Date: January 31, 2022

To: Centers for Medicare and Medicaid Services (CMS), HHS

From: LifeGift, Houston, Texas (Organ Procurement Organization)
Contact Lauren Quinn, VP for External Relations lquinn@lifegift.org for further information

Re: 86 FR 68594, CMS-3409-NC Request for Information; Health and Safety Requirements for Transplant Programs, Organ Procurement Organizations, and End-Stage Renal Disease Facilities

LifeGift, the organ and tissue procurement organization based in Houston, Texas appreciates the opportunity to provide information in response to the RFI CMS-3409-NC. LifeGift is one of the largest OPOs in the United States both in terms of service area size (geography) and in organ and tissue donor referrals (50,000+), authorized organ donors coordinated (578), organs recovered (1,523), and organs transplanted volume (1,254 in 2021). LifeGift also coordinated through our Organ Placement Center 576 distinct organ offers resulting in 421 additional organs transplanted in our partner transplant centers located in our DSA (see https://www.srtr.org/reports/opo-specific-reports/interactive-report?center=txgc&type=OPO). We also coordinate long distance organ recovery for multiple large transplant centers (8 of 9), provide kidney perfusion services (600+ kidneys perfused/pumped in 2021) and recover tissue as an AATB accredited and FDA approved recovery agency. Below is a snapshot of LifeGift:

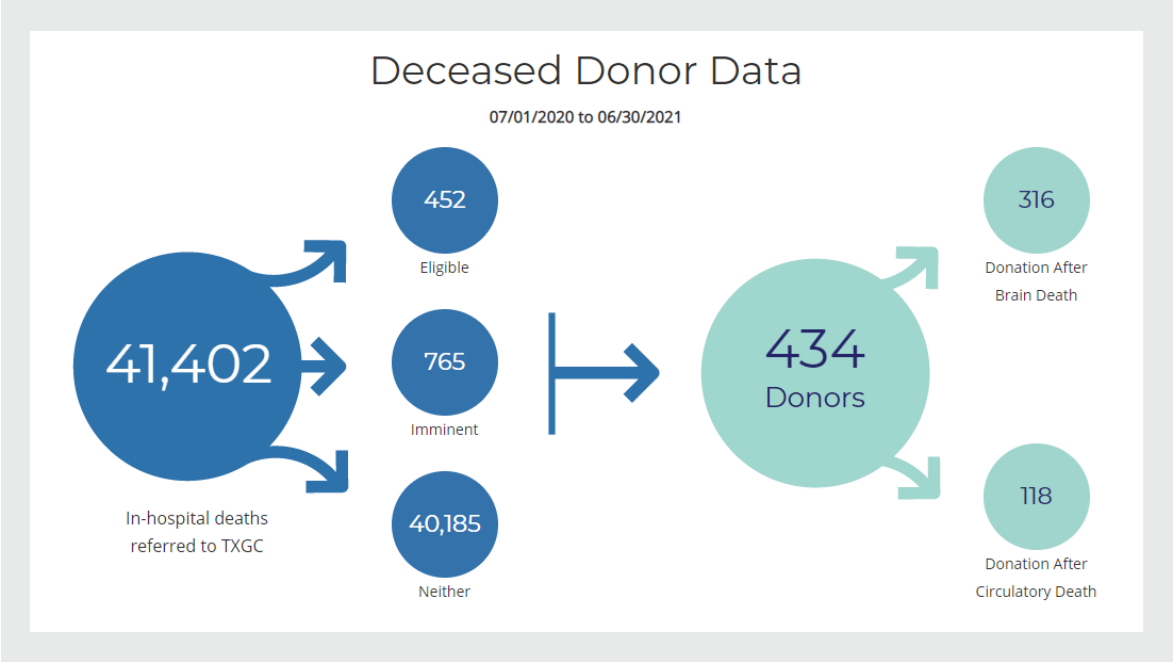
LifeGift Organ Donation Center (TXGC)
Population Served: 11,155,342
Population Density: 106 persons/mi2
Population Rank: 7 among the 57 DSAs
Land Area Served: 105,325 square miles
Land Area Rank: 9 among the 57 DSAs
Deaths: 76,048
Deaths per 1,000: 6.82
Deaths Rank: 10 among the 57 DSAs

