers in the LLF DSA. Every year from 2011 through 2017, the centers in the LLF DSA performed more adult liver transplants than the center in the WRTC DSA. In 2015, for instance, the LLF DSA centers performed 241 transplants on adult patients. The lone WRTC DSA center (MedStar's program at Georgetown)

performed only 49. The following table compares the number of transplants performed in the two DSAs serving Maryland between 2012 and 2017.

Adult Liver Transplants						
DSA	**2012**	**2013**	**2014**	**2015**	**2016**	**2017**
LLF	127	169	199	241	291	260
WRTC	98	76	79	49	84	97

Exhibit (Sourcing Document) at 2A

In 2015, only 62 residents of the WRTC DSA were transplanted within the WRTC DSA. This is equal to a rate of 11.4 per million population (PMP). By comparison, 161 residents of the LLF DSA were transplanted within the smaller LLF DSA. This is equal to a rate of 41.3 PMP. (These rates are shown on the table below.)

CY	DSA	JHH	UMMS	G'town	LOCAL Subtotal	Population	Local Rate PMP (Subtotal)
2015	LLF	57	104	-	161	3,900,632	41.28
	WRTC	-	-	62	62	5,464,786	11.35

Exhibit (Sourcing Document) at 5A

In 2015, only 12 of 173 residents of the LLF DSA who received a liver transplant (7%) went outside their DSA of residence to do so. In that same year, 72 of 134 WRTC residents who received a liver transplant (54%) went outside their DSA. This means that more than half of the residents in the WRTC DSA received a liver transplant outside of their DSA. Exhibit (Sourcing Document) at 6A

In short, because there is a lack of competition in the WRTC DSA, residents in the WRTC DSA—not in the LLF DSA—face problems with access.

III. MedStar's Application for a Third Program in the LLF DSA.

MedStar proposes to begin performing liver transplants at Franklin Square in 2019. It also proposes to open a kidney transplant program for which it requires a separate certificate of need. MedStar seeks to perform liver transplants on adult patients only—not pediatric patients. MedStar CQ.I 13. It projects that it will perform ten adult liver transplants in 2019; 14 in 2020; and 30 in 2021. Application 61. While MedStar states that it will avoid "patients deemed at high risk," CQ.I 35—which would include SLK transplant patients—MedStar does not specify whether it will limit transplants at Franklin Square to patients with any particular MELD score. Nor does MedStar explain what factors it considers when reaching a determination that a patient is "high risk." *See* CQ.I 35.

MedStar's application is grounded on improvements that MedStar alleges it can make in the LLF DSA. It contends that it will lower demand for liver transplants and claims it can increase the supply of livers in this region. Application 4, 42. MedStar asserts that it can lower demand by better managing liver disease and increase supply through split liver transplants and the use of living donors. *Id.* MedStar is unable to project the number of livers that it can free up through better disease management, Application 43, and it projects that it will perform no living donor transplants in 2019 or 2020, and just one living donor transplant in 2021, MedStar CQ.I 10. MedStar hasn't performed an adult living donor transplant at Georgetown since 2016, when it performed just two. Exhibit (Sourcing Document) at

7A. Therefore, it is unrealistic to assume living donor transplants will be performed at any time at Franklin Square.

MedStar also argues that it will improve access to liver transplants for certain minority populations in Baltimore City. Application 4-5. In that regard, MedStar claims that its program at Georgetown performs transplants on minority populations (including African-American, Hispanic/Latino, and Asian patients) at rates higher than the two programs in the LLF DSA. Application 13. In particular, MedStar asserts that it has reduced a historic disparity in transplantation rates among African-Americans in the WRTC DSA, and argues that a new center at Franklin Square will reduce what it perceives (incorrectly) to be a similar disparity in the LLF DSA. Application 17.

In the end MedStar rests its application on the potential for improvements rather than existing need. *See* Application 4, 8, 42, 56, 73, 83; CQ.I 2, 20, 46, 47, 50, 60, 69. And when asked by the Commission in the first round of completeness questions to explain why there is a need for its program, it avoided answering the question. CQ.I 36 (failing to respond to the Commission's insistence that MedStar "speak to the inability of existing programs to meet current need"). In its second round of responses to completeness questions, MedStar finally attempted to articulate a need argument, claiming that need can be determined simplistically by applying the national rate of chronic liver disease by the population of the LLF DSA to determine what percentage of that population suffers from liver disease. CQ.II

16. MedStar then assumed (without explanation or support) that 2% of all persons suffering from chronic liver disease require a liver transplant.

Yet need cannot be calculated in this simplified way. Apart from lacking any basis in reality, MedStar's calculations would suggest that no program in the country is meeting existing need for liver transplantation—particularly not Georgetown. As explained further below, MedStar's oversimplified analysis cannot be accepted by the Commission.

Argument

I. MedStar Has Failed to Show a Need in the LLF DSA for a Third Liver Transplant Program.

An applicant for a certificate of need must demonstrate by a preponderance of the evidence that a new organ transplant center is needed. Transplant Chapter 25, COMAR 10.24.15.04B(1).[3] To do so, an applicant must analyze historic utilization rates to show expected future trends. The applicant must also clearly define the population to be served. MedStar barely addresses these requirements, focusing instead on other arguments that could not establish need, even apart from their deficiencies.

MedStar's principal contention is that it can improve overall performance in the LLF DSA. Application 42. It asserts that it can reduce the need for liver transplants in the LLF DSA. First, MedStar makes no attempt to quantify this proposed reduction. And even putting aside the lack of quantification, proposing to reduce a

[3] All citations to the "Transplant Chapter" refer to Chapter 15 of the State Health Plan for Facilities and Services: Specialized Health Care Services—Organ Transplant Services, which is incorporated in the Code of Maryland Regulations. COMAR 10.24.15.00.

need does not demonstrate that the need exists. After all, MedStar is seeking a certificate of *need*—not a certificate of *improvement*. Indeed, MedStar doesn't require a certificate of need to improve its medical management of patients in the LLF DSA who suffer from liver disease. Besides, when coupled with the reality that MedStar's proposals to perform rare liver transplant procedures will have no effect on the supply of organs for adult liver transplants, MedStar's position that it will aim to reduce the need for liver transplants in the LLF DSA is in tension with its stated goal of "increas[ing] the total number of Marylanders who receive liver or kidney transplants." Application 86.

MedStar insists that it can increase the supply of organs in several ways, including by: (a) supporting the Organ Procurement Network in the LLF; (b) making optimal use of marginal organs; (c) performing split liver and domino liver transplants; (d) offering living donor transplantation; and (e) participating in clinical research. Application 44-55. But in making these suggestions, MedStar fails to analyze the level of services already being provided in the LLF DSA by the two high-volume, competitive programs. Its application is devoid of any analysis of the services provided by the two existing programs. It also ignores the fact that the innovative procedures it discusses already are performed in the LLF DSA. As a result, the improvements that MedStar is proposing are illusory.

To the extent that MedStar addresses need at all, it has failed to carry its burden. As further explained below, MedStar has not defined the population it proposes to serve. The rare procedures it discusses largely involve pediatric

patients, which it will not serve at Franklin Square. And it proposes to perform only a single living donor transplant, three years from now.

A. MedStar Never Defines the Population to Be Served.

MedStar proposes to serve patients in "Central Maryland," which it defines as including Prince George's County and Charles County. CQ.I 52. Those two counties are part of the WRTC DSA, however, not the LLF DSA. MedStar projects that it will perform 30 transplants in 2021, 24 of which it refers to as "routine" cases. CQ.II 17. But MedStar never defines a routine case. Nor does it identify the likely source of these 24 "routine" patients (or the other six "non-routine" patients for that matter). MedStar intends to avoid "high risk" transplants—which includes SLK transplants—but doesn't describe what other transplants it considers to be high risk. On this basis alone, MedStar's application should be denied.

B. Split Liver and Domino Liver Transplants Are Rare and Irrelevant.

MedStar perceives a "gap in access" in the LLF DSA for children who are appropriate for split or domino transplant. Application 62. A split liver transplant is a rare procedure that involves splitting a donor liver and transplanting it to two patients instead of one. Application 48. First, the existing programs in the LLF DSA perform split liver transplants.

Second, "In the US, splits are utilized primarily to increase organ availability for children." Perito, Emily *et al.*, "Split liver transplantation and pediatric waitlist mortality in the United States: potential for improvement." The large lobe is transplanted into an adult; the smaller lobe to a child or perhaps a smaller-sized

adult. A domino transplant occurs when a liver is split, with one lobe going to an adult and the other lobe going to a child with a genetic metabolic disease. The liver of the child affected by the genetic metabolic disease can then be transplanted into another child who can make use of that liver. Application 50. Even as it emphasizes its ability to perform split liver and domino transplants, MedStar makes clear that these procedures are irrelevant to its application: it projects that it will perform zero domino liver transplants at Franklin Square. CQ.II 17.

Contradicting itself, MedStar insists that "the split liver technique will make an immediate difference with . . . pediatric patients." Application 49. It further suggests that the domino technique will increase the supply of deceased donor organs in the LLF DSA. Application 50. But again, MedStar does not propose to treat pediatric patients at Franklin Square. And if a smaller lobe is used at another center in outside of the LLF DSA from a split liver transplant or a domino liver transplant, the smaller lobes generated from those techniques would not have any effect on the liver supply in the LLF DSA.

In its responses to the Commission's first set of completeness questions, MedStar explained for the first time that in a split liver operation, the smaller segment can be used in a "small adult." CQ.I 38. MedStar does not explain how often this procedure involves two adults, rather than an adult and a child. Nor does MedStar confirm that it has ever transplanted both halves of a split liver into two adults.

In addition, the medical literature that MedStar cites confirms that split liver transplantation "plays a significant role in maximizing the use of the available

organs and expanding the donor pool particularly for children." Elsabbagh, *et al.*, The impact of intercenter sharing on the outcomes of pediatric split liver transplantation, at 3.5.1. Accordingly, MedStar's own sources indicate that split liver transplants involving two adult recipients make up a fraction of what is, to begin with, an exceedingly rare procedure.

In short, because MedStar is proposing to perform only adult liver transplantation at Franklin Square, its discussions of the rare procedures of split liver transplantation and domino transplantation are irrelevant to its application and should be disregarded by the reviewer. MedStar also ignores the fact that split liver transplants are performed at both existing centers.

C. MedStar Projects A Single Living Donor Transplantation—in 2021.

MedStar further claims that it will increase the supply of livers in the LLF DSA through living donor transplants. It claims to be "at the forefront of living donor transplantation." Application 50. MedStar represents that its program at Georgetown "leads the country . . . in the number of [living donor] pediatric liver transplant procedures performed." Application 51. But again, MedStar concedes that it will *not* perform liver transplants on pediatric patients at Franklin Square. And while it contends that it will "increase the supply of livers for transplantation through offering these living donor options to Baltimore region patients," Application 53, its projections prove otherwise. Indeed, MedStar projects that it will perform only *one* living donor transplant in 2021—three years from now, CQ.II 17.

More importantly, MedStar has not shown a need for living donor transplants in the LLF DSA. MedStar has ignored the fact that both the University of Maryland and Johns Hopkins already perform adult living donor liver transplants. In fact, between 2012 and 2016, the two centers in the LLF DSA performed 74 live donor transplants on adults; Georgetown performed seven during this time frame and zero in 2017. Exhibit (Sourcing Document) at 7A. Adding a single live donor transplant, or worse, shifting one that otherwise would be performed at Johns Hopkins or the University of Maryland—three years from now—will not increase organ supply in the LLF DSA.

D. MedStar Is Wrong That No Program Is "Meeting the Need."

In its first set of completeness questions to MedStar, the Commission pointed out that MedStar's pronouncements that it can improve liver transplant service in the LLF DSA "does not speak to the inability of existing programs to meet current need." CQ.I 36. MedStar responded—not by showing an unmet need in the LLF DSA—but by proclaiming that because of a national shortage of available organs: "No program is 'meeting the need.'" *Id. See also* CQ.I 54.

MedStar's argument proves too much. If the nationwide shortage in available livers were a justification for opening a new center in the LLF DSA, then the well-known national shortage in available organs would be a justification for opening multiple new centers in the LLF DSA, and, for that matter, in every DSA. In effect, the requirement to establish need would be written out of the Transplant Chapter for all organs for which there is a national shortage.

The reality is that the existing programs in the LLF DSA in fact are meeting the need, in contrast to MedStar's program at Georgetown, the sole program in the WRTC DSA. The LLF DSA and the WRTC DSA liver transplant rates for adult, deceased donor, liver-only cases show that the two competitive centers in the LLF DSA are performing at peak efficiency—especially when compared with MedStar's program at Georgetown. When analyzing volume between the two health planning regions (the two DSAs), there is no comparison.

The table below quantifies liver transplant per million adult population per year for patients residing in the LLF DSA that were transplanted at Johns Hopkins, the University of Maryland, and for patients of the WRTC DSA that were transplanted at Georgetown, between 2010 and 2016. It demonstrates how the existing programs already are meeting the need in the LLF DSA.

Adult, Deceased Donor, Liver-Only Cases (Local Access)								
Year	DSA	JHH	UMMS	MGUH	Other Centers	Total	DSA Adult Population	Transplant Rate PMAP
2011	LLF	14	47			61	2,956,132	20.6
2011	WRTC			55		55	3,958,426	13.9
2012	LLF	22	41			63	2,982,818	21.1
2012	WRTC			79		79	4,031,532	19.6
2013	LLF	27	46			73	3,006,283	24.3
2013	WRTC			57		57	4,102,061	13.9
2014	LLF	36	65			101	3,022,937	33.4
2014	WRTC			66		66	4,152,146	15.9
2015	LLF	36	72			108	3,038,536	35.5
2015	WRTC			29		29	4,203,350	6.9
2016	LLF	45	93			138	3,044,923	45.3
2016	WRTC			56		56	4,225,282	13.3

Adult, Deceased Donor, Liver-Only Transplant Rate PMAP						
DSA	2011	2012	2013	2014	2015	2016
LLF	20.6	21.1	24.3	33.4	35.5	45.3
WRTC	13.9	19.6	13.9	15.9	6.9	13.3

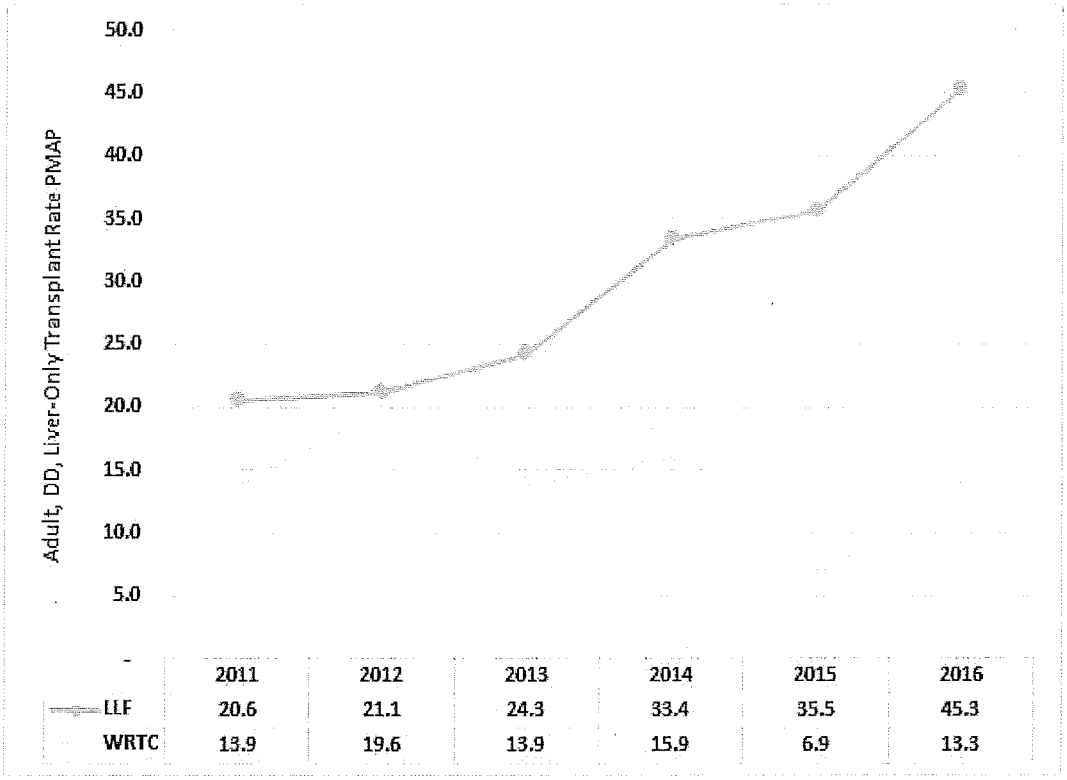


Exhibit (Sourcing Document) at 10A

In its responses to the Commission's second set of completeness questions, MedStar predicts that by 2021, there will be a need for an additional 30 liver transplants in the LLF DSA. CQ.II 16. Even assuming that an additional 30 livers can be procured, there is nothing to suggest that the two existing programs are unable to perform these additional liver transplants.

