Staff Summary
Life Alliance Organ Recovery Agency (FLMP)
HRSA-directed onsite peer visit

Please note that this accompanying summary information is included to only supplement the original documentation, and assist the peer team members in their thorough review of the source documentation provided onsite at the member OPO and in the peer review packet.

Staff Summary: On May 12, 2021, HRSA directed the Organ Procurement and Transplantation Network (OPTN) to perform an in-person investigation of Life Alliance Organ Recovery Agency (FLMP). This investigation is based on concerns provided to HRSA by the OPTN Membership Professional Standards Committee (MPSC) and the determination of an ongoing risk to patient health and public safety.

The MPSC has identified concerns about the professional culture and environment, at both the staff and administrative levels, whereby staff is uncomfortable stopping processes to identify errors. QAPI meetings appear to be focused on reporting of issues instead of performance improvement and FLMP does not appear to have tailored the QAPI plan to its specific needs. The MPSC also believes that improved patient safety training may be needed at all levels of staffing and that there may be a lack of consistent leadership accountability. A complete list of recent cases along with specific Committee concerns can be found at the bottom of this document.

Please review this summary completely before starting review of FLMP documentation in the **FLMP Peer Visit folder** linked below on page 3.

Relevant Policies:
2.15.H Organ Recovery: "Organ recovery will only proceed after circulatory death is determined, inclusive of a waiting period of circulatory cessation to ensure no auto-resuscitation occurs."

Member Timeline of Events

Date	Event
Dec 2015	The OPTN Board of Directors declared FLMP a Member Not in Good Standing based on the MPSC's review of culture issues and relationship problems in the DSA that may impact patient safety and the integrity of the transplant system. The MPSC's recommendation was based on multiple reported issues between 2013 and 2015, and the investigation included a peer visit.
July – Aug 2016	During the MPSC's review of FLMP, UNOS received anonymous complaints from someone who appeared to have organizational information, possibly an employee. The themes of the emails were staff turnover, training issues, and a toxic work environment. After discussion, HRSA directed the OPTN to conduct another HRSA-directed peer visit of the OPO to investigate progress during the OPO's period as Member Not in Good Standing and evaluate changes in the organization's general culture.
Oct 2016	The MPSC reviewed the new peer visit report which found that the OPO is making progress, although the progress seems slow. The team identified QAPI and leadership as the biggest challenges for the OPO moving forward.
Oct 2017	The MPSC felt that FLMP had made tremendous progress, and was on the right track to move forward and continue improving the organization. The MPSC

	recommended that the Board of Directors release FLMP from the adverse action of Member Not in Good Standing.
Dec 2017	The OPTN Board of Directors released FLMP from Member Not in Good Standing.
Feb 2019	Notice of Noncompliance for bypassing a transplant center when allocating a kidney, requiring the OPO to withdraw a primary offer.
Feb 2019	Notice of Noncompliance for allocating a liver-kidney to a candidate that was not eligible for SLK.
Feb 2020	Notice of Noncompliance for allocating three donor's hearts and/or lungs out of sequence. The MPSC was concerned FLMP appeared to unnecessarily expedite the recovery OR for these donors.
Feb 2020	Interview with the MPSC after the Committee reviewed a report FLMP staff recovered organs prior to asystole, despite family only authorizing DCD recovery. The MPSC initially recommended Probation, but after the interview the Committee decided to issue a Letter of Warning and continue to monitor FLMP.
July 2020	OPO staff incorrectly entered an EBV IgG result as negative in DonorNet, closed for self-reporting.
July 2020	The MPSC reviewed FLMP's submissions requested after its February interview. The MPSC reviewed the most recent QAPI plan; the most recent QAPI metrics; examples of recent RCAs OPO has conducted; and QAPI meeting minutes. The MPSC expressed concerns in its review, and requested that the OPO participate in a peer visit, but delayed that visit due to the COVID pandemic.
Feb 2021	FLMP staff affixed TransNet labels with the wrong ABO information on the liver, blood, tissue, and shipping packages. After reviewing this case, and taking into account the FLMP's other recent cases, the MPSC is considering recommending Probation. The MPSC also suggested conducting the peer visit as soon as possible. The OPO will have an interview at the July MPSC meeting.