In addition, we are actively engaged in numerous critically important research projects and have a strong track record of active participation in industry impacting projects (GTEx[1] completed 2017; dGTEx[2] starting this January, 2022; Stanford Donor Heart Study, Donor Hypothermia Study, Donor Management Goals Project, Hope Project for HIV+ donors, etc.). In summary, we are a full-service, expansive healthcare services organization that is deeply involved and committed to increasing donation and transplantation

and to supporting cutting edge medical and deceased donor research. We appreciate the opportunity to provide comment to the CMS RFI and have provided select feedback on specific questions that pertain to the OPO community.

We are seeking ways to harmonize policies across the primary HHS agencies (CMS, the Health Resources and Services Administration (HRSA), and the Food and Drug Administration (FDA)) that are involved in regulating stakeholders in the transplant ecosystem so that our requirements are not duplicative, conflicting, or overly burdensome.

We applaud this effort to harmonize systems and requirements. We suggest the removal of inconsistent potential donor classification "imminent, eligible" from UNOS data collection to make this process consistent with CMS changes already in effect. These definitions are antiquated and do not reflect the large number of referrals received, especially with the CMS new definition of donor potential. Per SRTR reporting, in a 1 year period of time (07/01/2020 to 06/30/2021) LifeGift received over 41,000 in-hospital death referrals, of which 97% did not meet the definition for UNOS organ donor potential. That is just over 1,200 or 3% of the total volume. In 2021 with the large numbers of COVID disease related deaths, LifeGift received 48,678 death referrals, of which 47,539 (97.7%) did not meet the criteria (463 eligible, 676 imminent).



https://report.srtr.org/opo/txgc

[1] The Genotype-Tissue Expression (GTEx) Project was supported by the Common Fund of the Office of the Director of the National Institutes of Health, and by NCI, NHGRI, NHLBI, NIDA, NIMH, and NINDS.

[2] The goal of the dGTEx initiative is to establish a resource database and associated tissue bank to study gene expression patterns in multiple reference tissues during human developmental stages, building upon the recently completed **Genotype-Tissue Expression** (GTEx) project.

Are there any current requirements for transplant programs, ESRD facilities, or OPOs that are unnecessarily duplicative of or in conflict with OPTN policies or policies that are covered by other government agencies? What are the impacts of these duplicative requirements on organ utilization and transplant program/ESRD facility/OPO quality and efficiency?

The specific redundant requirements are too numerous to be highlighted in this response; however, creating a crosswalk of current requirements and policies would highlight duplicative requirements that may be practical to consolidate. We also suggest a role for CMS to consolidate the numerous regulatory inspections to reduce administrative burden on OPOs and transplant centers.

Are there additional requirements that CMS could implement that would improve the manner, effectiveness and timeliness of communication between OPOs, donor hospitals, and transplant programs?

We ask CMS to consider specifically the role of the donor hospital in the donation process and the opportunities for increasing donation through stronger accountability for the donor hospital's responsibilities. While CoPs do currently address the donor hospital's role in facilitating donation, the OPO is generally disenfranchised from holding hospitals accountable for specific duties carried out during donor cases as well as overall donation outcomes. We have shared some examples of this below. We believe there is a role for CMS to include more specific requirements to this subspecialty that will positively impact the donation process and are not burdensome to hospitals.

While hospitals are required to provide services that support the evaluation and recruitment of organs for transplant, such as bronchoscopies and cardiac catheterizations, cases can be delayed or organs can lose viability for transplant due to an inability to secure these services in a timely manner from the hospital where the donor is located. We also face these risks continuously in securing an Operating Room (OR) at some donor hospitals for organ recovery. Scheduling an OR involves the careful coordination of up to six transplant teams traveling from offsite locations to the donor hospital. This process becomes more complicated when the organ recovery is delayed by the hospital due to use of the OR for other procedures, some of which are not emergent or even urgent. At times the delay is necessary, as when trauma cases must take precedence. Other times, the organ recovery is delayed for an elective procedure that can be easily rescheduled or moved for a life-saving procedure such as an organ recovery. These delays can result in the loss of organs for transplant as transplant teams may not be able to comply with necessary surgery times rescheduled at the last minute, or families may rescind authorization due to the length of case times. There is currently no CoP that addresses or monitors the donor hospital's responsibility to provide an OR in a timely manner for the purposes of organ recovery. We suggest specific guidance for hospitals on this opportunity.