Table 5: Liver 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
Chronic Liver Disease/1000 Pop.[2]	0.3178	0.3178	0.3178	0.3178	0.3178	0.3178
Transplant Need	1,205	1,237	1,244	1,251	1,281	1,313

[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; Chronic Liver Disease Prevalence: https://www.cdc.gove/nchs/fastats/leading-causes-of-death.htm. For this calculation, MFSMC assumed that 2.0% of chronic liver disease cases require transplant at any time.

Source: MedStar's response CQII 16.

Furthermore, the cornerstone of MedStar's belated need analysis (shown in the table above) is its assumption that 2% of all liver disease necessitates a transplant "at any time." CQ.II 16. MedStar cites no authority for its arbitrary assumption. Not only does MedStar fail to state what the Chronic Liver Disease/1,000 rate is, its supporting hyperlinks are in operative. The Transplant Chapter requires that an applicant establish need based on real world data, specific to the health planning region in which the proposed organ transplant service will be located (LLF DSA)—not unrealistic assumptions using national rates. For that reason, the Commission should reject MedStar's unsupported analysis out of hand.

MedStar's Methodology Applied to the WRTC DSA and USA			
Population	**CY2017**	**CLD Per 1000 & 2% Assumption**	**Liver Transplants "Needed"**
LLF DSA	3,937,205	0.3178	1,251
WRTC DSA	5,559,847	0.3178	1,767
USA	325,139,271	0.3178	103,329

Even if the Commission were to take MedStar's need methodology seriously, it would establish that in 2017, 1,767 liver transplants were needed in the WRTC, compared to the 97 adult liver transplants that were performed. This suggests a gap of 1,670 transplants per year, which would require 16 additional liver transplant programs in the WRTC performing 100 transplants per year. Nationally, the methodology would establish that in 2017, 103,329 liver transplants were needed, compared to the 8,082 that were performed; in a country where only 13,709 people are on the national waiting list. Because MedStar's analysis produces absurd results, it must be rejected.

In sum, MedStar's proposals to offer improvements to the liver transplant services already offered in the LLF DSA do not demonstrate a need for a third program. In any event, the improvements that MedStar claims it can achieve are illusory, while its attempt to show need in its responses to the Commission's second round of completeness questions by assuming unrealistically that 2% of all individuals who suffer from chronic liver disease require a liver transplant is unsupported, unexplained, and fails to show need.

II. MedStar Has Not Identified Barriers to Access.

MedStar concedes that it cannot identify barriers to access in the LLF DSA. Application 63. Still, in keeping with its suggestions about how to improve the LLF DSA, MedStar asserts that a third program in the LLF DSA would allow for "additional access." Application 63. In particular, MedStar states that it can improve access for: (a) MedStar patients in the LLF DSA; (b) patients who require simultaneous liver and kidney transplants; (c) all patients who cannot obtain a transplant because of the national shortage of available organs; and (d) minority populations in Baltimore City. Application 73.

Yet it is not enough for an applicant to suggest ways to improve access. Rather, an applicant must present "evidence to demonstrate that barriers to access exist," and "a credible plan to address those barriers." Transplant Chapter 27, COMAR 10.24.15.04B(3)(b). MedStar fails to deliver either. An analysis of MedStar's four access improvement arguments shows that there are no barriers to address.

A. There is No Travel Barrier for Residents of the LLF DSA.

MedStar contends that a third program in the Baltimore region will improve access for Maryland citizens by providing those citizens with "another program closer to the communities in which they reside." CQ.I 50. But the Franklin Square campus is less than ten miles away from The Johns Hopkins Hospital, which in turn, is less than three miles from the University of Maryland. MedStar asserts that Franklin Square will allow its patients who wish to remain within the MedStar continuum of care to do so. CQ.I 55 & 57. MedStar's continuity of care argument

falls flat, however, because patients are often referred to transplant programs from unaffiliated hospitals without incident. CQ.I 56. MedStar's contention that continuity of care is always desirable or relevant to access would mean that there is a need for every health system to have its own transplant program.

In addition, MedStar reports that Georgetown is performing liver transplants on Baltimore-area patients. CQ.I 49. But MedStar does not quantify those transplants. And MedStar ignores the fact that inter-DSA travel is far greater from the WRTC DSA to the two LLF DSA centers than in the opposite direction. In fact, in 2015 only seven LLF DSA residents traveled to the WRTC DSA center for transplant. Yet 47 WRTC DSA residents traveled to an LLF DSA center for transplant. Exhibit (Sourcing Document) at 6A.

The exodus of WRTC DSA residents to the LLF DSA for liver transplant, and the de minimis number of LLF DSA residents who travel to the WRTC, are inconsistent with MedStar's suggestion that a third center is needed in the LLF DSA to improve access. In addition, the two programs in the LLF DSA perform more transplants per capita than the lone program in the WRTC DSA. And the programs in the LLF DSA perform adult liver transplants on sicker patients (those with higher median MELD scores). As between the LLF DSA and the DSA in which MedStar operates a liver program (the WRTC DSA), the two programs in the LLF DSA are certainly meeting the needs of local residents.

B. There is No Barrier to Access for Multi-Organ Transplant Patients.

MedStar alleges that there is a barrier to access for "candidates requiring multi-organ transplant not available locally." Application 62. But both existing programs in the LLF DSA provide liver–kidney transplants. MedStar eschews any quantitative analysis of these procedures and never addresses how many kidney–liver transplants it will provide at Franklin Square—if any—despite the fact that the combination of these transplants is a purported cornerstone of its dual applications to open liver and kidney transplant programs at Franklin Square. Even more puzzling is that MedStar states that high risk cases will be transferred to Georgetown, but never acknowledges that multi-organ transplants such as a simultaneous liver–kidney transplants are, by any measure, high risk.

C. MedStar Cannot Resolve Any National "Organ Availability" Barrier.

MedStar cites the limited national supply of organs as a barrier. CQ.I 23. MedStar points to Georgetown's supposed track record of optimal organ use to suggest that it can make better use of that limited supply than either Johns Hopkins or the University of Maryland. But in making this claim, MedStar offers no data concerning organ use, either by the centers in the LLF DSA or by Georgetown. And it ignores export data which show that its center in the WRTC DSA, far from making optimal use of the local supply of organs, consistently exports more organs than the LLF DSA centers. Before the regional organ sharing program known as Share 35 was put in place in 2013, 5% of organs were exported from the LLF DSA, while nearly 20% of organs were exported from the WRTC DSA. After

implementation of Share 35, the imbalance worsened: 19% of LLF DSA organs and 39% of WRTC DSA organs were exported in 2014, and in 2015, 20% were exported from the LLF DSA versus 60% exported from the WRTC DSA. Exhibit (Sourcing Document) at 12A.

In addition, from 2014 to 2016, 21 organs were exported from the WRTC DSA and accepted and transplanted at JHH alone. Of these, six were exported as a result of Share 35, and the remaining 15 were exported because they were rejected by Georgetown but accepted by Johns Hopkins. Exhibit (Sourcing Document) at 39A. These data show that, even if the national supply of organs could itself be considered a barrier to access in the LLF DSA, the existing programs in the LLF DSA are doing a better job of making use of that limited supply than MedStar could.

D. There is No Barrier to Access for Minority Patients in the LLF DSA.

MedStar claims that "minorities in Baltimore receive transplants at lower rates than non-minorities." Application 86. MedStar is wrong. As the Commission has recognized, MedStar has failed to analyze rates of service. CQ.I 60. Instead, MedStar points to "minority distributions" in Washington, D.C. and Baltimore City. CQ.I 63. But the LLF DSA and the WRTC DSA consist of far more than those two cities, and the populations of each city is not representative of the larger populations of the LLF DSA and WRTC DSA. The populations of the two DSAs differ by 1.6 million people (3.9 million and 5.5 million respectively).

Center(s)	Liver Recipient Ethnicity	2017 Adult Liver Transplants	2017 Percent of Adult Total	2017 DSA Population	2017 DSA Population Percent of Total	2017 Transplant Rate Per Million DSA Population
MGUH	All Ethnicities	97	100%	5,559,847	100%	**17.45**
	White	60	62%	2,348,818	42%	25.54
	Black	21	22%	1,458,935	26%	14.39
	Hispanic	10	10%	930,477	17%	10.75
	Asian	3	3%	626,213	11%	4.79
	Am. Indian/Alaska Native*	1	1%	195,404	-	-
	Multiracial*	2	2%		-	-
JHH & UMMS	All Ethnicities	260	100%	3,924,235	100%	**66.25**
	White	196	75%	2,445,569	62%	80.14
	Black	52	20%	951,216	24%	54.67
	Hispanic	9	3%	227,092	6%	39.63
	Asian	2	1%	189,640	5%	10.55
	Am. Indian/Alaska Native*	1	0%	110,718	-	-
	Multiracial*	0	0%		-	-

* Population "All Others"

Exhibit (Sourcing Document) at 40A

Minority patients are transplanted at a higher rate in the LLF DSA than the WRTC DSA. The chart above shows the rate of transplant broken down by race and ethnicity. It shows that African-American adult patients are transplanted at a rate of 14.39 PMP in the WRTC DSA and 54.67 PMP in the LLF DSA. This means that—contrary to MedStar's claims—African Americans are transplanted at three times the rate in the LLF DSA as they are in the WRTC DSA. In fact, all the liver recipient ethnicity groups listed experience a higher transplant rate in the LLF DSA than the WRTC DSA.

In sum, MedStar has failed to identify any barrier to access in the LLF DSA.

III. MedStar Fails to Meaningfully Analyze the Impact of a Third Program.

MedStar asserts that its proposed third program "will have no significant volume impact on the two current providers of transplant service in the LLF DSA." Application 68. MedStar reasons that because the University of Maryland and Johns Hopkins perform well in excess of the minimum volume thresholds, a shift in volume from the existing centers will be immaterial. Application 68; CQ.I 49. But MedStar has estimated volume shifts based on the number of MedStar patients referred to the University of Maryland or Johns Hopkins. CQ.I at 36. And yet MedStar does not maintain data on those referrals, so it was only able to guess the number. This is nothing more than guesswork and cannot be accepted as a sufficient basis on which to predicate an impact analysis.

Furthermore, MedStar estimates that the number of its referrals to existing programs in 2016—the last year for which full-year data was available to allow for an estimate—is ten. CQ.I 47. That is the same number of cases that MedStar forecasts will be completed at Franklin Square in 2019. Application 61. While any new program is going to result in *some* shifting of cases from existing programs, what MedStar's impact analysis suggests is that MedStar will not fill any need. Rather it will operate a third program in the LLF DSA that will do nothing more than siphon off a portion of cases from existing programs. And to the extent it's not siphoning off cases that otherwise would be handled at the high-volume, existing centers, MedStar will shift transplant cases from Georgetown to Franklin Square. CQ.I 49-50. To make matters worse, MedStar has not even attempted to offer

assurances that the two existing programs will be able to make up losses in revenue that it estimates the programs will lose annually as a result of this siphoning. CQ.I 50; CQ.II 3.

MedStar assumes, without any basis, that it "would expect that the existing programs would be able to replace the small number of cases with additional transplant volume." CQ.I 46, 50. And when asked directly by the Commission whether it projects to serve patients who are not currently receiving transplants, MedStar refused to say one way or the other. CQ.I 46-47. Its non-response is a tacit admission that it cannot project that its proposed new program will meet any need in the LLF DSA that is not already being served.

On top of that, MedStar's proposal to add a third program that would perform transplants on a small scale and at a fraction of the number of transplants currently being performed by the two existing programs in the LLF DSA is inconsistent with the State Health Plan. That is because the State Health plan favors a small number of high volume organ transplant programs. State Health Plan 13.

In the end, MedStar's impact analysis falls short, and its application should be denied on this independent basis.

Conclusion

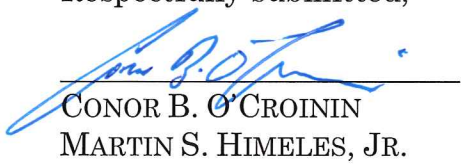
MedStar's application fails to meet the fundamental requirements for a certificate of need. MedStar does not demonstrate need. COMAR 10.24.15(B)(1) & 10.24.01.08G(3)(b). Rather it attempts to show the mere potential for making modest improvements. But even the marginal improvements it describes prove, in the end, to be illusory. Accordingly, MedStar's application must be denied.

Even if MedStar had shown a need for a third liver transplant program in the LLF DSA, MedStar's application should be denied for additional, independent reasons: MedStar hasn't shown the existence of barriers to access in the LLF DSA or that it would reduce such barriers if they existed, COMAR 10.24.15(B)(3)(b), and it has failed to sufficiently analyze the impact, COMAR 10.24.15(B)(5)(d) & 10.24.01.08G(3)(f), that a third program would have on the existing liver transplant programs maintained by the University of Maryland and The Johns Hopkins Hospital.

For each of these reasons, MedStar's application should be denied.

Dated: October 15, 2018
Baltimore, Maryland

Respectfully submitted,



CONOR B. O'CROININ
MARTIN S. HIMELES, JR.
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100 East Pratt Street, Suite 2440
Baltimore, Maryland 21202

Counsel for Johns Hopkins Hospital

Certificate of Service

I certify that I caused a copy of the foregoing interested party comments to be served by electronic and first class mail on:

Patricia G. Cameron
Director, Regulatory Affairs
MEDSTAR HEALTH
10980 Grantchester Way
Columbia, Maryland 21044
patricia.cameron@medstar.net

Conor B. O'Croinin

AFFIRMATION

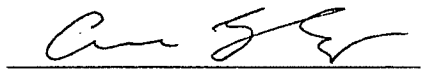
I hereby declare and affirm under the penalties of perjury that the facts stated in these comments and its attachment are true and correct to the best of my knowledge, information, and belief.