Survey information: A routine on site survey of the OPO occurred on June 26, 2018. The OPO had a clinical score of 99 percent and a few administrative errors. The MPSC reviewed the results of the survey at its meeting in February 2019 and closed the review with no action.

OPO Volumes

Year	Donors Recovered	Organs Recovered
2018	149	536
2019	157	585
2020	211	672
2021	64*	217*

*As of June 4, 2021

Items for consideration: Please review the documentation provided in the peer visit folder to prepare for the onsite peer visit. Identify specific areas of concern based on your review of the documentation and be prepared to share your concerns with the peer team before the onsite visit and interview OPO leadership and staff accordingly. If you would to see specific member documentation or donor records while onsite, please let me know as soon as possible.

Supporting Documents: OPO 135169P Monitoring

Recent Cases and Specific MPSC Concerns

- **February 2019: Notice of Noncompliance for allocating a liver-kidney to a candidate that was not eligible for SLK.**

  Subcommittee Concerns after Initial Review: "The OPO noted this error (simultaneous Liver Kidney allocation) one day after the donor OR when match-run was being reviewed by internal QA. Had the OPO performed a "time-out" or "Huddle" with AOC prior to donor OR it would have been noted that recipient was not correctly identified as being on the match run. OPO does not routinely contact AOC to review allocations when a kidney is involved. They note that they always take this step for non-renal, multi-organ allocations. This safety step appears indicated in all allocations not just multi-organ situations."

- **February 2019: Notice of Noncompliance for bypassing a transplant center when allocating a kidney, requiring the OPO to withdraw a primary offer.**

  Subcommittee Concerns after Initial Review: "This was self-reported which is good. The OPO however states it is considering limiting multiple staff from making organ offers on a case. This should be implemented. Disciplinary action and staff retraining is not sufficient as this could occur again. Especially given the OPO's history with strained relationships in the DSA, it is imperative that the OPO conduct organ offers in a manner that will minimize withdrawing offers or confusion over which center is primary."

- **February 2020: Interview with the MPSC after the Committee reviewed a report the OPO recovered organs prior to asystole, despite family authorization. The MPSC initially recommended Probation, but after the interview the Committee decided to issue a Letter of Warning and continue to monitor the OPO. However, the MPSC was very concerned the OPO re-approached the donor's mother months after organ recovery and asked her to submit a letter stating she verbally authorized DCD recovery.**

  Full MPSC Concerns

  "The letter bothered me. It's something he [the OPO director] could have obtained an affidavit from people that were in the OR that said it was clear, the intent was clear from the professionals involved. Approaching the grieving parent for that shows a lack of judgement and I don't understand how he could perceive that this body was asking for that."

  "My concerns with this case going in have not been alleviated because at the end of the day...they have only demonstrated now in my years of experience of talking to them...that when told we want you to do x, y, z and produce documentation they will do it but are never ahead of the game. They never come and say we had this problem and here is how we fixed it. There's nothing proactive, it is all reactive and is basically filling in the blanks of what any reasonable person could interpret from our comments, questions, and requests for information. So we may not have an issue of recurrence of this particular event again, which it the traditional definition of risk of recurrence, but we have a likely recurrence there are other huge holes in their process from an operational standpoint and a quality standpoint. The questions I asked lead me to believe they have changed their policy but they really haven't changed

their mindset as to how they're approaching this. There aren't going to be policies or protocols to cover every nuance...but at the end of the day the ability to stop and have a constructive thought process about what might work, what might go wrong and then be able to defend that is not there...I do doubt they have any meaningful QAPI process, that their policies prepare their staff to deal with challenges that they have, and that their administrators on call are properly engaged to say okay, this is how we're going to handle this. There were a lot of good questions that were asked here that they just were not able to process...They need to get the strongest message we feel is appropriate that they have serious operational issues relative to their quality and their policies."