We have found challenges with some hospitals in recent years in moving potential donors to hospice services to avoid the patient death being listed on the hospital mortality report. This is particularly impactful for potential Donation After Cardiac Death (DCD) donors, as we have experienced hospitals transferring these patients to hospice service earlier in the care of the patient, especially when virtual hospice is an option. Hospitals are not required to refer hospice patients to the OPO so there are missed opportunities for donation. There is a role for CMS to provide guidance to hospitals such that deceased donors/potential donors are exempt from mortality calculations.

As DCD cases continue to increase each year, we believe there is an opportunity for CMS to clarify the responsibility of the donor hospital to provide a physician or physician extender to declare cardiac death prior to DCD organ recovery. In most DCD cases, the patient is extubated in the OR or moved immediately to the OR after extubation but prior to death. In these cases, the attending physician or his/her designee is required to be proximate to the patient and at time of circulatory death, provide formal declaration of death. As DCD cases can require a physician to stay in the OR for up to 120 minutes, it can be very difficult for an OPO to secure a physician willing to commit that time, which can delay cases or even lead to loss of a donor.

We also respectfully request that CMS consider strengthening the hospital's accountability for its responsibilities in implementing action items to improve overall donation outcomes. At LifeGift, we provide hospitals with a monthly dashboard highlighting key performance indicators associated with a successful donation program, such as timely referral rate, collaborative approach rate (the number of times a potential donor family was appropriately approached by a designated requestor), and donation rate (the number of donors out of all potential donors). We also provide timely follow-up and feedback when there is a missed death referral or barrier to donation during a referral or organ donation case. CMS requires that the hospital integrate its organ, tissue and eye donation program into the hospital's QAPI program (§482.45(a)(1)). However, our experience has been that while many hospitals seek to improve their donor program, some hospitals do not take proactive steps to ensure donation outcomes are optimized at their institution, such as developing and implementing an improvement plan when there a high number of missed death referrals or when a timely referral rate or donation rate are below expectations. Some hospitals consider the LifeGift-generated dashboard to be evidence of their hospital QAPI program. Given the importance of the donor hospital in donation outcomes we ask CMS to consider ways to hold hospitals more accountable for improving outcomes when hospital key performance indicators fall below goals or predetermined expectations.

Are there additional data, studies, and detailed information on why the current number of organ discards remains high, despite CMS' decision to eliminate the requirements for data submission, clinical experience, and outcome requirements for re-approval?

Yes, harmonizing oversight by UNOS/OPTN with oversight by CMS would reduce current regulatory pressure while still maintaining vigilance for performance improvement and patient safety. In addition, organ discard data is difficult to understand because of a lack of specific and uniform nomenclature pertaining to such topics as "late turndown of organ" and "size difference," etc. Detailed data in this area is essentially unavailable on a system level due to reluctance at UNOS/OPTN/HHS levels to add necessary data points to better understand the issues in detail.

While it is important to create incentives to utilize available organs for transplantation and to create disincentives to reduce organ discards, the regulatory community including CMS should work to find ways to help OPOs accept that some recovered organs are too medically complex for utilization. Neither the OPO nor the transplant programs should be penalized for recovering and evaluating organs for appropriately matched candidates, even if the organ is discarded for valid reasons. Recovered organ donors from which no organs are transplanted ("zero organ donors" should be counted in the total donor count (donation rate) and should be excluded from the denominator when estimating the transplant rate. This adjustment aligns the important metric and recertification requirements with clinical practice.