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

10/15/2018
Date

AFFIRMATION

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



10/15/2018

Anne Langley
Senior Director, Health Planning and Community Engagement
Health Care Transformation and Strategic Planning
Johns Hopkins Health System

Date

AFFIRMATION

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

Terry Langbaum
Administrative Director
Johns Hopkins Comprehensive Transplant Center

10/15/18
Date

AFFIRMATION

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

October 15, 2018

Benjamin Philosophe
Surgical Director
Johns Hopkins Comprehensive Transplant Center

Date

AFFIRMATION

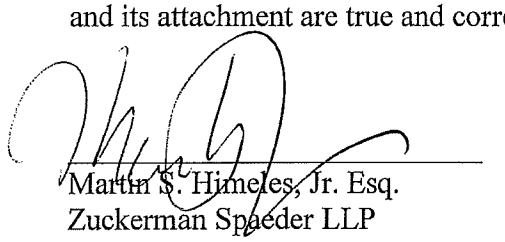
I hereby declare and affirm under the penalties of perjury that the facts stated in these comments and its attachment are true and correct to the best of my knowledge, information, and belief.

Conor O'Croinin, Esq.
Zuckerman Spaeder LLP

15 Oct 2018
Date

AFFIRMATION

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



Martin S. Himeles, Jr. Esq.
Zuckerman Spaeder LLP

10/15/2018
Date

Exhibit

Data Sourcing

Adult Liver Transplants

Adult Liver Transplants						
DSA	**2012**	**2013**	**2014**	**2015**	**2016**	**2017**
LLF	127	169	199	241	291	260
WRTC	98	76	79	49	84	97

Source:
OPTN Build Advanced Website:
https://optn.transplant.hrsa.gov/data/viewdata-reports/build-advanced/

Methodology:
Step 1: For "Choose a data category", Select "Transplant"
Step 2: For "Choose report columns", Select "Transplant Year (30 items)"
Step 3: For "Choose report rows", Select "Transplant Center (343 items)"
For "Organ", Select "Liver"
For "Area of Center", Select "Maryland"*
For "Recipient Age", Select "Adult"
To run the report, click "Go" blue button

*Repeat all steps above, substituting "District of Columbia" for "Maryland", to produce a volumes report for the DC centers.

Screenshots included below.

Build Advanced

Home » Data » View Data Reports » Build Advanced » Transplant : Transplant Year by Transplant Center

Transplant : Transplant Year by Transplant Center
U.S. Transplants Performed : January 1, 1988 - August 31, 2018
For Organ = Liver, State = Maryland, Recipient Age = Adult, Format = Portrait
Based on OPTN data as of September 23, 2018

	To Date	2018	2017	2016	2015	2014	2013	2012	2011	2010	2009	2008	2007	2006	2005	2004	2003	2002	2001	2000	1999	1998	1997	1996	1995	1994	1993	1992	1991	1990	1989	1988
All Centers	3,047	157	260	291	241	199	169	127	112	91	108	105	102	107	104	67	50	61	74	67	65	62	57	64	60	47	44	36	37	34	30	19
MDJH-TX1 Johns Hopkins Hospital	1,602	78	99	122	95	84	79	41	34	36	60	50	58	67	64	41	28	36	46	35	42	50	33	35	43	46	44	36	37	34	30	19
MDUM-TX1 Univ of Maryland Med System	1,445	79	161	169	146	115	90	86	78	55	48	55	44	40	40	26	22	25	28	32	23	12	24	29	17	1	0	0	0	0	0	0

Build Advanced

Home » Data » View Data Reports » Build Advanced » Transplant : Transplant Year by Transplant Center

Transplant : Transplant Year by Transplant Center

U.S. Transplants Performed : January 1, 1988 - August 31, 2018

For Organ = Liver, State = District of Columbia, Recipient Age = Adult, Format = Portrait

Based on OPTN data as of September 23, 2018

	To Date	2018	2017	2016	2015	2014	2013	2012	2011	2010	2009	2008	2007	2006	2005	2004	2003	2002	2001	2000	1999	1998	1997	1996	1995	1994	1993	1992	1991	1989
All Centers	1,322	62	97	84	49	79	76	98	82	68	73	64	53	58	55	53	48	51	46	37	31	14	5	6	5	14	5	6	1	2
DCGU-TX1 Georgetown Univ Med Ctr	1,278	62	97	84	49	79	76	98	82	68	73	64	53	58	55	53	48	51	46	37	31	14	0	0	0	0	0	0	0	0
DCHU-TX1 Howard University Hospital	44	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	5	6	5	14	5	6	1	2

Residents Transplanted Locally, Per Million Population

CY	DSA	JHH	UMMS	G'town	LOCAL Subtotal	Population	Local Rate PMP (Subtotal)
2015	LLF	57	104	-	161	3,900,632	41.28
	WRTC	-	-	62	62	5,464,786	11.35

Source: UNOS Data Request 1 – 04112016

Methodology:

- Because public data sources such as OPTN and SRTR do not report center data by patients' zip code, Johns Hopkins Medicine ("JHM") requested data from the United Network for Organ Sharing ("UNOS"). The dataset UNOS generated in response included patients' zip code, year transplanted, center transplanted, and age category (i.e., pediatric or adult) for 2008-2015 for Maryland, DC, and Virginia residents. JHM sought and obtained permission from UNOS to share this dataset with the Commission, and has done so. To clarify, this data request will be referred as UNOS Data Request 1 – 04112016.
- The table above reports the number of DSA residents transplanted at the center's listed above, omitting non-local centers from the calculations.
- Divide the Local transplants for each DSA by the population of the DSA and multiple by 1 million, to report the transplant rate, per million population per year.

All-Patients, Out-Migration

CY	DSA	JHH	UMMS	G'town	Other Centers	TOTAL	Total Out-migrants	% of Out-migrants
2015	LLF	57	104	7	5	173	12	7%
	WRTC	22	25	62	25	134	72	54%

Source: UNOS Data Request 1 – 04112016

Methodology:

- Because public data sources such as OPTN and SRTR do not report center data by patients' zip code, Johns Hopkins Medicine ("JHM") requested data from the United Network for Organ Sharing ("UNOS"). The dataset UNOS generated in response included patients' zip code, year transplanted, center transplanted, and age category (i.e., pediatric or adult) for 2008-2015 for Maryland, DC, and Virginia residents. JHM sought and obtained permission from UNOS to share this dataset with the Commission, and has done so. To clarify, this data request will be referred as UNOS Data Request 1 – 04112016.
- The table above reports the number of DSA residents transplanted at the center's listed above.
- Total Out-Migrants = sum of transplants performed at non-local center
- % of Out-Migrants = (Total Out-migrants) / (TOTAL)

Adult Live Donor Liver Transplants

	Adults - Living Donors						
	2011	2012	2013	2014	2015	2016	6 Year Total
LLF CENTERS	0	5	12	18	21	18	74
WRTC CENTER	0	1	0	1	3	2	7
DSA VARIANCE (LLF-WRTC)	0	4	12	17	18	16	67

Source:
OPTN Build Advanced Website:
https://optn.transplant.hrsa.gov/data/view-data-reports/build-advanced/

Methodology:
Step 1: For "Choose a data category", Select "Transplant"
Step 2: For "Choose report columns", Select "Transplant Year (30 items)"
Step 3: For "Choose report rows", Select "Transplant Center (343 items)"
For "Organ", Select "Liver"
For "Area of Center", Select "Maryland"*
For "Recipient Age", Select "Adult"
For "Donor", Select "Living Donor"
To run the report, click "Go" blue button
*Repeat all steps above, substituting "District of Columbia" for "Maryland", to produce a volumes report for the DC centers.

Screenshots included below.

Build Advanced

Home » Data » View Data Reports » Build Advanced » Transplant : Transplant Year by Transplant Center

Transplant : Transplant Year by Transplant Center
U.S. Transplants Performed : January 1, 1988 - August 31, 2018
For Organ = Liver, State = Maryland, Recipient Age = Adult, Donor Type = Living Donor, Format = Portrait
Based on OPTN data as of October 1, 2018

	To Date	2018	2017	2016	2015	2014	2013	2012	2010	2009	2008	2007	2006	2005	2004	2003	2002	2001	2000	1999	1998
All Centers	161	17	14	18	21	18	12	5	1	1	2	3	5	3	1	2	8	12	11	6	1
MDJH-TX1 Johns Hopkins Hospital	74	7	4	6	9	8	4	0	0	0	2	3	4	0	0	2	4	7	8	5	1
MDUM-TX1 Univ of Maryland Med System	87	10	10	12	12	10	8	5	1	1	0	0	1	3	1	0	4	5	3	1	0

Build Advanced

Home » Data » View Data Reports » Build Advanced » Transplant : Transplant Year by Transplant Center

Transplant : Transplant Year by Transplant Center

U.S. Transplants Performed : January 1, 1988 - August 31, 2018

For Organ = Liver, State = District of Columbia, Recipient Age = Adult, Donor Type = Living Donor, Format = Portrait

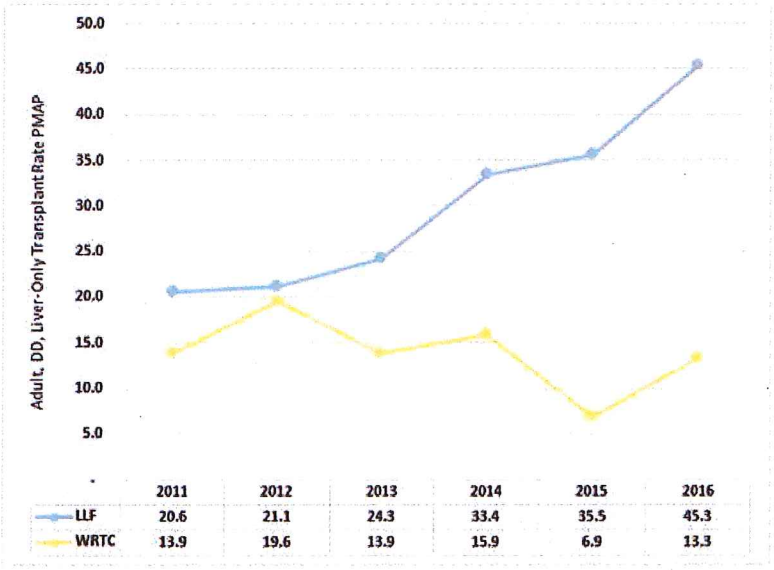
Based on OPTN data as of October 1, 2018

	To Date	2016	2015	2014	2012	2010	2009	2008	2007	2005	2004	2003	2002	2001	2000	1999
All Centers	33	2	3	1	1	1	1	4	2	3	1	2	3	5	3	1
DC001-TX1 Georgetown Univ Med Ctr	33	2	3	1	1	1	1	4	2	3	1	2	3	5	3	1

Adult, Deceased Donor, Liver-Only Cases (Local Access)

Adult, Deceased Donor, Liver-Only Cases (Local Access)								
Year	DSA	JHH	UMMS	MGUH	Other Centers	Total	DSA Adult Population	Transplant Rate PMAP
2011	LLF	14	47			61	2,956,132	20.6
2011	WRTC			55		55	3,958,426	13.9
2012	LLF	22	41			63	2,982,818	21.1
2012	WRTC			79		79	4,031,532	19.6
2013	LLF	27	46			73	3,006,283	24.3
2013	WRTC			57		57	4,102,061	13.9
2014	LLF	36	65			101	3,022,937	33.4
2014	WRTC			66		66	4,152,146	15.9
2015	LLF	36	72			108	3,038,536	35.5
2015	WRTC			29		29	4,203,350	6.9
2016	LLF	45	93			138	3,044,923	45.3
2016	WRTC			56		56	4,225,282	13.3

Adult, Deceased Donor, Liver-Only Transplant Rate PMAP						
DSA	2011	2012	2013	2014	2015	2016
LLF	20.6	21.1	24.3	33.4	35.5	45.3
WRTC	13.9	19.6	13.9	15.9	6.9	13.3



Source: UNOS Data Request 2 - 10012017

Methodology:

- Johns Hopkins Medicine ("JHM") requested a dataset from UNOS quantifying all liver transplant patients residing in the LLF DSA, WRTC DSA, or Other DSA that were transplanted at JHH, UMMS, MGUH, or some Other Center. These statistics were requested for 2010-2016. JHM asked UNOS to exclude pediatric, live donor, and multi-organ cases.
- The table above reports the number of DSA residents transplanted at the center's listed above, omitting non-local centers from the calculations.

- Divide the Local transplants for each DSA by the population of the DSA and multiple by 1 million, to report the transplant rate, per million population per year.

LLF DSA and WRTC DSA Exports

Fiscal Year 2013 (7/1/2012 - 6/30/2013)				
OPO	Livers Procured by OPO	Procured by OPO and Transplanted at Local Center(s)	Livers Exported	Percentage of Livers Exported
LLF	102	97	5	4.9%
WRTC	92	74	18	19.6%

Calendar Year 2014				
OPO	Livers Procured by OPO	Procured by OPO and Transplanted at Local Center(s)	Livers Exported	Percentage of Livers Exported
LLF	119	96	23	19.3%
WRTC	97	59	38	39.2%

Calendar Year 2015				
OPO	Livers Procured by OPO	Procured by OPO and Transplanted at Local Center(s)	Livers Exported	Percentage of Livers Exported
LLF	121	97	24	19.8%
WRTC	89	36	53	59.6%

Source:
SRTR OPO-Specific Reports Website:
https://www.srtr.org/reports-tools/opo-specific-reports/

Methodology:
Livers Procured sourced for page 40, Chart 1 of 1 – Livers Procured

For CY 2015 and 2014:

Step 1: select "The Living Legacy Foundation of Maryland (MDPC), Baltimore, MD" or ""Washington Regional Transplant Community (DCTC), Annandale, VA"
Step 2: go to "Previous Reports"
Step 3: 2015: select "June 2016" report for CY 2015 Data
2014: select "June 2015" report for CY 2014 Data
Step 4: go to page 12
Step 5: Find Table C1 Organ Utilization → Row "Liver" → Column "Recovered for Transplant, Transplanted"

For FY 2013, the SRTR website does not currently link to this report, so JHM requested the report from SRTR.

For CY 2015 and 2014:

Step 1: select "The Living Legacy Foundation of Maryland (MDPC), Baltimore, MD" or ""Washington Regional Transplant Community (DCTC), Annandale, VA"
Step 2: go to "Previous Reports"
Step 3: 2015: select "June 2016" report for CY 2015 Data
2014: select "June 2015" report for CY 2014 Data
Step 4: go to "Figure E4. Programs transplanting livers procured by …"
Step 5: "Procured by OPO and Transplanted at Local Centers" = sum of Transplants labeled "Local" under "Geography"
Step 5: "Livers Exported" = sum of Transplants NOT labeled "Local" under "Geography"

For FY 2013, the SRTR website does not currently link to this report, so JHM requested the report from SRTR

Corresponding documents included below.