"Just go back the last 12 months. This OPO bypassed a transplant center while allocating a kidney, which required them to withdraw an offer; allocated a kidney for an SLK to somebody that wasn't on the SLK list; and now has this. And they actually have the audacity to say this isn't as bad as a ABO error. This is a process problem, and the list is ten years long. I think with where we go, it would be okay – well, it wouldn't be okay – if this was their first time in front of us, I think you could look to say there's a learning opportunity, but I think they probably failed that part of grade school. I know they're turned over leadership and everything, but we're going to be here 12 months from now talking about another event going oh we didn't see this one coming, but it will be the same OPO."

"They have a systemic issue with quality systems. Our peer review teams looked at that, our peer review teams were concerned about it. We felt like they had fixed it, and here we have how many incidents since they've be released as a Member Not in Good Standing...it's the same cycle over and over again...you need to think very carefully about what message you are sending them, because they will be back."

- **February 2020: Notice of Noncompliance for allocating three donors hearts and/or lungs out of sequence.**

Subcommittee Concerns after Initial Review

Reviewer One: "Recommend notice of uncontested violation for violations of policies 5.4, 6, and or 10. A couple of these cases are sloppy but there is no real policy violation, just unnecessary delays or questionable interpretation of stability. The remainder appear to me to have been poorly managed cases (medically or logistically or both), and were thus expedited unnecessarily. I would like to ask staff to look at where the organs were expedited to (which center or centers) and whether they are in the OPOs DSA or affiliated hospital. This OPO has a long and checkered track record extending back roughly 6 years and some of that history has involved allocation practices. If these are being expedited to a local center, I'd like to discuss and possibly discuss raising this to a letter of warning." *(UNOS staff note: Two organs were allocated to local centers; three to regional centers; and two to national centers.)*

Reviewer Two: "This is not a huge number of allocation variances given the organ transplant volume. But I am concerned that four of the seven appear to have no rational basis. I am also concerned about the possibility that allocation is being expedited to benefit a local center; we are unable to see who the ultimate transplant center was, so this is unproven. But even if these are being allocated to non-local centers, the reasons for out-of-sequence allocation are not acceptable. I think this should go on the discussion agenda. [redacted] (LU) Lung allocation should have continued and the OR held until it was completed. There appears to be no clinical reason to expedite this OR. Recommend notice of violation. [redacted] Long delay in lung allocation from 2314-0619. Doesn't seem to have bypassed as many candidates as suggested; lots of refusals. Close with no action. [redacted] Long delay in allocation start,

then a seeming rush to have the case completed by Christmas. But echo was sub-optimal, so likely not able to place with anyone else. Close with no action. [redacted] There appears to have been a significant delay in brain death to allocation (>6 hours, with time before brain death available for additional testing to be performed). Especially on a case where family is pushing to go to recovery sooner, this should have been expedited. This can be closed with no action because it's not a policy violation, per se, but it's not good practice either. [redacted] Reason given is donor instability. Allocation not begun for ~24 hours after brain death (registered donor). Conflicting reports of donor stability. This donor did not need to be expedited. The reason given is "family time constraints" but this was a brain dead registered donor, so time constraints should not have been an issue. Recommend a notice of violation on this one. [redacted] This was two late declines prior to OR (the first about 2 hours prior to the first OR time, the second about 4 hours prior to the second OR time), but the OPO was able to re-schedule a 3rd OR for ~22 hours after the 1st OR time, and they completed heart allocation >12 hours prior to this 3rd rescheduled OR. They should not have expedited heart placement, but should have continued normal allocation procedures until the heart was placed. (Of note, the late-declining centers hold some responsibility in this as well.) Recommend notice of violation. [redacted] (HR) Heart allocation should have continued and the OR held until it was completed. There appears to be no clinical reason to expedite this OR. Recommend notice of violation."

Reviewer Three: "I'm not sure if policy violations have occurred but their history and behavior are certainly concerning as pointed out by my colleagues on this discussion."