In addition, removing the UNOS/OPTN policy requirement 8.7.b to have all "national offers for kidneys" go through the UNOS Organ Center (the OPO must allow the UNOS Organ Center to take over kidney allocation on these most difficult organs to place) would allow OPOs to handle these medically complex kidneys themselves, rather than creating additional complexity and slowing down organ allocation time. This is a singular and extremely outdated and misdirected policy still in the policy requirements from a different era and created with no justification for increased utilization. UNOS has received numerous requests from LifeGift and many other OPOs to make this change over the past 3 years and to date, nothing has changed.

Similar to the outcome requirements that OPOs must meet, should CMS again consider additional metrics of performance in relation to the organ transplantation rate, considering that the number of organs discarded remains high? What should these metrics be? Are there additional quality measures that CMS should consider to measure a transplant program's performance?

Numerous publications such as: (Goldberg DS, French B, Lewis JD, Scott FI, Mamtani R, Gilroy R, Halpern SD, Abt PL. Liver transplant center variability in accepting organ offers and its impact on patient survival. J Hepatol. 2016 Apr;64(4):843-51. doi: 10.1016/j.jhep.2015.11.015. Epub 2015 Nov 25. PMID: 26626495; PMCID: PMC4799773) highlight the fact that it is not uncommon for transplantable organs to be repeatedly declined by centers at varying levels without patient knowledge or monitoring by any regulatory agency. While it is critical to support clinical/medical judgement, there is a need to identify centers that are statistically declining more organs than peer group centers. While OPOs are appropriately required and incentivized to recover all organs with attention to older and more medically complex donors, centers are not incentivized to use these organs even when acceptable quality outcomes are possible.

Are there revisions that can be made to the transplant program CoPs or the OPO CfCs to reduce disparities in organ transplantation?

There is a role for CMS to encourage transplant hospitals to accept broader types of insurance/ reimbursement including Medicaid to help patients in financial need overcome financial barriers that are silent access limiters, especially in areas where there are lower levels of private insurance coverage availability.

Further, are there ways that transplant programs or OPOs could or should consider social determinants of health in their policies, such as those relating to requesting consent for donation, patient and living donor selection, or patient and living donor rights?

We suggest further research and support in these areas from academic experts not necessarily from OPO backgrounds. We welcome input and suggestions for improving access to communities and populations which donate at levels below the mean. SRTR collects and reports race of recovered organ donors for each OPO compared to the national average. The information for LifeGift is here under "Donor Date" as an example:
https://www.srtr.org/reports/opo-specific-reports/interactive-report?center=txgc&type=OPO

We suggest CMS require inclusion of OPO or donation information in the vast array of required social services/programs already in place in communities that could serve as an additional method of sharing information to communities who may have difficulty accessing this health information. This requirement would help create a smoother pathway into communities through other service providers that would allow OPOs to facilitate more awareness of donation. We suggest including in the wide array of already distributed preventive health information around tobacco cessation, hypertension, etc.

How can those in the transplant ecosystem better educate and connect with these communities about organ donation, so as to address the role that institutional mistrust plays in consenting to organ donation?

There is a role for CMS to assess OPOs workforce diversity as well as financial resources allocated to these types of programs and establish incentives for OPOs to bring greater material commitment to this important area of opportunity. CMS can require a formal process for each OPO to formalize and report its DEIB programming. In addition, there is an opportunity to consider increased cost reimbursement for this specific type of community education and outreach.

How can the CoPs/CfCs ensure that transplant programs, ESRD dialysis facilities, and OPOs distribute appropriate information and educate individuals in underserved communities on organ transplantation and organ donation?

We again suggest the role for CMS in requiring that this type of information be provided with other community health outreach to make the distribution of this information more efficient and consistent. Utilize the same evidence-based approaches already in place for years for health information on prevention of diabetes, hypertension, etc.

Independent of CMS' specific outcome measures, what other metrics or attributes reflect a model or highest performing OPO?

Every OPO in the U.S. has the opportunity to commit to research and innovation programs. This additional and critically important effort should be recognized as a differentiator among clustered OPOs. For example, every OPO in the U.S. should be required to participate in HIV donor organ recovery as it seems inexcusable for any OPO to not contribute to this important work. That is one example of a clear differentiator that highlights an OPO that is working to expand its impact both in clinical areas (more donors, more organs transplanted) and in research/scientific areas.