LLF
FY 2013 DATA
FROM SRTR

C. Organ Utilization

Table C1. Organ utilization, 07/01/2012 to 06/30/2013

Organ	Organs Authorized	Not Recovered*	Recovered Not for Transplant*	Recovered for Transplant, Not Transplanted*	Recovered for Transplant, Transplanted*
Heart	134	92	14	2	26
Intestine	135	132	2	1	0
Kidney	272	22	6	69	175
Liver	136	17	6	11	102
Lung	272	204	27	3	38
Pancreas	136	101	6	14	15

*Each liver or pancreas segment is counted separately. Pancreas islet cells are not included.

Table C2. Organ specific donation rates per 100 eligible deaths*, 07/01/2012 to 06/30/2013

Organ	Observed	Expected	P Value
Heart	19.2	23.2	0.190
Kidney	67.1	65.4	0.681
Liver	65.1	64.8	0.948
Lung	15.1	15.5	0.861
Pancreas	17.1	12.5	0.017

*Organ-specific rates are calculated as the number of deceased donors meeting eligibility criteria donating at least one organ of that type per 100 eligible deaths.

Figure C4. Standardized donation rate ratio, 07/01/2012 to 06/30/2013

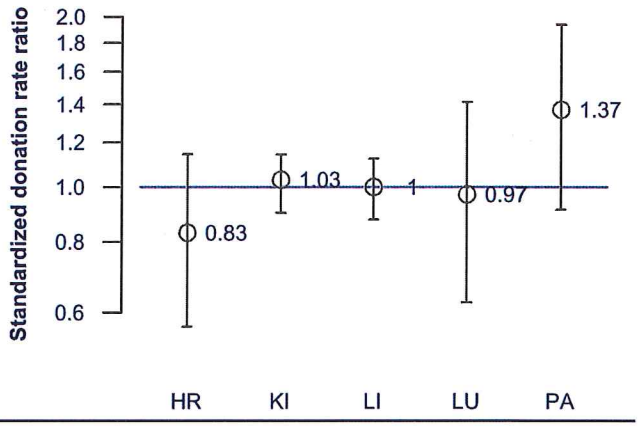
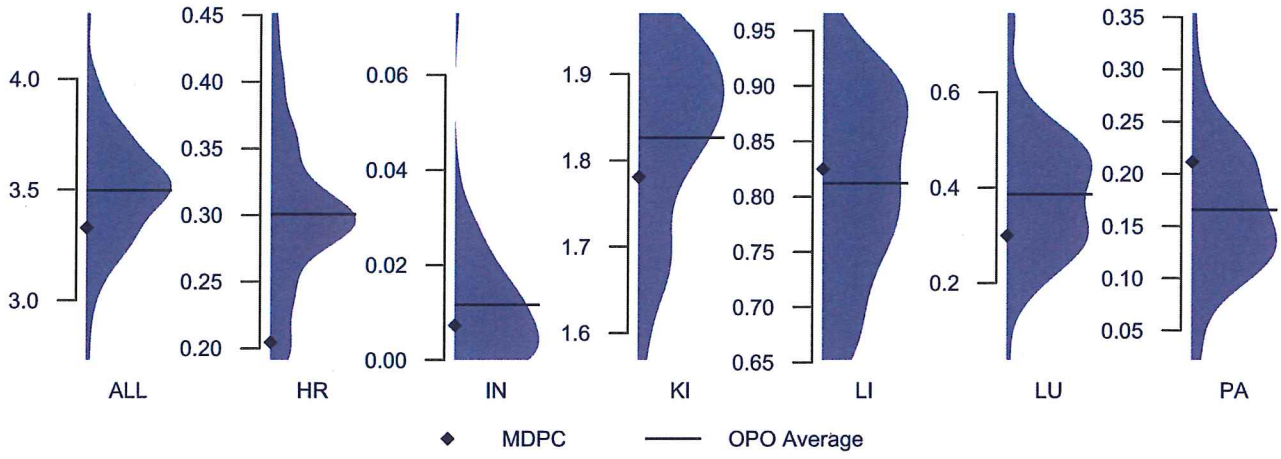


Figure C5. Organs recovered per eligible donor, 07/01/2012 to 06/30/2013



WRTC
FY 2013 DATA
FROM SRTR

C. Organ Utilization

Table C1. Organ utilization, 07/01/2012 to 06/30/2013

Organ	Organs Authorized	Not Recovered*	Recovered Not for Transplant*	Recovered for Transplant, Not Transplanted*	Recovered for Transplant, Transplanted*
Heart	130	86	18	1	25
Intestine	126	122	4	0	0
Kidney	272	31	3	27	211
Liver	131	13	9	19	92
Lung	260	185	20	1	54
Pancreas	129	104	9	5	11

*Each liver or pancreas segment is counted separately. Pancreas islet cells are not included.

Table C2. Organ specific donation rates per 100 eligible deaths*, 07/01/2012 to 06/30/2013

Organ	Observed	Expected	P Value
Heart	17.2	18.3	0.696
Kidney	54.3	59.7	0.196
Liver	53.0	59.0	0.165
Lung	20.5	13.4	<0.01
Pancreas	9.3	8.7	0.730

*Organ-specific rates are calculated as the number of deceased donors meeting eligibility criteria donating at least one organ of that type per 100 eligible deaths.

Figure C4. Standardized donation rate ratio, 07/01/2012 to 06/30/2013

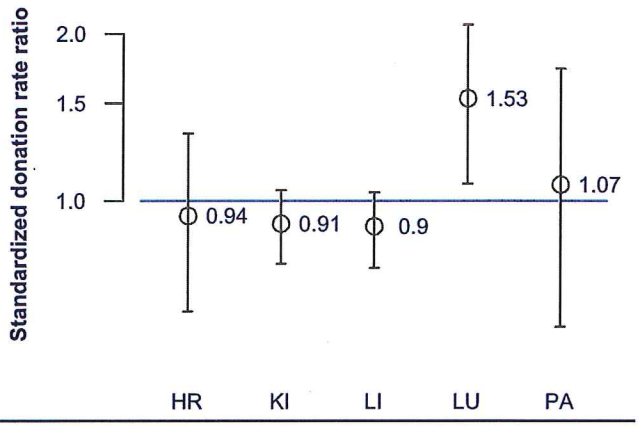
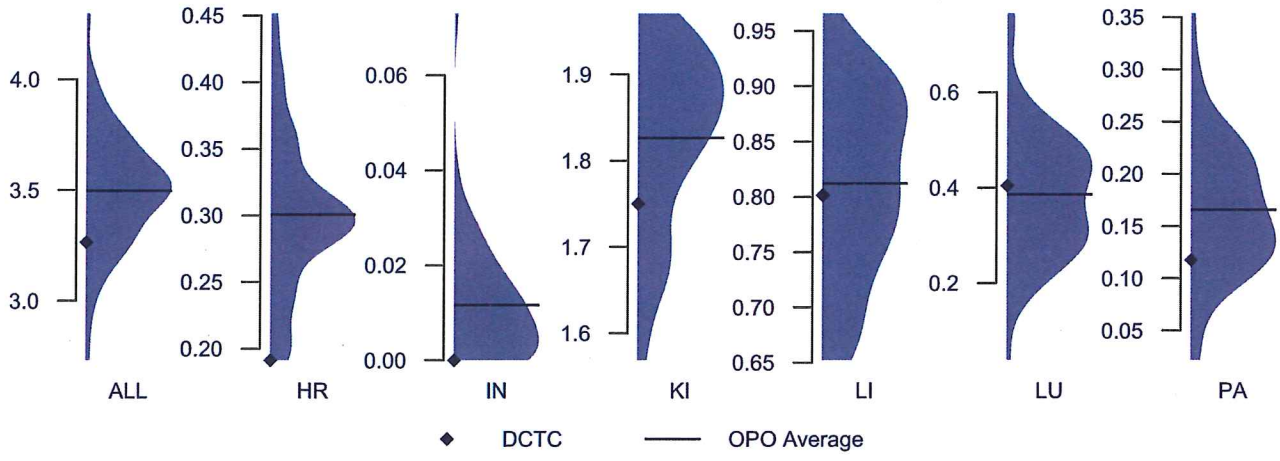


Figure C5. Organs recovered per eligible donor, 07/01/2012 to 06/30/2013



LLF
CY 2014 DATA
FROM SRTR

C. Organ Utilization

Table C1. Organ utilization, 01/01/2014 to 12/31/2014

Organ	Organs Authorized	Not Recovered*	Recovered Not for Transplant*	Recovered for Transplant, Not Transplanted*	Recovered for Transplant, Transplanted*
Heart	145	109	6	1	29
Intestine	144	132	12	0	0
Kidney	294	43	4	84	163
Liver	147	14	4	11	119
Lung	290	220	23	4	43
Pancreas	144	123	5	7	9

*Each liver or pancreas segment is counted separately. Pancreas islet cells are not included.

Table C2. Organ specific donation rates per 100 eligible deaths*, 01/01/2014 to 12/31/2014

Organ	Observed	Expected	P Value
Heart	20.3	25.3	0.107
Kidney	63.5	66.6	0.440
Liver	67.6	67.2	0.935
Lung	17.6	16.8	0.796
Pancreas	10.1	12.3	0.236

*Organ-specific rates are calculated as the number of deceased donors meeting eligibility criteria donating at least one organ of that type per 100 eligible deaths.

Figure C4. Standardized donation rate ratio, 01/01/2014 to 12/31/2014

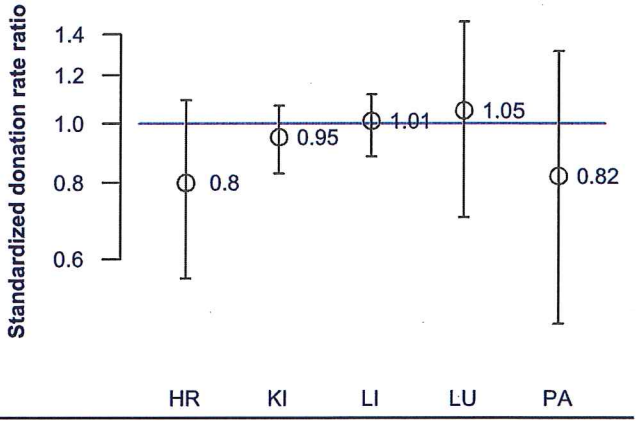
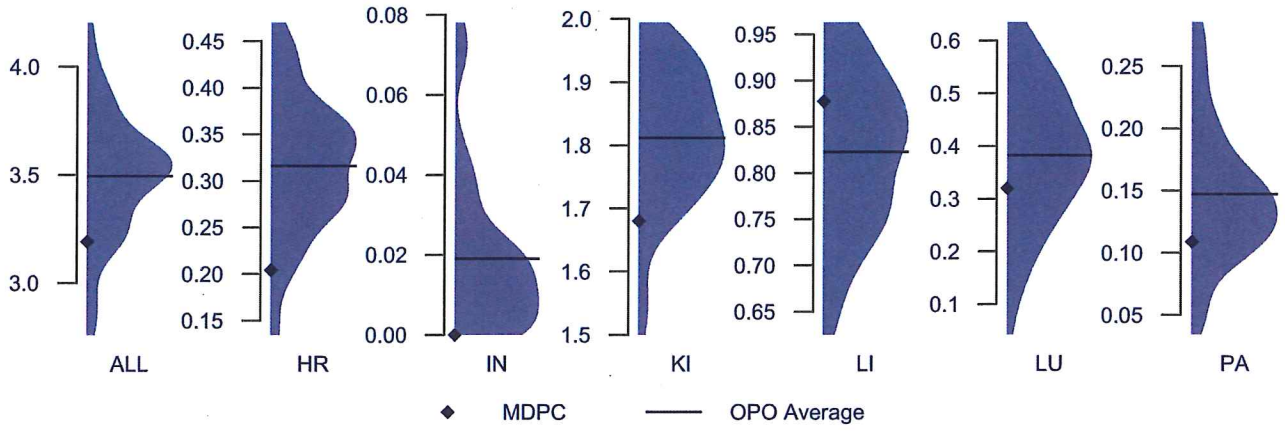


Figure C5. Organs recovered per donor, 01/01/2014 to 12/31/2014 (unadjusted for donor characteristics)



WRTC
CY 2014 DATA
FROM SRTR

C. Organ Utilization

Table C1. Organ utilization, 01/01/2014 to 12/31/2014

Organ	Organs Authorized	Not Recovered*	Recovered Not for Transplant*	Recovered for Transplant, Not Transplanted*	Recovered for Transplant, Transplanted*
Heart	128	71	27	0	30
Intestine	133	119	13	0	1
Kidney	280	18	5	70	187
Liver	141	19	14	13	97
Lung	272	198	32	8	34
Pancreas	134	108	9	5	12

*Each liver or pancreas segment is counted separately. Pancreas islet cells are not included.

Table C2. Organ specific donation rates per 100 eligible deaths*, 01/01/2014 to 12/31/2014

Organ	Observed	Expected	P Value
Heart	20.1	22.1	0.498
Kidney	57.0	59.3	0.586
Liver	59.1	60.2	0.787
Lung	12.8	13.8	0.671
Pancreas	10.7	9.3	0.379

*Organ-specific rates are calculated as the number of deceased donors meeting eligibility criteria donating at least one organ of that type per 100 eligible deaths.

Figure C4. Standardized donation rate ratio, 01/01/2014 to 12/31/2014

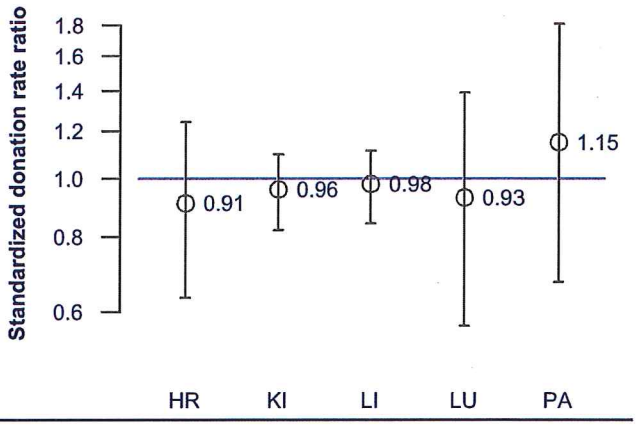
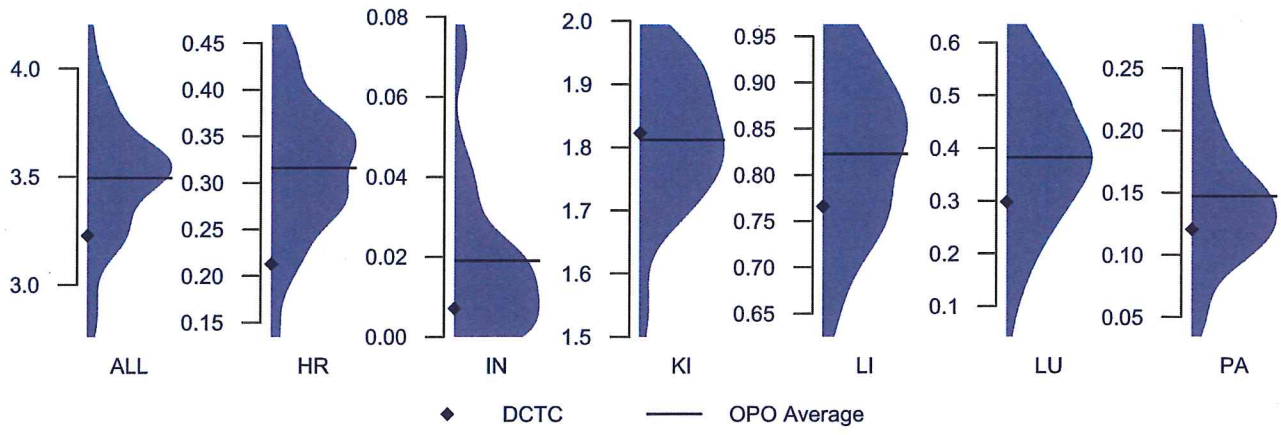


Figure C5. Organs recovered per donor, 01/01/2014 to 12/31/2014 (unadjusted for donor characteristics)



LLF
CY 2015 DATA
FROM SRTR

C. Organ Utilization

Table C1. Organ utilization, 01/01/2015 to 12/31/2015

Organ	Organs Authorized	Not Recovered*	Recovered Not for Transplant*	Recovered for Transplant, Not Transplanted*	Recovered for Transplant, Transplanted*
Heart	149	94	17	0	38
Intestine	149	140	7	0	2
Kidney	304	32	2	87	183
Liver	151	19	1	12	121
Lung	298	191	34	1	72
Pancreas	149	120	2	8	19

*Each liver or pancreas segment is counted separately. Pancreas islet cells are not included.