- **July 2020: OPO staff incorrectly entered an EBV IgG result as negative in DonorNet, closed for self-reporting.**

Subcommittee Concerns After Initial Review: "I will support a close with no action, but I feel obligated to mention that this same OPO was noted on a recent MPSC discussion to have problems with staff not feeling empowered to speak out on perceived errors. This is another example of that kind of situation, and I am concerned that perhaps leadership telling us that staff feels empowered is not the same as staff feeling empowered."

- **July 2020: The MPSC reviewed OPO's submissions requested after its February interview. The MPSC reviewed the most recent Quality Assurance and Performance Improvement (QAPI) plan; the most recent QAPI metrics; examples of recent RCAs OPO has conducted; and QAPI meeting minutes. The MPSC expressed concerns in its review, and requested that the OPO participate in a peer visit, but delayed that visit due to the COVID pandemic.**

Subcommittee Concerns After Initial Review

Reviewer One: "The QAPI plan looks good on paper but does looks like it was pieced together from other sources and not created specially to meet the needs of the organization. Certainly we all borrow and cut and paste at times, why reinvent the wheel, but this goes beyond that level. The QAPI minutes do not show the process improvement, responsibility assignments and follow through that I am used to seeing when a Quality work group comes together. As was noted it seems more a round table report of activity than a process improvement road map. I am concerned by the long history and continued culture issues. I honestly do not have a good recommendation. The MSPC put a lot of time and effort into coaching and helping and it doesn't seem to have moved things forward as much as we would like... Is there some sort of Peer mentoring that can be recommended? Maybe a more hands on

approach from an OPO with a highly functioning highly efficient Quality department can assist more than the MSPC has been able to?"

Reviewer Two: "My general thoughts after reviewing FLMP's documentation:

- I continue to have concerns that they "get it". After countless hours spent reading documents about this OPO over five-plus years, participating in a number of interviews, formal discussion, informal discussions, and a hearing, I still do not have a sense that they understand their issues in the realms of policy violation, safe and appropriate operations, or quality.
- I continue to have concerns that they submit significant amounts of verbiage that looks like the equivalent of stock photos. In other words, they buy and read books then transcribe the lingo into a policy document but when issues arise, their application of the policy indicates they don't fully understand their own policies.
- I continue to be concerned that they frequently do not provide everything we ask of them nor do they proactively provide much of what they should if they had a true grasp of the issues. In most cases, they are like a witness being led by the questioning lawyer: "You have a QAPI plan? Please provide it." Then it arrives.
- The MPSC has, since 2015 at least, provided them with countless hours of consulting and guidance at who knows what cost. Yet they are still before the MPSC, not because they have failures or errors (every OPO and transplant center does), but because of their reaction or lack there-of.
- Their overall quality culture, and for that matter, the core organizational culture is still lacking, in my opinion. Mention is made in these documents that staff are uncomfortable asking questions.

I am troubled that this member has been under scrutiny since at least 2015 and remains under scrutiny. It is further troubling that this level of scrutiny is not superficial nor has it been for unconnected issues but rather that it is a continuation of the same themes: lack of a quality culture, lack of understanding, lack of progress, and ineffective leadership/governance. Finally, it is troubling that after all the effort the MPSC has put into educating, leading, and sometimes guiding this member, they are still in this state. My recommendation is continued high-level monitoring, further sanctions to hopefully get their attention (although MNGS obviously didn't work), and further communication with the Secretary as there is something clearly broken here that five-plus years of significant intervention and oversight have been unable to address."

Reviewer Three: "Common themes appear to continue after discussions with them, those of culture, clarity of procedures and execution of quality systems. With the letter of warning they received, I am not sure the next steps to be taken. They still need monitoring and help – although they don't appear to think they do."