What are quantitative or qualitative indicators of excellent performance and how can CMS incorporate these with outcome measures when assessing OPOs for recertification purposes?

We suggest organ utilization assessment by using data and analysis available through the UNOS Benchmark Report that LifeGift and some OPOs subscribe to for internal performance improvement efforts. For example, this would allow CMS to observe how diligently each OPO works to offer all organs by type, etc. We believe this is a practical additional data point that is useable in assessing the transplantation rate metric for OPOs.

Are there ways to scale, or rate, performance of other (new) factors that CMS may consider in assessing OPO performance?

We suggest that CMS should Inquire about OPO participation in deceased donor research and collaborative improvement efforts such as the UNOS DCD Collaborative and the Donor Management Goals project. These efforts provide concrete evidence of commitment to improve both as an OPO and as an active participant in the donation and transplantation community. Such efforts are reasonable and practicable ways to use as differentiators in tight clusters of OPOs based on CMS metric ranking (tiebreakers).

Are there additional factors or criteria that CMS should consider when determining which OPO should be selected for an open service area?

Yes, we believe as in all merger & acquisition efforts, an assessment of leadership acumen and organizational scale and competency should be mandatory. Many OPOs have zero experience in managing and financing/resourcing multiple organizational units dispersed over wide geographic areas. For example, LifeGift manages services in 3 large, non-contiguous and distinct geographic units (Houston, Fort Worth, Lubbock/Amarillo) each with distinct demographics and varying levels of ethnic diversity. "High Performance" by an OPO in a smaller and geographically isolated DSA does not infer anything about its ability or competence or confidence to transfer that performance to a larger and more geographically complex service area. An assessment of organizational competence should be considered in any decision regarding OPO territory assignment.

Should CMS consider other performance measures when selecting an OPO for an open DSA? Such measures could include performance on converting donor referrals to potential donors or the number of "zero organ donors" or the number of organ discards (see section C.5. for additional information), reflected in the discard rate, or improvement, over time.

While these measures are all important to consider, CMS avoids the usual analysis of organizational capacity in its stated approach to selecting OPOs to absorb or manage other OPO services areas. We suggest the inclusion of a standardized approach to assessing organizational competence and capacity for such a potential organizationally disruptive change to an already traditionally high performing OPO.

Furthermore, using a singular organ utilization rate, for example, totally ignores the role of transplant programs in organ acceptance. This is certainly an area to review, and as suggested above, reviewing the UNOS Benchmark Report may help highlight any differences of patterns of one OPO compared to another in organ placement efforts as a balancing metric.

Should CMS continue to consider the contiguity of an OPO to an open DSA?

Yes, in general, the population and demographics of contiguous areas may indicate a higher likelihood of extending its successes with similar populations in nearby geographic areas. However, some organizations may have appropriate resources and experience to manage OPO services in disparate areas.

What are the challenges that an OPO would face if taking over an open DSA? Are there specific disincentives within the current regulatory requirements to taking over an open DSA?

Any OPO "taking over" another DSA would face numerous challenges and opportunities in areas well documented in the merger and acquisition experiences and literature. Organizational culture, financial resources constraints, staff resources and retention, dispersal of financial reserves and legal structural complexities are just a few looming challenges considering the majority of OPO leaders have zero experience in such matters. Using examples of other industry mergers and acquisitions would highlight the typical challenges of organizational structure, behavior and performance (structure, process, outcome). A current concern in the field that CMS can address is how an acquisition of a low performing OPO by a high performing OPO will affect the evaluation of the higher performing OPO metrics in the next certification period, as it will be highly likely the outcome measures of the high performing OPO will be diluted by the acquisition and result in lower overall metric rankings.

Are the current CMS requirements for a governing body and advisory board adequate for OPO governance? Have OPOs included additional board positions or structures beyond what is required by CMS to improve operations? What structure best serves accountability and efficient and effective organ procurement?

Yes, we believe current CMS requirements are adequate. We believe that successful structure is highly dependent on the geography and demographics of an assigned DSA. Like all organizations across all industries, each organizational approach is unique and if successful and effective, organizational performance should improve over time. LifeGift has sought additional expertise in healthcare leadership and innovation as well as DEIB to strengthen our leadership and accountability to CMS and the public.