Table C2. Organ specific donation rates per 100 eligible deaths*, 01/01/2015 to 12/31/2015

Organ	Observed	Expected	P Value
Heart	22.2	25.0	0.342
Kidney	66.1	66.1	0.987
Liver	66.7	66.1	0.881
Lung	22.8	17.1	0.029
Pancreas	15.2	10.8	<0.01

*Organ-specific rates are calculated as the number of deceased donors meeting eligibility criteria donating at least one organ of that type per 100 eligible deaths.

Figure C4. Standardized donation rate ratio, 01/01/2015 to 12/31/2015

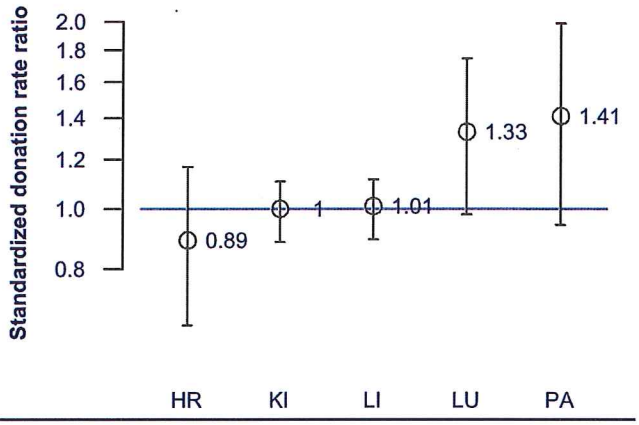
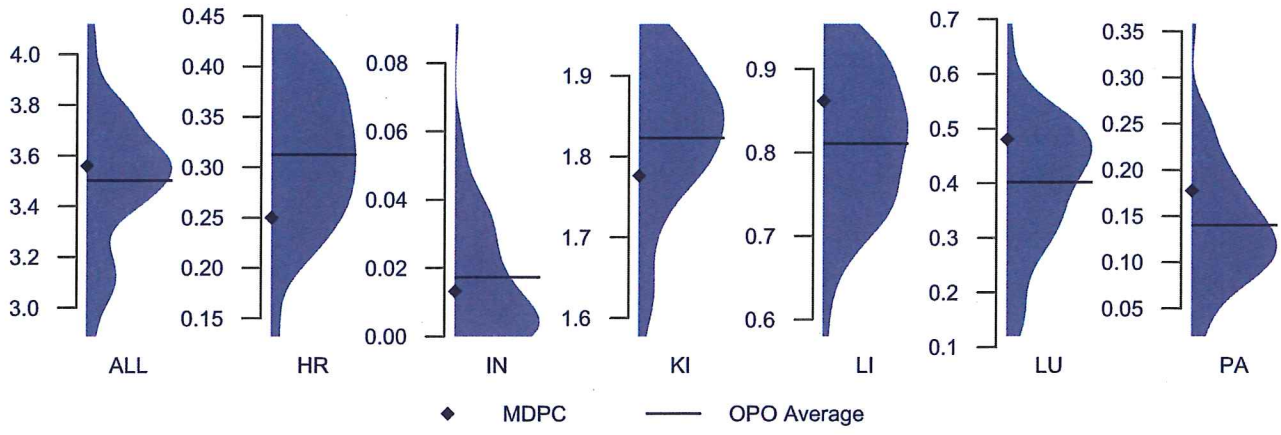


Figure C5. Organs recovered per donor, 01/01/2015 to 12/31/2015 (unadjusted for donor characteristics)



WRTC
CY 2015 DATA
FROM SRTR

C. Organ Utilization

Table C1. Organ utilization, 01/01/2015 to 12/31/2015

Organ	Organs Authorized	Not Recovered*	Recovered Not for Transplant*	Recovered for Transplant, Not Transplanted*	Recovered for Transplant, Transplanted*
Heart	134	65	34	0	35
Intestine	134	111	22	0	1
Kidney	282	30	6	49	197
Liver	140	19	15	20	89
Lung	272	171	48	3	50
Pancreas	135	104	14	1	16

*Each liver or pancreas segment is counted separately. Pancreas islet cells are not included.

Table C2. Organ specific donation rates per 100 eligible deaths*, 01/01/2015 to 12/31/2015

Organ	Observed	Expected	P Value
Heart	24.8	23.2	0.598
Kidney	56.7	59.6	0.496
Liver	58.9	60.0	0.797
Lung	19.9	14.9	0.067
Pancreas	11.3	9.1	0.160

*Organ-specific rates are calculated as the number of deceased donors meeting eligibility criteria donating at least one organ of that type per 100 eligible deaths.

Figure C4. Standardized donation rate ratio, 01/01/2015 to 12/31/2015

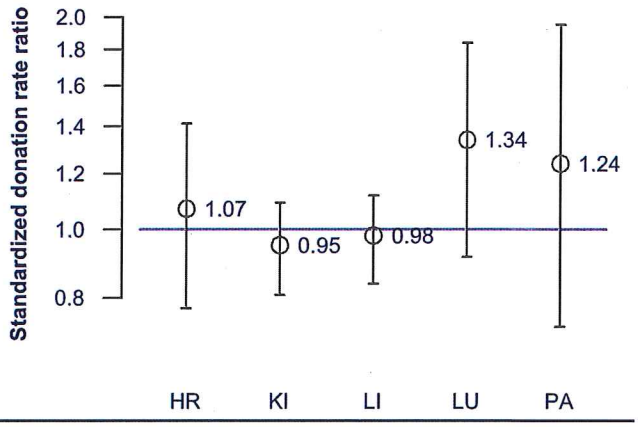
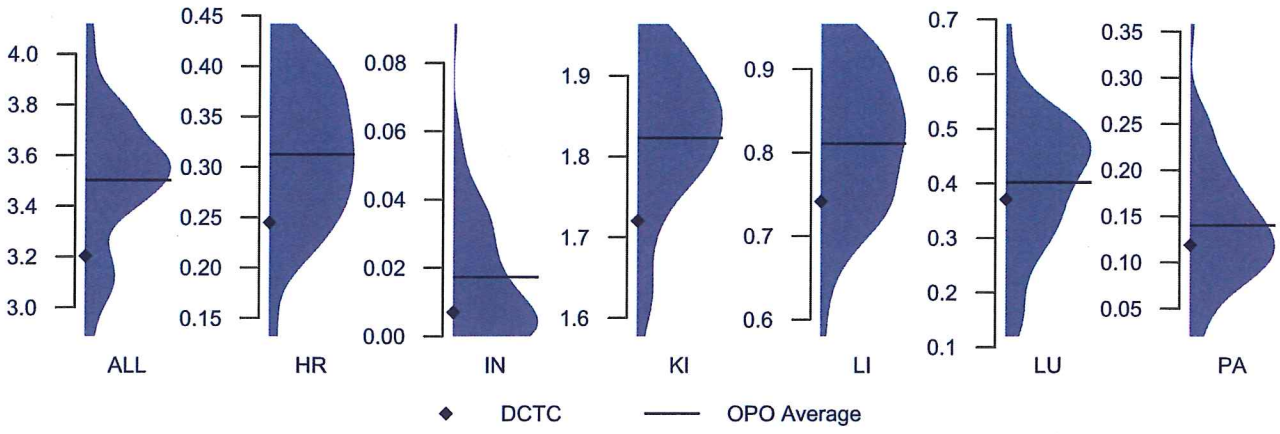


Figure C5. Organs recovered per donor, 01/01/2015 to 12/31/2015 (unadjusted for donor characteristics)



LLF
FY 2013 DATA
FROM SRTR

E. Programs Transplanting Organs Procured by MDPC

Figure E4. Programs transplanting livers procured by MDPC, 07/01/2012 to 06/30/2013*

● Location of OPO headquarters

* Transplants within the local area of the OPO are not always visible on the map due to scale. See Table E4 for full details.

Table E4. Programs transplanting livers procured by MDPC, 07/01/2012 to 06/30/2013

Hospital Name (Code)	Geography*	Transplants
Johns Hopkins Hospital (MDJH)	Local	45
University of Maryland Medical System (MDUM)	Local	52
Albert Einstein Medical Center (PAAE)	Regional	1
Children's Hospital of Philadelphia (PACP)	Regional	2
Georgetown University Medical Center (DCGU)	Regional	2

* Local = within same DSA; Regional = within same OPTN region, but not same DSA; National = not within same DSA or OPTN region

WRTC
FY 2013 DATA
FROM SRTR

E. Programs Transplanting Organs Procured by DCTC

Figure E4. Programs transplanting livers procured by DCTC, 07/01/2012 to 06/30/2013*

Location of OPO headquarters

* Transplants within the local area of the OPO are not always visible on the map due to scale. See Table E4 for full details.

Table E4. Programs transplanting livers procured by DCTC, 07/01/2012 to 06/30/2013

Hospital Name (Code)	Geography*	Transplants
Georgetown University Medical Center (DCGU)	Local	74
Children's Hospital of Philadelphia (PACP)	Regional	1
Children's Hospital of Pittsburgh of UPMC (PACH)	Regional	1
Hospital of the University of Pennsylvania (PAUP)	Regional	2
Johns Hopkins Hospital (MDJH)	Regional	2
Thomas Jefferson University Hospital (PATJ)	Regional	1
University of Maryland Medical System (MDUM)	Regional	5
University of Pittsburgh Medical Center (PAPT)	Regional	1
UMass Memorial Medical Center (MAUM)	National	3
University of North Carolina Hospitals (NCMH)	National	1
Yale New Haven Hospital (CTYN)	National	1

* Local = within same DSA; Regional = within same OPTN region, but not same DSA; National = not within same DSA or OPTN region

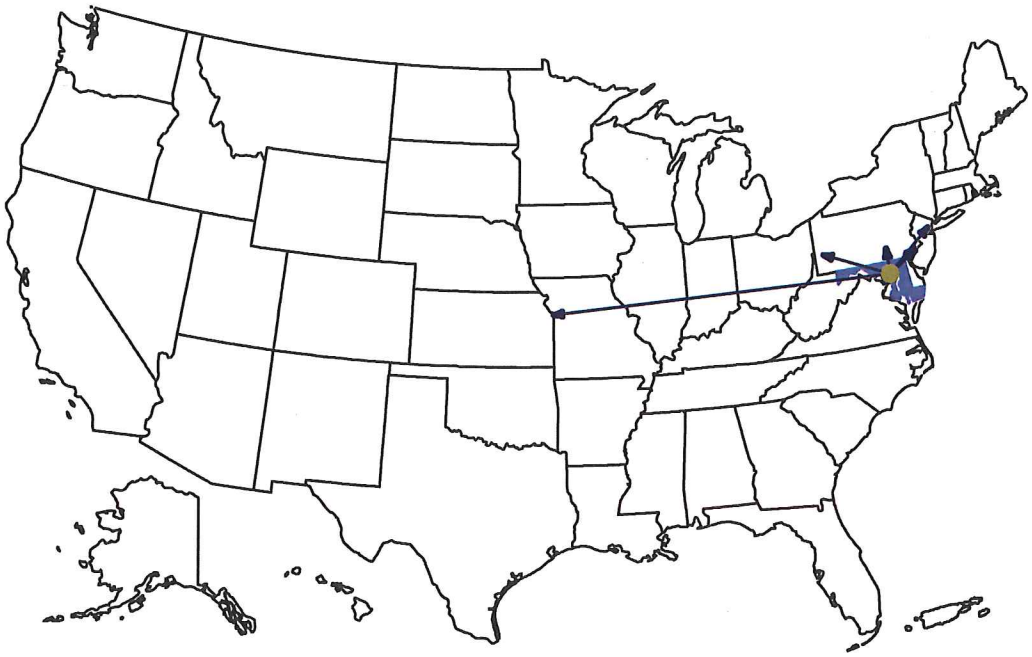
LLF

CY 2014 DATA

FROM SRTR

E. Programs Transplanting Organs Procured by MDPC

Figure E4. Programs transplanting livers procured by MDPC, 01/01/2014 to 12/31/2014*



● Location of OPO headquarters

* Transplants within the local area of the OPO are not always visible on the map due to scale. See Table E4 for full details.