Full MPSC Concerns

"During the in person interview with the OPO we gave them some very clear feedback around their quality program, their QAPI program in general, how they can set that up. In looking at what they have submitted my concern as an MPSC member is that if we just continue to monitor then it's as if we're telling the OPO what their providing is appropriate at this point and we're going to continue to monitor to make sure that continues and then potentially release them. I think what we're seen is there's not a strong culture of quality. The QAPI program looks more like a huddle process or a roundtable discussion, not necessarily a review or an improvement process. I think we're setting ourselves up to likely have this same type of discussion in our next meeting as MPSC members because I think we're

going to continue to see problems. And I'm wondering if it is time to escalate instead of just continue to monitor...I'm wondering if we can continue to monitor with a peer visit when possible."

- **February 2021: FLMP affixed TransNet labels with the wrong ABO information on the liver, blood, tissue, and shipping packages. After reviewing this case, and taking into account the OPO's other recent cases, the MPSC is considering recommending Probation. The MPSC also suggested conducting the peer visit as soon as possible.**

  Subcommittee Concerns After Initial Review

  Reviewer One: "A notice of noncompliance is the bare minimum for this. Though it won't make me popular, I think we should bring this before the entire committee, given the OPO's sordid history with policy compliance. This seems to be further evidence of poorly-developed procedures. I would like to see better patient safety training for their leadership and staff."

  Reviewer Two: "Vote no-I see value in the full committee discussing this case. I think we should consider a Letter of Warning as this seems to be a near miss in terms of misreporting a donor ABO."

  Reviewer Three: "We have engaged with this member many times; they are well known to us from prior MPSC engagements. Does a policy violation exist? Yes. Has CAP addressed problem? I believe so. RCA looks appropriate, CAP appropriate. Recurrence unlikely. No systemic quality issues seem evident. I see no reason for going above a level of Notice of Noncompliance. A policy violation did occur, so a Notice of Noncompliance is certainly warranted. I advocate for issuance to member of Notice of Noncompliance."

  Reviewer Four: "This OPO has had 6 events reviewed by MPSC within the past 2 years including a letter of warning and on-site peer review pending. This latest event highlights on-going patient safety concerns at the staff level as well as the administrative level (AOC). I appreciate the response and CAP to the latest issue, but in the presence of the extensive history with policy violation, I support full committee discussion."

  Reviewer Five: "I vote no to include this labeling error of ABO blood type into the previous letter of warning (February 2020) for an on-site peer visit which is currently pending. Normally, I believe a notice of noncompliance would be appropriate however this OPO has had three notices of noncompliance in the past 18 months in addition to the letter of warning. This suggests a problem with culture and leadership in this OPO which needs to be addressed."

  Reviewer Six: "I vote no and recommend a full committee review to discuss. This is the 6th violation in a short period of time with this one involving a discrepancy in ABO documentation. With the known MPSC history, it seems this OPO needs to implement additional levels of quality checks and consistent leadership accountability."

  Full MPSC Concerns

  "I want to agree the virtual peer visit, it seems unlikely to best get at these cultural issues, and also not as good to convey messages that we are really feeling that something needs to change. I just wonder why don't we just do a peer visit? I know there must be impediments, but we figured out how to transplant during this pandemic. We're talking about an OPO that has recovered over 600 organs in a

year, so shutting it down seems like a bad idea, but we're highly concerned. This just reaches the highest level of concern, so why aren't we doing a peer visit? It seems like that would help guide us with these other things like referral to the HHS. It seems like it would be hard to refer to the Secretary without having boots on the ground."

"I think it [the peer visit] needs to be in person rather than virtual. I think it needs to be a team who can meet with a lot of different people in the OPO. The office environment being what it is in COVID it may not be as easy to happen in an unplanned fashion, which I think would be best. You know, the idea of just happening to pull someone aside while we're there and saying they come and talk to me for a few minutes. We need to do something like that. I personally volunteer to travel; I think it is that important."

- **June 2021: The HRSA-directed MPSC onsite peer visit of Life Alliance Organ Recovery Agency (FLMP) occurred on June 16-17, 2021. The peer visit report is located in the Subcommittee Documents folder-OPO 135169P Monitoring.**