What would be the anticipated impact from consolidation or expansion of the OPO recertification and competition processes. Would consolidation or expansion of OPOs facilitate increased competition and improved performance or have a negative impact? Any other helpful information that could inform potential changes to the current recertification and competition processes.

LifeGift believes that OPO performance is already improving following announcements from CMS regarding increased regulatory pressure, even without any structural changes to date. Consolidation of smaller OPOs into larger geographic units may bring increased performance at the next level by adding scale and resource availability for organizational competence and staffing. We have not seen any evidence of any reluctance by our community to pull back or actively limit collaboration or cooperation as some previously have expressed concern over. Finally, there is a role for CMS to provide education and or share effective approaches and practices for OPO Boards and leadership to consider prior to any organization change, whether required or voluntary.

Are there best practices regarding the arrangement of organ transportation between an OPO and a transplant program? How can the tracking of organs during transport be improved? Should specific requirements be implemented to facilitate real-time tracking of organs? What additional factors should be considered to ensure organs undergoing real-time tracking arrive at their intended destination timely? Can the OPO CfCs address the issue of organs that are lost during transport to a transplant program?

We believe the addition of CMS requirements for standardized tracking of all organs being transported unaccompanied by staff for transplantation is vital. With increased attention to the logistics of transplantation, there are numerous startup and proprietary groups offering services that create further decentralization and increased costs for the OPO industry. Additionally, like numerous other OPOs, we have seen organs declined due to additional ischemic time that negatively impacts the organ as a result of long transportation times between the OPO and transplant center. There is an important role for CMS to encourage a standardized and centralized organ tracking system that is accessible for all OPOs and transplant centers using some model such as FlightAware in a centralized location like the UNOS organ center. The expertise of the Department of Defense or private industry would be very helpful to leverage expertise and resource availability for such an important lifesaving mission. Events resulting in organs lost during transport should be required to be reported with the caveat that reporting these events does not infer poor performance or an adverse event until an investigation and root cause analysis is completed.

Are there clinical decision support protocols or algorithms that can reduce the cognitive burden and thereby assist clinicians in identifying potential donor candidates? If so, are there concerns regarding potential bias in clinical decision support protocols or algorithms that can introduce or exacerbate inequities, and how can those biases be addressed? Should a patient being placed on invasive mechanical ventilation, except for a planned medical or surgical procedure, be one of the triggers for a referral to the OPO? Should these triggers exclude certain patient populations? Are there aspects to donor referral processes or how referrals are made that help to engender trust or potentially worsen mistrust among underserved populations, including racial, ethnic, and religious minorities?

We believe CMS has an opportunity to standardize the criteria for a "referral." The current CoP (§482.45(a)(1)) requires that the OPO and hospital collaboratively define these items in the written agreement. However, this latitude has unintentionally resulted in a wide variation of referral criteria, also called "clinical triggers" across the country, with some hospitals advocating for definitions of timeliness and imminent death that will allow the hospital the convenience of making a referral at a time that suits their immediate needs instead of reflecting best practices and optimizing opportunities for donation. Currently, the clinical triggers used by many OPOs including LifeGift are: a ventilated patient with a Glasgow Coma Scale of 5 or less, or absent one neurological reflex or any ventilated patient to be removed from ventilator or pharmacological support for the purposes of end-of-life care. In our experience, we have found that imminent death referrals on patients who are not brain dead but are DCD candidates are often made immediately before withdrawal of life-sustaining therapy, which greatly increases the likelihood of a family denying authorization. We suggest that CMS use a broad definition to define criteria for referral; a patient with invasive ventilation (intubated) except for a planned medical or surgical procedure that also meets certain additional criteria may be a better approach. We suggest CMS solicit feedback from hospitals and OPOs to develop a set of criteria that can be integrated into the hospital CoP's and provide standardization across the country.