Table E4. Programs transplanting livers procured by MDPC, 01/01/2014 to 12/31/2014

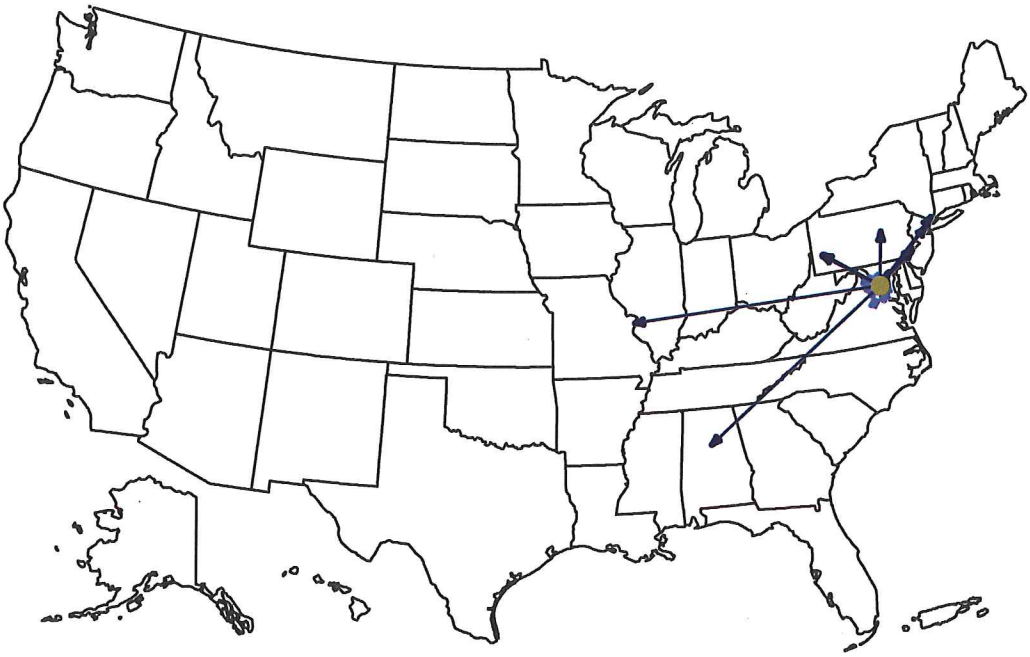
Hospital Name (Code)	Geography*	Transplants
Johns Hopkins Hospital (MDJH)	Local	**46**
University of Maryland Medical System (MDUM)	Local	**50**
Albert Einstein Medical Center (PAAE)	Regional	**1**
Allegheny General Hospital (PAAG)	Regional	**1**
Georgetown University Medical Center (DCGU)	Regional	**9**
Hospital of the University of Pennsylvania (PAUP)	Regional	**2**
Our Lady of Lourdes Medical Center (NJLL)	Regional	**1**
Penn State Milton S Hershey Medical Center (PAHE)	Regional	**4**
Temple University Hospital (PATU)	Regional	**1**
Thomas Jefferson University Hospital (PATJ)	Regional	**2**
University Hospital (NJUH)	Regional	**1**
Children's Mercy Hospital (MOCM)	National	**1**

* Local = within same DSA; Regional = within same OPTN region, but not same DSA; National = not within same DSA or OPTN region

WRTC
CY 2014 DATA
FROM SRTR

E. Programs Transplanting Organs Procured by DCTC

Figure E4. Programs transplanting livers procured by DCTC, 01/01/2014 to 12/31/2014*



Location of OPO headquarters

* Transplants within the local area of the OPO are not always visible on the map due to scale. See Table E4 for full details.

Table E4. Programs transplanting livers procured by DCTC, 01/01/2014 to 12/31/2014

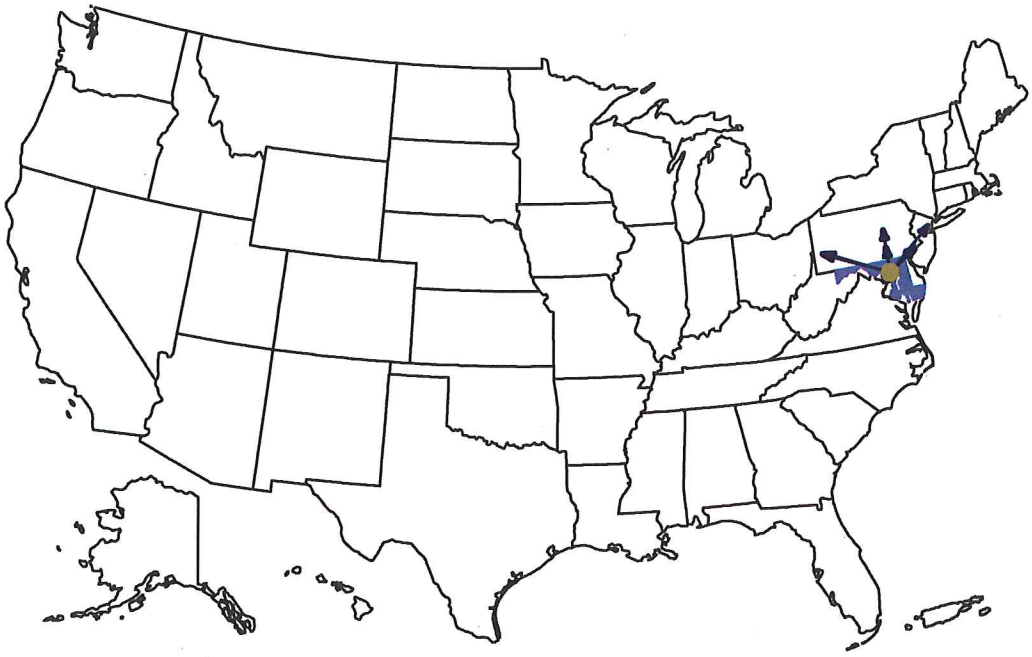
Hospital Name (Code)	Geography*	Transplants
Georgetown University Medical Center (DCGU)	Local	59
Albert Einstein Medical Center (PAAE)	Regional	3
Children's Hospital of Philadelphia (PACP)	Regional	1
Children's Hospital of Pittsburgh of UPMC (PACH)	Regional	3
Geisinger Medical Center (PAGM)	Regional	1
Hahnemann University Hospital (PAHM)	Regional	2
Hospital of the University of Pennsylvania (PAUP)	Regional	1
Johns Hopkins Hospital (MDJH)	Regional	5
Temple University Hospital (PATU)	Regional	2
Thomas Jefferson University Hospital (PATJ)	Regional	2
University Hospital (NJUH)	Regional	3
University of Maryland Medical System (MDUM)	Regional	8
University of Pittsburgh Medical Center (PAPT)	Regional	2
VA Pittsburgh Healthcare System (PAVA)	Regional	1
Children's of Alabama (ALCH)	National	1
St. Louis Children's Hospital at Washington University Medical Center (MOCH)	National	2
Westchester Medical Center (NYWC)	National	1

* Local = within same DSA; Regional = within same OPTN region, but not same DSA; National = not within same DSA or OPTN region

LLF
CY 2015 DATA
FROM SRTR

E. Programs Transplanting Organs Procured by MDPC

Figure E4. Programs transplanting livers procured by MDPC, 01/01/2015 to 12/31/2015*



Location of OPO headquarters

* Transplants within the local area of the OPO are not always visible on the map due to scale. See Table E4 for full details.

Table E4. Programs transplanting livers procured by MDPC, 01/01/2015 to 12/31/2015

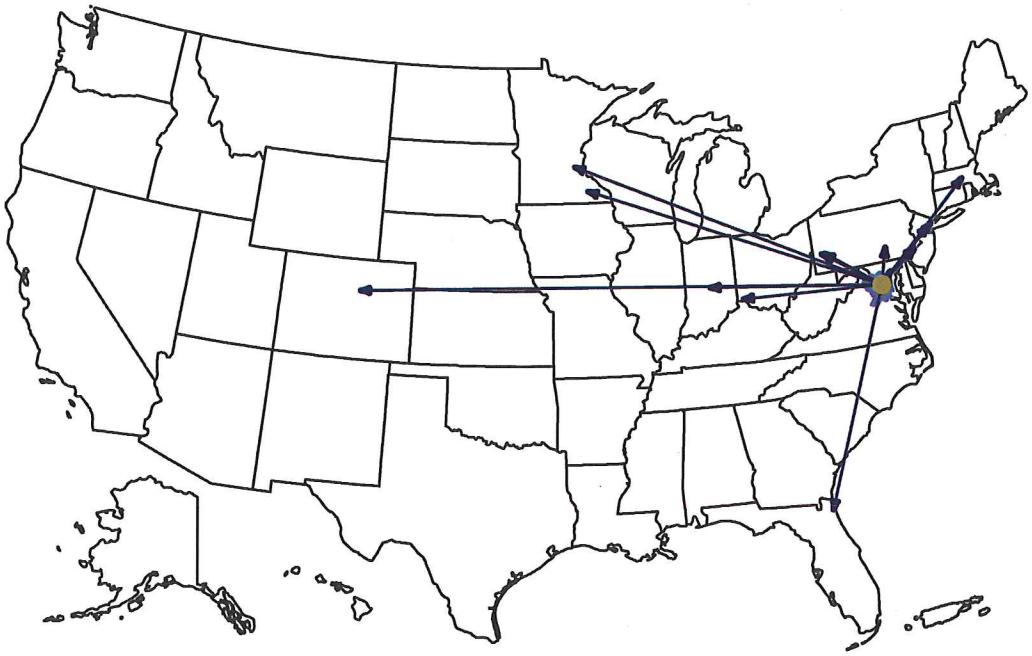
Hospital Name (Code)	Geography*	Transplants
Johns Hopkins Hospital (MDJH)	Local	**37**
University of Maryland Medical System (MDUM)	Local	**60**
Albert Einstein Medical Center (PAAE)	Regional	**3**
Allegheny General Hospital (PAAG)	Regional	**2**
Children's Hospital of Philadelphia (PACP)	Regional	**1**
Children's Hospital of Pittsburgh of UPMC (PACH)	Regional	**2**
Geisinger Medical Center (PAGM)	Regional	**1**
Georgetown University Medical Center (DCGU)	Regional	**4**
Hospital of the University of Pennsylvania (PAUP)	Regional	**2**
Penn State Milton S Hershey Medical Center (PAHE)	Regional	**2**
Thomas Jefferson University Hospital (PATJ)	Regional	**3**
University Hospital (NJUH)	Regional	**1**
University of Pittsburgh Medical Center (PAPT)	Regional	**2**
VA Pittsburgh Healthcare System (PAVA)	Regional	**1**

* Local = within same DSA; Regional = within same OPTN region, but not same DSA; National = not within same DSA or OPTN region

WRTC
CY 2015 DATA
FROM SRTR

E. Programs Transplanting Organs Procured by DCTC

Figure E4. Programs transplanting livers procured by DCTC, 01/01/2015 to 12/31/2015*



Location of OPO headquarters

* Transplants within the local area of the OPO are not always visible on the map due to scale. See Table E4 for full details.

Table E4. Programs transplanting livers procured by DCTC, 01/01/2015 to 12/31/2015

Hospital Name (Code)	Geography*	Transplants
Georgetown University Medical Center (DCGU)	Local	36
Albert Einstein Medical Center (PAAE)	Regional	2
Allegheny General Hospital (PAAG)	Regional	3
Children's Hospital of Pittsburgh of UPMC (PACH)	Regional	2
Hospital of the University of Pennsylvania (PAUP)	Regional	5
Johns Hopkins Hospital (MDJH)	Regional	13
Penn State Milton S Hershey Medical Center (PAHE)	Regional	2
Thomas Jefferson University Hospital (PATJ)	Regional	2
University Hospital (NJUH)	Regional	3
University of Maryland Medical System (MDUM)	Regional	10
University of Pittsburgh Medical Center (PAPT)	Regional	1
VA Pittsburgh Healthcare System (PAVA)	Regional	2
Children's Hospital Colorado (COCH)	National	1
Children's Hospital Medical Center (OHCM)	National	1
Indiana University Health (INIM)	National	1
Mayo Clinic Florida (FLSL)	National	1
NY Presbyterian Hospital/Columbia Univ. Medical Center (NYCP)	National	2
Rochester Methodist Hospital (Mayo Clinic) (MNMC)	National	1

* Local = within same DSA; Regional = within same OPTN region, but not same DSA; National = not within same DSA or OPTN region

E. Programs Transplanting Organs Procured by DCTC

Table E4. Programs transplanting livers procured by DCTC, 01/01/2015 to 12/31/2015 (continued)

Hospital Name (Code)	Geography*	Transplants
UMass Memorial Medical Center (MAUM)	National	1
Univ of MN Amplatz Children's Hosp (MNAC)	National	1

* Local = within same DSA; Regional = within same OPTN region, but not same DSA; National = not within same DSA or OPTN region

Liver Imported From WRTC OPO to JHH

Livers Imported from WRTC OPO to JHH					
Year	Total	Imported for Share 35 Recipient (Count)		Imported for Share 35 Recipient (Percentage)	
		Yes	No	Yes	No
2014	5	1	4	20%	80%
2015	13	4	9	31%	69%
2016	3	1	2	33%	67%
Total	**21**	**6**	**15**	**29%**	**71%**

Source:
Data requested from. Living Legacy Foundation OPO.

Adult Liver Transplant Recipient Ethnicity

Center(s)	Liver Recipient Ethnicity	2017 Adult Liver Transplants	2017 Percent of Adult Total	2017 DSA Population	2017 DSA Population Percent of Total	2017 Transplant Rate Per Million DSA Population
MGUH	All Ethnicities	97	100%	5,559,847	100%	**17.45**
	White	60	62%	2,348,818	42%	25.54
	Black	21	22%	1,458,935	26%	14.39
	Hispanic	10	10%	930,477	17%	10.75
	Asian	3	3%	626,213	11%	4.79
	Am. Indian/Alaska Native*	1	1%	195,404	-	-
	Multiracial*	2	2%		-	-
JHH & UMMS	All Ethnicities	260	100%	3,924,235	100%	**66.25**
	White	196	75%	2,445,569	62%	80.14
	Black	52	20%	951,216	24%	54.67
	Hispanic	9	3%	227,092	6%	39.63
	Asian	2	1%	189,640	5%	10.55
	Am. Indian/Alaska Native*	1	0%	110,718	-	-
	Multiracial*	0	0%		-	-

* Population "All Others"

Source:
OPTN Build Advanced Website:
https://optn.transplant.hrsa.gov/data/viewdata-reports/build-advanced/

Methodology:
Step 1: For "Choose a data category", Select "Transplant"
Step 2: For "Choose report columns", Select "Transplant Year (2016 - 2017)"
Step 3: For "Choose report rows", Select "Transplant Center (343 items)", Select "Recipient Ethnicity (9 items)"
For "Organ", Select "Liver"
For "Area of Center", Select "Maryland"*
For "Recipient Age", Select "Adult"
To run the report, click "Go" blue button

*Repeat all steps above, substituting "District of Columbia" for "Maryland", to produce a volumes report for the DC centers.

Population data sourced to Truven Health Analytics

Screenshots included below.

Build Advanced

Transplant : Transplant Year (2016 - 2017) by Transplant Center, Recipient Ethnicity

U.S. Transplants Performed : January 1, 1988 - August 31, 2018

For Organ = Liver, State = District of Columbia, Recipient Age = Adult, Format = Portrait

Based on OPTN data as of September 23, 2018

		2017	2016
All Centers	All Ethnicities	97	84
	White	60	42
	Black	21	24
	Hispanic	10	9
	Asian	3	8
	American Indian/Alaska Native	1	1
	Multiracial	2	0

Build Advanced

Transplant : Transplant Year (2016 - 2017) by Transplant Center, Recipient Ethnicity

U.S. Transplants Performed : January 1, 1988 - August 31, 2018

For Organ = Liver, State = Maryland, Recipient Age = Adult, Format = Portrait

Based on OPTN data as of September 25, 2018

		2017	2016
All Centers	All Ethnicities	260	291
	White	196	210
	Black	52	64
	Hispanic	9	8
	Asian	2	7
	American Indian/Alaska Native	1	1
	Multiracial	0	1

LLF Population Demographics:

RACE/ETHNICITY			
	Race/Ethnicity Distribution		
Race/Ethnicity	2017 Pop	% of Total	USA % of Total
White Non-Hispanic	2,445,569	62.3%	60.8%
Black Non-Hispanic	951,216	24.2%	12.4%
Hispanic	227,092	5.8%	18.0%
Asian & Pacific Is. Non-Hispanic	189,640	4.8%	5.7%
All Others	110,718	2.8%	3.2%
Total	3,924,235	100.0%	100.0%

WRTC Population Demographics:

RACE/ETHNICITY			
	Race/Ethnicity Distribution		
Race/Ethnicity	2017 Pop	% of Total	USA % of Total
White Non-Hispanic	2,348,818	42.2%	60.8%
Black Non-Hispanic	1,458,935	26.2%	12.4%
Hispanic	930,477	16.7%	18.0%
Asian & Pacific Is. Non-Hispanic	626,213	11.3%	5.7%
All Others	195,404	3.5%	3.2%
Total	5,559,847	100.0%	100.0%

WESTLAW

Subtitle 5—False Statements

Select all items | No items selected

Part: 1 of 1

Subtitle 5—False Statements

§ 9-501. False statement--To law enforcement officer

Prohibited

(a) A person may not make, or cause to be made, a statement, report, or complaint that the person knows to be false as a whole or in material part, to a law enforcement officer of the State, of a county, municipal corporation, or other political subdivision of the State, or of the Maryland-National Capital Park and Planning Police with intent to deceive and to cause an investigation or other action to be taken as a result of the statement, report, or complaint.

