March 1, 2017

To the United States Office of Special Counsel regarding OSC File No. DI-14-3637:

I appreciate this opportunity to comment on the report published by the Department of Veterans Affairs Office of Medical Investigation in response to my complaints. The following information is offered as a rebuttal to the many inaccuracies I noted while reading their self-examination of facts as they pertain to the National Surgery Office and the National Transplant Program as a whole.

1) *Communication between referring and receiving centers is problematic and results in delay in care;*

The VA **substantiated** that problems existed but have been addressed. A team of more than 10 employees at the South Texas Veterans Health Care System (STVHCS) interviewed for 30 minutes or more per person regarding these systemic issues, and a very small fraction of what was reported is used in their findings. For example, our complaint was communication issues throughout the Veterans Administration Transplant Centers (VATCs) is problematic and results in delays in care. However, the OMI only investigated the Houston VATC and none of the others we are affiliated with and refer to. They (OMI) on page 4 use my statement of how difficult it is to communicate with the Houston VATC but then counter it with my statement that their kidney program has gotten better. This report does not address their substandard liver program (SRTR reports), nor does it address Nashville, Iowa City, Portland, or the many others we work with. We (STVHCS) continue to experience lag times greater than 24 hours for

responses from some of the VATCs, so our team would not agree that these issues are resolved.

2) *VATCs apply inconsistent and overly restrictive eligibility criteria in evaluating candidates for liver and kidney transplants, further limiting patients' access to care;*

The conclusions of VA's investigation are pending and will be included in their supplemental report.

3) *Effectively requiring veterans to undergo transplants at one of only six or seven VATCs located throughout the country, or at a handful of affiliated hospitals, often requires veterans and their family members to relocate for weeks or months, causing significant hardship to veterans and a substantial expense for VA;*

The VA **does not substantiate** that this travel is a violation of law, rule or regulation, mismanagement or a substantial and specific threat to public health. First, our center alone has numerous patients that cannot travel long distances with their social support person to receive transplants at these centers. They have families to maintain, children that need to attend school, etc. This also eliminates the ability to seek assistance from their extended family because of the distance they must travel. The Veteran literally declines transplant services and dies because of this issue. Not only is this common at our center, but numerous others experience these problems (Google VA Transplant travel issues for news articles/reports of other Veterans experiences). Yes, the OMI reports the VA does pay for travel assistance (airfare/mileage/hotel). However, numerous recent cases demonstrate support people, usually the spouse, spending months or years at the transplant center. How do they maintain their employment and pay their bills? To say this is not mismanagement and a threat to public health is simply false.

Second, the OMI reports examining date ranges and not noting a relationship between distance and time to transplantation. I specifically cited a report from Goldberg et al. (2014) to OMI and provided a copy of the results, which apparently were not used by the investigating team. Dr. Goldberg, who actively participated in news stories regarding his research and this systemic issue in the VA, examined over 50,000 cases in the VATC program and noted **"a greater distance…was associated with lower likelihood of being waitlisted, receiving a liver transplant, and greater likelihood of death".** Included in the findings are issues of living greater than 100 miles from a transplant center, which is exactly the case at STVHCS and our VATCs, and reduced abilities of the support people/families to relocate, which is exactly what I cited at the beginning of complaint number 3. The OMI on page 6 of their report note those Veterans living within 100 miles did receive evaluation and listing more quickly, but they found no relationship to time of transplant. The complaint that I made refers to actually being able **to be listed**, not an issue with time to transplant once listed. In reality, the OMI did not investigate the actual complaint. Of note, they also found that only 10 percent of Veterans who received transplant lived within 100 miles of a VATC, but they did not note that the majority live within 100 miles of a community based transplant center who could readily offer their services.

Third, the OMI on page 7 states the risks of coordinating care between two health care systems promotes an increased risk of hospitalization. The current system is that half of the VATCs use transplant services outside their own systems by contractual agreements, as noted in their own report. Is this not directly in disagreement with their own statements that this increases the risk of hospitalization? Wouldn't performing the

transplant and care at a community based system eliminate duplication of testing? The OMI also states transplantation care is complex but argue later in the paper that although our physician staff, cited in the paper as not being comfortable caring for this patient population, are sufficient to do so with outside community transplant centers assistance? This seems to be a contradiction as I have routinely identified in this rebuttal.

Fourth, the OMI finds that CHOICE is able to be used for transplantation and that community transplant providers will not agree to accept care of the donor at Medicare rates. I have directives from the VA Central Office (VACO) that state specifically CHOICE cannot and will not be used for pre-transplantation. The reason is that VACO has stated CHOICE cannot be used for the care of a non-Veteran, which is in direct conflict with congressional statements on the matter (Google VA Transplant and Congressman Jeff Miller, Mark Kirk, and John Cornyn). Also, more than 50% of transplants performed in the community are done at Medicare rates, which are readily accepted. The issue is that VACO has denied us access to local transplant contracts, which I have in the way of emails, and is counter to the statements of the OMI on page 7 that we are authorized to contract with non-Department facilities. Only recently have we been given permission to attempt contracts in the community, and this is only because of the pressure applied to leadership by the media in their pursuit of justice. We, STVHCS, have yet to obtain these formal contracts.