If referrals can be made automatically (see our comments below) this referral criteria would eliminate any unintended bias in identifying patients to refer, greatly reduce hospital staff cognitive burden and workload, and ensure there are no missed opportunities for donation. Automated referrals could also support efforts to ease mistrust in diverse communities, as a key aspect of the donor referral process is the timing of referrals and what is communicated to the OPO to families prematurely about the notification to the OPO. If the referral is made electronically it is likely that pre-mentions to families will

decrease, permitting the OPO to approach families of all backgrounds in a sensitive and supportive manner and ensuring families do not harbor mistrust about the timing of the referral.

We welcome comments from staff in the electronic medical record (EMR) and EHR industries on ways to automate reporting requirements in a cost-effective manner, as well as how such an approach may be implemented on a national scale. Finally, we are also interested in challenges OPOs may have in gaining access to donor hospital EHRs for organ procurement activities once referrals are received. Since OPOs have agreements with a large number of hospitals within its DSA, and timely access to potential donor information facilitates donation, we are interested to learn of any potential barriers to accessing information via EMRs and how CMS may facilitate better access to information through its requirements.

We strongly believe that CMS has the opportunity to increase donation and greatly ease the operational burden of referring potential donors by driving the implementation of automated electronic referrals. There are currently for-profit and non-profit entities facilitating automated referrals via API's for several OPOs, using both proprietary and non-proprietary systems. The current options require OPOs to either pay a vendor to provide the system or expend the resources to develop one independently. All options currently depend on the voluntary participation of donor hospital(s). We suggest CMS use the regulations of "meaningful use" to require all EMR vendors provide this capability and incentivize their adoption by all OPOs and hospitals. We also suggest that limiting access to such a critically important system by permitting various EMR vendors to provide this service for a fee slows the diffusion of innovation that the entire industry would benefit from.

Gaining and maintaining EHR access has been a continuous challenge for the OPO community. In our experience, many hospitals misunderstand the relationship of the OPO to the hospital and attempt to place vendor or business associate requirements on the OPO before providing EHR access to OPO staff. For example, we have navigated hospital requirements to train all OPO staff needing EHR access on their EHR system, resulting in the need to commit approximately 100 staff to multiple, redundant trainings. We believe CMS should use the CoP's to clarify the relationship between OPO and hospital and make it clear that OPOs are not subject to hospital-imposed requirements on vendors or business associates, such as hospital-based training, vaccination records, background checks, etc. It would be helpful if CMS emphasized the importance of OPO access to the hospital EHR and incentivized hospitals to create pathways that ease this process.

CMS is interested in learning about the potential benefits and concerns for the use of organ recovery facilities in greater detail and determining whether it would be appropriate or beneficial to establish specific health and safety requirements that would apply to these facilities. Specifically, CMS would like to explore aspects related to the effectiveness, operations, donor families, and impacts to other stakeholders. Since this is an emerging model of practice, there is limited information currently available.

There are several models in place for specialized organ recovery centers. It is well known that some OPOs have constructed and operate freestanding organ recovery facilities structurally apart from hospitals. Our approach has been to establish specialized organ recovery centers within our DSA's largest hospitals that are also transplant centers. This approach in our DSA has helped minimize costs of capital improvement and created efficiencies of joining locations and already available resources for both donation and transplantation without huge capital outlays.

How does organ donation at organ recovery facilities impact donor families? Does the process for transfer to organ recovery facilities make the process more difficult for the donor family if the facility is remote from the donor hospital? How are distance challenges addressed to ensure family involvement in the donation process? What are the reasons why donor families reject transfer from the donor hospital to an organ recovery facility? Have there been any studies specifically focused on evaluating donor family satisfaction when utilizing an OPO operated organ recovery facility versus traditional organ recovery in donor hospitals?

In our experience of transferring to our specialized recovery center in one of our larger donor hospitals, most families have been receptive to transferring for the purpose of facilitating the donation process. A common reason families reject transfer to another facility is personal preference to remain close to the donor for continued visitation. Other reasons include transportation and fees for parking, hotel accommodation and meals depending on the distance from the originating hospital to the recovery facility. There is an opportunity for CMS to conduct research to evaluate donor family satisfaction when utilizing an OPO operated organ recovery facility. Most research conducted has been focused on the impact of such facilities on efficiencies, cost, and organ utilization.