Penalty

(b) A person who violates this section is guilty of a misdemeanor and on conviction is subject to imprisonment not exceeding 6 months or a fine not exceeding $500 or both.

§ 9-502. False statement--When under arrest

Prohibited

(a) A person who is arrested by a law enforcement officer of the State, of a county, municipal corporation, or other political subdivision of the State, or of the Maryland-National Capital Park and Planning Police may not knowingly, and with intent to deceive, make a false statement to a law enforcement officer concerning the person's identity, address, or date of birth.

Penalty

(b) A person who violates this section is guilty of a misdemeanor and on conviction is subject to imprisonment not exceeding 6 months or a fine not exceeding $500 or both.

§ 9-503. False statement--To public official concerning crime or hazard

Prohibited

(a) A person may not make, or cause to be made, a statement or report that the person knows to be false as a whole or in material part to an official or unit of the State or of a county, municipal corporation, or other political subdivision of the State that a crime has been committed or that a condition imminently dangerous to public safety or health exists, with the intent that the official or unit investigate, consider, or take action in connection with that statement or report.

Penalty

(b) A person who violates this section is guilty of a misdemeanor and on conviction is subject to imprisonment not exceeding 6 months or a fine not exceeding $500 or both.

§ 9-504. False statement--Concerning destructive device or toxic material

Scope of section

(a) This section does not apply to a statement made or rumor circulated by an officer, employee, or agent of a bona fide civilian defense organization or unit, if made in the regular course of the person's duties.

Prohibited

(b) A person may not circulate or transmit to another, with intent that it be acted on, a statement or rumor that the person knows to be false about the location or possible detonation of a destructive device or the location or possible release of toxic material, as those terms are defined in § 4-501 of this article.

Penalty

(c) A person who violates this section is guilty of a felony and on conviction is subject to imprisonment not exceeding 10 years or a fine not exceeding $10,000 or both.

Venue

(d) A crime under this section committed using a telephone or other electronic means may be prosecuted in the county in which:

(1) the communication originated;

(2) the communication was received; or

(3) the destructive device or toxic material was stated or was rumored to be located.

Restitution

(e)(1) In addition to the penalty provided in subsection (c) of this section, a court may order a person convicted or found to have committed a delinquent act under this section to pay restitution to:

(i) the State, county, municipal corporation, bicounty unit, multicounty unit, county board of education, public authority, or special taxing district for actual costs reasonably incurred in responding to a location and searching for a destructive device as a result of a violation of this section; and

(ii) the owner or tenant of a property for the actual value of any goods, services, or income lost as a result of the evacuation of the property as a result of a violation of this section.

(2) This subsection may not be construed to limit the right of a person to restitution under Title 11, Subtitle 6 of the Criminal Procedure Article.

(3)(i) If the person convicted or found to have committed a delinquent act under this section is a minor, the court may order the minor, the minor's parent, or both to pay the restitution described in paragraph (1) of this subsection.

(ii) Except as otherwise provided in this section, the provisions of Title 11, Subtitle 6 of the Criminal Procedure Article apply to an order of restitution under this paragraph.

License suspension of minor

(f) In addition to any other penalty authorized by law, if the person convicted or found to have committed a delinquent act under this section is a minor, the court may order the Motor Vehicle Administration to initiate an action, under the motor vehicle laws, to suspend the driving privilege of the minor for a specified period not to exceed:

(1) for a first violation, 6 months; and

(2) for each subsequent violation, 1 year or until the person is 21 years old, whichever is longer.

§ 9-505. Representation of toxic material or destructive device

Prohibited

(a) A person may not manufacture, possess, transport, or place:

(1) a device or container that is labeled as containing or is intended to represent a toxic material, as defined in § 4-501 of this article, with the intent to terrorize, frighten, intimidate, threaten, or harass; or

(2) a device that is constructed to represent a destructive device, as defined in § 4-501 of this article, with the intent to terrorize, frighten, intimidate, threaten, or harass.

Penalty

(b) A person who violates this section is guilty of a felony and on conviction is subject to imprisonment not exceeding 10 years or a fine not exceeding $10,000 or both.

Restitution

(c)(1) In addition to the penalty provided in subsection (b) of this section, a person convicted or found to have committed a delinquent act under this section may be ordered by the court to pay restitution to:

(i) the State, county, municipal corporation, bicounty unit, multicounty unit, county board of education, public authority, or special taxing district for actual costs reasonably incurred as a result of a violation of this section; and

(ii) the owner or tenant of a property for the actual value of any goods, services, or income lost as a result of the evacuation of the property as a result of a violation of this section.

(2) This subsection may not be construed to limit the right of a person to restitution under Title 11, Subtitle 6 of the Criminal Procedure Article.

(3)(i) If the person convicted or found to have committed a delinquent act in violation of this section is a minor, the court may order the minor, the minor's parent, or both to pay the restitution described in paragraph (1) of this subsection.

(ii) Except as otherwise provided in this section, the provisions of Title 11, Subtitle 6 of the Criminal Procedure Article apply to an order of restitution under this paragraph.

License suspension of minor

(d) In addition to any other penalty authorized by law, if the person convicted or found to have committed a delinquent act under this section is a minor, the court may order the Motor Vehicle Administration to initiate an action, under the motor vehicle laws, to suspend the driving privilege of the minor for a specified period not to exceed:

(1) for a first violation, 6 months; and

(2) for each subsequent violation, 1 year or until the person is 21 years old, whichever is longer.

§ 9-506. Maryland Higher Education Commission Fund application--False or concealed material fact

Prohibited

(a) A person may not knowingly and willfully falsify or conceal a material fact in connection with an application for funds from the Maryland Higher Education Commission.

Penalty

(b) A person who violates this section is guilty of a misdemeanor and on conviction is subject to imprisonment not exceeding 1 year or a fine not exceeding $5,000 or both.

Notice to applicant

(c) The Maryland Higher Education Commission shall notify each applicant for funds of the conduct that constitutes a violation of this section before a State scholarship award or grant is awarded.

§ 9-507. Common-law criminal defamation repealed The common-law crime of criminal defamation is repealed.

§ 9-508. False information in filing statement prohibited

Financing statement defined

(a) In this section, "financing statement" has the meaning stated in § 9-102 of the Commercial Law Article.

In general

(b) A person may not file a financing statement or an amendment to a financing statement that the person knows contains false information.

Fines and penalties

(c)(1) A person who violates this section is guilty of a misdemeanor and on conviction is subject to a fine not exceeding $500.

(2) Each act of filing a financing statement or an amendment to a financing statement is a separate violation.

UNITED STATES OF AMERICA,

v.

ANDREW S. MACKEY, Defendant.

No. 1:10-cr-310-WSD.

United States District Court, N.D. Georgia, Atlanta Division.

August 8, 2012.

OPINION AND ORDER

WILLIAM S. DUFFEY, Jr., District Judge.

This matter is before the Court on Defendant Andrew S. Mackey's ("Defendant" or "Mackey") Motion for New Trial [152]. Also before the Court is Mackey's *pro se* Amended Motion for New Trial [165].[1]

I. BACKGROUND

On May 16, 2012, a jury convicted Mackey of conspiracy to commit wire fraud (Count 1), five counts of wire fraud (Counts 2-4, 6 and 8), and eight counts of mail fraud (Counts 9-17), in connection with investments offered through Mackey's company, A.S.M. Financial Funding Corporation ("ASM").[2] [143].

Mackey contends that he is entitled to a new trial because: (1) admission of evidence relating to the memorandum prepared by attorney Robert Townsend ("Townsend Memo") violated Mackey's attorney-client privilege; (2) the Court impermissibly limited the scope of Mackey's cross-examination of investor-witnesses, thereby violating Mackey's Fifth and Sixth Amendment right of confrontation, right to cross-examination, right to present a defense and due process rights; and (3) the Court's refusal to instruct the jury on Mackey's requested "Theory of the Defense" violated Mackey's right to present a defense. The Townsend Memo and Joint Venture Agreements were the subject of pre-trial evidentiary motions that were briefed, argued and considered by the Court. See [97]; [101]; [103]; [112]; [114].

1. The Townsend Memo

In February 2009, in response to requests for information in civil fraud proceedings brought against Mackey and ASM by the New York Attorney General's Office ("NYAGO"), Mackey voluntarily produced to the NYAGO several computer hard drives that he had used in connection with his investment business. One of the hard drives that Mackey produced contained a June 29, 2005, memo from attorney Robert Townsend. In the memo, Townsend discusses representations made by Mackey on his business's website and provides opinions about the legality of Mackey's business. When Mackey produced the hard drives, neither he nor his attorney in those proceedings asserted that the Townsend Memo was privileged or confidential, and neither he nor his attorney objected to the production of the Townsend Memo to the NYAGO.

In 2011, the NYAGO transferred the hard drives to the FBI's Atlanta field office. The Government moved for an order in this case declaring that certain communications, including the Townsend Memo, were not protected by the attorney-client privilege because the communications were disclosed to third parties. Mackey argued that he did not knowingly waive the privilege when he turned over the hard drives to the NYAGO and that any purported waiver in the civil proceeding should not apply to the memorandum in this criminal case. The Court found that Mackey had waived the attorney-client privilege with respect to the Townsend Memo, and that the memorandum could be admitted in the Government's case-in-chief for the limited purpose of showing whether Mackey possessed the necessary intent to defraud investors. [112].

Additional testimony was offered about the Townsend Memo at trial. Inconsistent with Mackey's pre-trial representation about the memorandum and whether an attorney-client privilege extended to it, during the second day of his testimony at trial Mackey disclosed that some person in his network, other than himself, had asked Townsend to review the

> "[A]t the point where attorney-client communications are no longer confidential, i.e., where there has been a disclosure of a privileged communication, there is no justification for retaining the privilege. For that reason, it has long been held that once waived, the attorney-client. privilege cannot be reasserted.

United States v. Suarez, 820 F.2d 1158, 1160 (11th Cir. 1987) (internal citations omitted). Federal Rule of Evidence 502(b)[6] provides that inadvertent disclosure of privileged communications does not waive the attorney-client privilege if the proponent of the privilege satisfies three requirements: "(1) the disclosure is inadvertent; (2) the holder of the privilege or protection took reasonable steps to prevent disclosure; and (3) the holder promptly took reasonable steps to rectify the error. ..." Mackey has the burden to prove that all three requirements are satisfied. See Bogle v. McClure, 332 F.3d 1347, 1358 (11th Cir. 2003) ("The party invoking the attorney-client privilege has the burden of proving that an attorney-client relationship existed and that the particular communications were confidential," quoting United States v. Schaltenbrand, 930 F.2d 1554, 1562 (11th Cir. 1991)); In re Sulfuric Acid Antitrust Litig., 235 F.R.D. 407, 417 (N.D. Ill. 2006) ("Generally, the burden of proving inadvertent disclosure is on the party asserting the privilege.").

Whether the Townsend Memo is protected by attorney-client privilege has been the subject of lengthy briefing and discussion prior to, and during, trial. In its February 7, 2012, Order, the Court found that the Townsend Memo is no longer confidential (if it ever was), has not been confidential since Mackey provided his computer hard drives to the NYAGO in February 2009, and was not confidential when the hard drives were provided to the Government, with the knowledge of Mackey's defense counsel, in May 2011. [112 at 11]. The Court found that Mackey failed to show that disclosure of the Townsend Memo was inadvertent, including because Mackey had not shown that he, or his attorney in the NYAGO proceeding, took reasonable steps to prevent disclosure of the Townsend Memo.

That Mackey asserts again that he retained counsel in the NYAGO proceeding does not change that he and his counsel failed to take any steps, reasonable or otherwise, to prevent disclosure of the Townsend Memo. The evidence is that Mackey voluntarily provided to the NYAGO several computer hard drives he used in connection with ASM; that Mackey did not disclose to the NYAGO that the Townsend Memo was on the hard drive; and that neither Mackey, nor his attorney, asserted that the Townsend Memo was privileged or confidential. Simply retaining counsel in the NYAGO proceeding, without more, is insufficient to meet Mackey's burden to demonstrate that his disclosure of the Townsend Memo was inadvertent. To the contrary, it appears that Mackey and his lawyer may have made the reasoned, strategic choice to produce to the NYAGO the information it requested.

Mackey relies on Cox v. Adm't U.S. Steel & Carnegie, 17 F.3d 1386, 1417 (11th Cir. 1994), to support his argument that, because he never placed the Townsend Memo or its alleged conclusions at issue in this case, he did not waive the attorney-client privilege. [164 at 3]. Mackey's reliance on Cox is misplaced. In Cox, the court considered the issue of "waiver by implication," whereby the party asserting the privilege places the privileged information at issue in the case through some affirmative act, such that "fairness requires an examination of otherwise protected communications." Cox at 1419. Here, Mackey waived the privilege by disclosing the Townsend Memo to third parties. It is not necessary to find that Mackey placed the Townsend Memo at issue in this case, and Cox does not provide otherwise.

Even if Mackey had not directly waived the privilege by disclosing the Townsend Memo to third parties, Mackey waived any privilege by implication when he raised a "good faith" defense and asserted that he did not intend to defraud investors. At trial, Mackey presented evidence that he believed his sale of investments was legal. He injected the issue of his knowledge of the law into the case and thus waived the attorney-client privilege. See, e.g., Cox, 1386 at 1419 (when employer asserted that it believed its leave of absence policy was lawful, employer injected the issue of its knowledge of the law into the case and thereby waived attorney-client privilege on the issue; employer could have denied criminal intent without affirmatively asserting that it believed its acts were legal); United States v. Bilzerian, 926 F.2d 1285, 1292-93 (2d Cir. 1991) cert. denied 112 S. Ct. 63 (1991) (in trial for securities fraud, defendant's testimony that he thought his actions were legal would have put his knowledge of the law and the basis for his understanding of what the law required at issue; the court reasoned that " [defendant's] conversations with counsel regarding the legality of his schemes would have been directly relevant in determining the extent of his knowledge and, as a result, his intent").

Mackey next argues that the Townsend Memo should have been excluded because it was not relevant, and even if it were, admission of the Townsend Memo was unduly prejudicial. At trial, Mackey argued: (1) that Townsend's opinions and advice relate to the Loan Warrantee Program, an investment program separate and structurally different from the Wealth Enhancement Club upon which the charges in the Indictment are based; (2) that the central issue in the memo concerns whether the Warrantee Program is a security; and (3) that any probative value would be substantially outweighed by undue

> The evidence of these acts may be similar to those charged in the Indictment, but you must not consider this other program as evidence that they committed the crimes charged in the Indictment, except you may, as I have already instructed you, consider this evidence for the limited purpose of evaluating Defendant Mackey's intent with respect to the crimes charged in the Indictment. You may not consider this evidence against Defendant Jensen.
>
> Finally, I instruct you that the memorandum was written by an attorney. However, you must not consider the statements or opinions of the attorney in the memorandum as the basis of the Defendants' guilt or innocence of the crimes charged in this case.
>
> It will be your responsibility after considering all of the evidence in the case to determine whether or not the Defendants are guilty of the crimes charged and specifically what their intent was.