Fifth and finally, we are forced to work with substandard centers. The OMI notes on page 9 that the VATCs have "survival outcomes comparable to national survival outcomes". However, recent Scientific Registry of Transplant Recipients (SRTR) data demonstrates that the Houston VATC Liver Program is operating under expected survival

outcomes. We know this is factual because a few of our Veterans have died at their center post-transplantation. The community based centers in San Antonio are all noted to have as expected or above expected survival outcomes while transplanting more than 5 times the numbers of patients.

4) *VA medical centers often lack the level of specialty care required to treat and care for post-transplant patients;*

VA **does not substantiate** that a substantial and specific threat to public health existed. Our center, as **most referring** VATCs experience, lack specialists capable of providing care in house. STVHCS currently does not have a kidney, heart, or liver transplant specialist on staff. The OMI specifically cites a supervising physician and a gastroenterologist at STVHCS who state they are not adequately trained to care for this patient population. However, OMI feels since they have some training and local expertise available this is sufficient and not a threat to public health. VACO requires post-transplant patients to go by CHOICE as a first option, and the result is seen by delays of 3 months or more where the patient is not seeing a transplant specialist locally but is being seen by physician staff who state they are not adequately trained to provide the care this population needs. Although our center is working diligently to recruit these providers, their uniqueness and monetary value make it a remote possibility for hiring. In the long run we provide treatments we are not comfortable with, or we send them to the community where a transplant physician is asked to provide treatment they are not comfortable with and outside standard practices, or we determine their status (example hepatocellular carcinoma) for transplant based on limited knowledge. Again, this is not unique to our center. In speaking with numerous other referring VA facilities this is a

common theme. No further discussion is needed since this obviously demonstrates a specific threat to public health.

5) *VA's unwillingness to perform living donation kidney transplants denies patients timely, life-prolonging treatment options and results in VA spending millions of dollars in dialysis costs.*

VA **does not substantiate** that VHA is unwilling to perform living donor kidney transplantations. The OMI report noted that their VATCs only performed 10 percent of their kidney transplantations as living donors. However, they note national averages outside the VATCs are 31 percent, or age adjusted to 26 percent. This is a significant finding that is not substantiated? So, the VATCs performed 439 kidney transplants from January 2013 through December 2015. Of this number, 42 (10 percent) were living donations (p. 11). Had they performed at even the age adjusted 26 percent in line with the community average, the number would have been 114 transplants instead of 42, a difference of **72** cases. We know that dialysis costs alone are roughly $87,945 per year (CMS), not including more frequent hospitalizations, emergency room visits, graft revisions, etc. We also know that research consistently demonstrates the following:

1) Transplant is cheaper than dialysis over time
2) Transplant provides a longer, healthier lifespan than dialysis and prevents premature deaths

Dialysis Cost

72 cases not performed x $87,945 (dialysis cost) = $6.3 million dollars x 5 years = $31.5 million dollars

Transplant Cost

72 cases performed x $250,000 (transplant cost + first year) = $18 million dollars x 1 year, then $25,000 yearly (post-transplant medications/care) x 4 years x 72 cases = $7.2 million dollars = $25.2 million dollars

Even in overestimating the actual cost of the transplant and first year care, which is cheaper by Medicare cost analysis, the savings over a five year period versus dialysis is still in excess of $6 million dollars to our organization. This does not address the fact that dialysis morbidity and mortality are much higher versus transplant, so we in essence are increasing death rates among Veterans because of the inability or unwillingness to perform more living donor kidney procedures. This obviously highlights a threat to public health (early death from dialysis vs. transplant), and a waste of government funds.

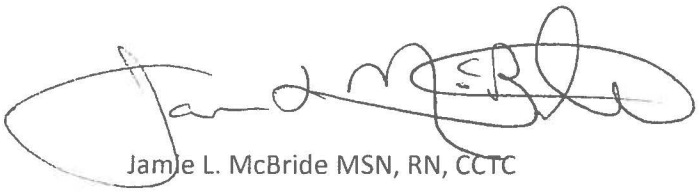
Conclusion

In conclusion, I believe I have identified numerous issues within the report. Although I do not possess a large staff that consists of researchers and stenographers, I am surrounded by medical professionals who know the truth in these facts. The local transplant community and my colleagues support these findings, and above all, the Veterans support them because they live this nightmare that is the VA Transplant Program on a daily basis. The frustrating part of this process is that other than my initial interview I was never again contacted by the OMI, and the pages and pages of data and information I cited here and submitted to them were not reproduced in the report. My experience is that self-investigation tends to produce this type of finding.

March 1, 2017

My appreciation goes out to the staff of the Office of Special Counsel for their assistance in this process. I truly appreciate the opportunity I was provided to speak out on behalf of our Veterans in the initial investigation and this subsequent rebuttal I have authored and submitted.

Sincerely,



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