(Transcript of Trial ("Tr.") at 468:4-469:11). Any prejudice perceived by Mackey was addressed and resolved by the redaction of extraneous material and the limiting instruction given. See, e.g., Davis v. Washington, 547 U.S. 813, 829 (2006) (trial courts "should redact or exclude the portions of any statement that have become testimonial, as they do, for example, with unduly prejudicial portions of otherwise admissible evidence"); United States v. Gari, 572 F.3d 1352, 1363 n.8 (11th Cir. 2009) (rejecting defendant's argument that if any portion of a document is inadmissible, entire document must be excluded, and observing that "[t]rial courts routinely redact inadmissible portions of documents prior to their admission in evidence"); United States v. Perkins, 204 F. App'x 799, 804 (11th Cir. 2006) (per curium) (any error in admission of recorded jailhouse conversation in which defendant referenced her decision to remain silent was harmless; references to defendant's silence were not highlighted by prosecutor, and district court gave curative instruction and redacted references at issue from transcript before giving it to jury); United States v. Bianco, 181 F. App'x 846, 854 (11th Cir. 2006) (per curium) ("because the district court carefully restricted and redacted the evidence such that no direct references were made to the nature of [defendant's] prior criminal offenses and twice instructed the jury on the proper use of the evidence, the danger of unfair prejudice was minimal as compared to its probative value"); United States v. Calderon, 127 F.3d 1314, 1334 (11th Cir. 1997) (the court's instructions cure prejudice because the jury is presumed to follow them).[7]

Finally, Mackey's attempt to compartmentalize the Loan Warrantee and Wealth Enhancement programs and argue that they are separate and distinct was discredited by the evidence presented at trial. The evidence was that Mackey structured and touted them to investors as based on the same high-yield kind of investment which would produce extraordinary returns. (Tr. at 1207:11-21; 1209:1-1210:3). Funds generated by the sales of both programs were commingled into the same bank accounts, funds from which were used by Mackey for the same purposes, including personal ones. (See, e.g., Tr. at 1006:9-1007:7; 1029:2-1030:8; 1017:10-1019:13; Gov. Exs. 35.1-35.19).

There is no new evidence or legal authority to require the Court to reach a decision different from its earlier rulings on the arguments Mackey reiterates here in his Motion for New Trial. The evidence is that Mackey did not request the opinion from Townsend and the attorney-client privilege thus does not apply. Even if it did, Mackey waived the attorney-client privilege when he disclosed the Townsend Memo to the NYAGO, and neither Mackey nor his attorney took any action to prevent the disclosure. The Court finds that the Townsend Memo was highly probative of Mackey's intent in entering into financial agreements with investors, a central issue in this case and the linchpin of Mackey's defense. Finally, admission of the Townsend Memo, subject to the Court's limiting instructions, was not substantially outweighed by undue prejudice. The Court finds that the interest of justice does not require a new trial based on the admission of the Townsend Memo.

C. Limitation of the Defense's Cross-Examination Concerning the Joint Venture Agreements

Mackey asserts that the knowledge and understanding of the JVA by those investors who testified at trial was relevant to their credibility and that Mackey should have been allowed to question the witnesses about the JVA risk provisions to challenge and impeach the credibility of the testifying investors. [152 at 13]. Mackey argues he is entitled to a new trial because the Court's limitation on the scope of cross-examination of the investor-witnesses violated his rights of confrontation and cross-examination, his right to present a defense and his due process rights. [152 at 14].

The Confrontation Clause guarantees a criminal defendant an opportunity to impeach, through cross-examination, the testimony of witnesses for the prosecution. United States v. Baptista-Rodriguez, 17 F.3d 1354, 1370 (11th Cir. 1994). A

examination.") (quoting Garcia, 13 F.3d at 1469). The interest of justice does not require a new trial based on the Court's limitation of Mackey's cross-examination of investor-witnesses.

D. Proposed "Theory of the Defense" Instruction

Mackey next argues that the Court's refusal to instruct the jury on his proposed theory of the defense "deprived him entirely of an opportunity to fully and specifically present his theory of his defense." [152 at 15]. The requested instruction provides:

> The Defendants' intent to commit an offense is an essential element of each of the offenses charged against the Defendants. In order to find the Defendants guilty of the offense of conspiracy, you must find beyond a reasonable doubt that each of the Defendants knowingly and willfully conspired to commit wire fraud or mail fraud. In order to find the Defendants guilty of the offenses of wire fraud or mail fraud, you must find that each of the Defendants knowingly devised or participated in a scheme to defraud or to obtain money or property by using false pretenses, representations, or promises, and acted with the intent to defraud.
>
> It is the Defendants' defense that the Defendants did not intend to defraud anyone and that they acted in good faith in investing investors' funds. If you find or possess a reasonable doubt that the Defendants did not possess an intent to defraud, or to conspire to commit fraud, you cannot find the Defendants guilty of the charged offenses. Likewise, if you find or possess a reasonable doubt that the Defendants acted in good faith, you cannot find the Defendants guilty of the charged offenses.
>
> You may consider all of the following as evidence to support any reasonable doubt that the Defendants did not possess the required intent to defraud, or to conspire to commit wire fraud or mail fraud, or that the Defendants acted in good faith:
>
> • Any evidence that the Defendants did not convert the investment funds to their own use;
>
> • Any evidence that the Defendants did not retain control of the funds, but sent the funds to other persons or entities for investment;
>
> • Any evidence that the Defendants actually invested the funds provided by investors;
>
> • Any evidence that the Defendants did not realize a profit from the investments;
>
> • Any evidence that the Defendants contacted any law enforcement agencies, including the Federal Bureau of Investigation, claiming that they had been defrauded by other persons or entities;
>
> • Any evidence that the Defendants did not want any new investors, and considered ceasing conducting business; and
>
> • Any evidence that the failure of the investments was merely a business venture which went bad.
>
> If any of the evidence above creates any reasonable doubt that the Defendants did not intend to defraud anyone, or conspire to defraud anyone, or leads you to conclude that the Defendants were acting in good faith, you must acquit the Defendants.

[109.1]. Mackey asserts that, "[s]ince there was some evidence supporting Mackey's proposed theory of the defense instruction, the Court should have given the instruction." [164 at 8].

"[A] refusal to give a requested instruction is an abuse of discretion if: (1) the instruction is correct; (2) the court did not address the substance of the instruction in its charge; and (3) the failure to give the instruction seriously impaired the defendant's ability to present an effective defense." United States v. Maxwell, 579 F.3d 1282, 1303 (11th Cir. 2009) (quoting United States v. Sirang, 70 F.3d 588, 593 (11th Cir. 1995)). Thus, while "the defendant is entitled to have presented instructions relating to a theory of defense for which there is any foundation in the evidence," United States v. Ruiz, 59 F.3d 1151, 1154 (11th Cir. 1995), the second prong of the analysis requires a court to determine also "whether the subject matter of the requested instruction was substantially covered by other instructions," United States v. Martinelli, 454 F.3d 1300, 1315 (11th Cir. 2006) (quoting United States v. Carrasco, 381 F.3d 1237, 1242 (11th Cir. 2004)).

E. Mackey's Additional Claims

Despite being represented by counsel, Mackey filed *pro se* his "Defendant's Amendment Reply to Government's Opposition Motion for a New Trial" ("Amended Motion"). Rule 57.1D(3) of the Court's Local Rules of Criminal Procedure provides:

> *Pro Se* Appearance Limitations. Whenever a party has appeared by attorney, the party may not thereafter appear or act in the party's own behalf in the action or proceeding or take any step therein unless the party has first given notice of the party's intention to the attorney of record and to the opposing party and has obtained an order of substitution from the court.

LCrR 57.1D(3), ND Ga.; see also United States v. Daniels, 572 F.2d 535, 540 (5th Cir. 1978) (a defendant has the right to represent himself in a criminal trial and he also has the right to the assistance of counsel, but he does not have the right to a "hybrid representation," partly by counsel and partly by himself). Mackey has not complied with the Court's Local Rules and his *pro se* filings are not properly before the Court. While not required to do so, the Court elects to address Mackey's arguments.

Mackey first contends that the Court erred in allowing the Government to introduce "hearsay testimony into evidence, from a deceased, unindicted co-conspirator," Archie McKinnon, who worked as an intermediary of ASM in dealing with investors, but who passed away in 2009. [163.3 at 1]. Several of the investor-witnesses testified at trial about their interactions with Mr. McKinnon and what Mr. McKinnon told them about ASM and the Government introduced emails sent by Mr. McKinnon to the investor-witnesses. The Court allowed the testimony and exhibits, but instructed the jury with each investor-witnesses' testimony that his or her testimony was not being offered for the truth of the matter asserted, and that the jury could consider the statements only to show the investor's election to participate in the ASM program. (See, e.g., Tr. at 496:18-497:1; 600:3-10; 726:24-727:1). These statements were admissible for the nonhearsay purpose as limited by the Court's limiting instruction. See Fed. R. Evid. 801(c); United States v. Jimenez, 564 F.3d 1280, 1287 (11th Cir. 2009) (admission of a statement made by a declarant whom the defendant has not had the opportunity to cross-examine, for a purpose other than for the truth of the matter asserted, does not violate the Confrontation Clause); United States v. Jordan, 316 F.3d 1215, 1258 (2003) (what defendant said to witnesses was admissible to show witnesses' state of mind).

Mackey next argues that the Government failed to disclose evidence related to the investigation of other Ponzi schemes in which Mackey purportedly invested. Mackey contends that "F.B.I. agent Rice did not give the defense any contracts nor did she say anything about the about the F.B.I. [sic] agents that defendant [sic] Mackey spoke to and testified to, in his trial." [165.3 at 3]. Under Brady v. Maryland, "suppression by the prosecution of evidence favorable to an accused upon request violates due process where the evidence is material either to guilt or to punishment, irrespective of the good faith or bad faith of the prosecution." 373 U.S. 83, 87 (1963). In deciding if a new trial is warranted based on a Brady violation, a defendant must show that: (1) the government possessed evidence favorable to him; (2) he did not possess the evidence and could not have discovered it with reasonable diligence; (3) the prosecution suppressed this evidence; and (4) had the evidence been revealed to the defense, there is a reasonable probability that the outcome of the proceedings would have been different. United States v. Newton, 44 F.3d 913, 918 (11th Cir. 1995). The exculpatory value of the evidence must be supported by more than the defendant§s "bare assertion" that it supports a particular theory. See United States v. Kersey, 130 F.3d 1463, 1466 (11th Cir.1997).

To the extent Mackey contends that the Government withheld evidence which would show that Mackey was an alleged victim of a Ponzi scheme himself, Mackey testified and presented evidence about his involvement in these other fraudulent investment programs, such as Eel River and U.S. Funds. The Court notes that the defense called Special Agent Eileen Rice, who testified about her interaction with Mackey, specifically that Mackey had reported to her allegations of financial losses in connection with investments Mackey made with other people's funds through ASM. Mackey was free to interrogate Agent Rice about documents or other matters he thought relevant to this case. Mackey does not present any evidence showing he did not possess the documents he suspects was denied and has not shown that the government failed to meet its discovery or Brady obligations. Mackey also fails to show that the outcome of the proceedings would have been different if he had the documents he suggests were withheld.

Finally, Mackey argues that "with the fact the defense counsel allowed all o [sic] these violations to his client's rights ... and counsel knew of all of the abuses of defendants [sic] rights, does raise the issue of his effectiveness." [165.3 at 6]. Mackey

representations were made to Mackey that any information produced would be kept confidential." Order (by docket entry), Feb. 9, 2012. It is axiomatic that "at the point where attorney-client communications are no longer confidential, i.e., where there has been a disclosure of a privileged community, there is no justification for retaining the privilege." United States v. Suarez, 820 F.2d 1158, 1160 (11th Cir. 1987). Mackey fails to present any evidence that he waived privilege for the purposes of the NYAGO proceeding only.

[6] Federal Rule of Evidence 502(c)(1) provides that a disclosure made in a state proceeding does not operate as a waiver of the attorney-client privilege in a federal proceeding if the disclosure would not be considered a waiver under the Federal Rules of Evidence if the disclosure had been made in a federal proceeding.

[7] To the extent Mackey asserts that the memo was prejudicial because Townsend's legal opinions and advice involved specialized knowledge, any perceived prejudice resulting from Townsend being an attorney was also addressed by the Court's limiting instruction, which provided: "Finally, I instruct you that the memorandum was written by an attorney. However, you must not consider the statements or opinions of the attorney in the memorandum as the basis of the Defendants' guilt or innocence of the crimes charged in this case." (Tr. at 469:3-7).

[8] For example, on cross-examination of Donald Bowen, Mackey's attorney showed Bowen his JVA and asked:

Q. You signed these; correct?

A. Yes, sir.

Q. And so it is your signature on these documents; correct?

A. Yes, sir.

Q. Prior to signing the document, did you review the contents of the document?

A. Yes, sir.

...

Q. ... Were you — is there a — to your recollection, a paragraph regarding risk in your agreement?

A. There is a paragraph I believe in there, something about risk.

Q. And did you read that?

A. Yes, sir.

Q. On page ten of your agreement at Paragraph 16 regarding risk, did you read that paragraph when you signed?

A. Yes, sir.

...

Q: Staying with the [JVA], I will refer you to page two, Paragraph 4, Subparagraph (A):

The earnings received from this joint venture agreement are based on a, quote, best efforts basis, end quote. No specific returns or guarantee of success, profit or safety are stated or implied.

Is that contained within your agreement?

A. Yes, sir, that's what it states.

(Tr. at 685:21-686:3; 687:7-687:15; 688:20-689:3).

[9] The Court notes further that Mackey provided testimony over two days that he did not intend to defraud investors, including because he disclosed that there was risk involved in investing and that rates of return were not guaranteed. In convicting Mackey, the jury appears to have found Mackey not credible and rejected the majority of his testimony.

[10] Mackey's proposed "good faith" instruction did not include the sentence, "The Defendants contend in this case that they did not intend to defraud investors and acted in good faith in making representations to investors." [73].

[11] The Court gave a similar instruction regarding the wire fraud counts: "The `intent to defraud' is the specific intent to deceive or cheat someone usually for personal financial gain or to cause financial loss to someone else." (Tr. Jury Charge at 10:8-10).

[12] In Bonner v. City of Prichard, 661 F.2d 1206, 1207 (11th Cir. 1981) (en banc), the Eleventh Circuit adopted as binding precedent all decisions of the Fifth Circuit Court of Appeals issued before the close of business on September 30, 1981.

[13] Mackey argues also that the Government introduced "perjured evidence," and parenthetically refers to Government Exhibit 1205, an April 2011 email from Mackey to an ASM investor, Judy Callaway, soliciting her participating in a questionable business opportunity. Mackey fails to demonstrate how this evidence was "perjured."