Re zero organ donors: We are seeking input on areas where our policies may create additional burdens or conflict with policies of the OPTN. We are particularly interested in ways to facilitate better communication and collaboration between OPOs and transplant centers and how this information can be incorporated into our requirements.

Excluding organ donors where no organs are transplanted could result in disincentivizing OPOs in pursuing donors that are medically complex, specifically DCD donors. As is well documented, the biggest opportunity for growth in organs available for transplantation is from DCD donors. DCD donor suitability is very complex and prior to organ recovery, the potential warm ischemic time is simply a guess despite numerous efforts to create and utilize decision support tools. Longer warm ischemic time despite adequate organ function, biopsy and pumping can result in organ discard due to transplant center acceptance practices and challenges surrounding allocation time and logistics for organ transportation.

How has the sharing of information on organ offer and acceptance data impacted practice, including information on root causes for failure to place organs as well as organs that were declined but later successfully transplanted at another center?

Sharing of information surrounding acceptance practices is helpful. The challenge with current data sharing is that by the time information is shared, it is old data. It would be very helpful to have current information surrounding transplant center acceptance criteria as close to real-time as possible. For instance, transplant centers are changing their acceptance practices for donors with a history of COVID on a very frequent basis now and without OPOs being aware of these changes there is the potential to miss an opportunity to transplant a COVID positive organ. Other transplant center criteria for donors that would be useful for OPOs to know are weight thresholds (neonatal and morbidly obese donors), organ specific upper and lower age limits, DCD heart/lung acceptance practices, warm ischemic cutoff times, etc. Knowledge of these data points will decrease the time the OPO spends offering organs to centers that will not accept based on criteria. Currently, many transplant centers keep criteria as broad as possible that do not match their actual acceptance practices, which can increase case times and potentially result in lost organs for transplant. Furthermore, with machine preservation and perfusion

devices spreading in use across some centers, the awareness of center practice with devices will help OPOs find more opportunities for use of medically complex organs when centers may be willing to accept knowing that the organs may be reconditioned on device.

What is the impact to these types of information sharing in practice, and if they have been productive, how can CMS build requirements around OPO—transplant center collaboration to support best practices in reducing the number of organ discards? Should this type of collaboration between OPOs and transplant programs be incorporated into quality assurance performance improvement (QAPI) requirements for OPOs and transplant centers?

Yes absolutely. There is a role for CMS to provide guidance on routine quality review efforts by both transplant programs and OPOs simultaneously to drive shared accountability and joint learning to increase utilization and decrease discards. Groups such as The Alliance and AST/ASTS would be ideal partners to help facilitate more opportunities like this on a larger scale as well at the local level.

We are interested in ways information on organ discard rates and organ acceptance practices can become more available and whether CMS should track and evaluate this information more closely and consider it for recertification purposes. We are also interested in ways in which it may be possible to determine an "acceptable" baseline rate of organ discards based on medically disqualifying factors and how this should be assessed.

Discard rates and organ acceptance practices should be monitored and evaluated as there are a number of organs discarded every year as a result of poor and inconsistent transplant program acceptance practices. Transplant centers should not be penalized for accepting medically complex organs and OPOs should also not be penalized for pursuing extended criteria donors. The variability of acceptance patterns even within singular organ transplant programs is well documented. Monitoring should not occur as a baseline approach to penalize any center but rather to monitor and highlight opportunities for increased use. If the center will not accept organs that they list as acceptable with UNOS, then those centers should be held accountable for "truth in advertising" of their acceptance criteria by reviewing trends/patterns over a certain time period such as 6-month periods.

We believe CMS has an opportunity to decrease organ discards by collaborating with OPTN to change and standardize the requirements for kidney crossmatches. Specifically, we ask that CMS and OPTN stipulate that all transplant centers conduct virtual-only crossmatches prior to the kidney leaving the OPO for transport to the transplant center. Currently, there is a wide variation of transplant center practices in conducting crossmatches, with some centers requiring blood/tissue for physical crossmatches and others accepting virtual crossmatches. There are no evidence-based reasons for physical crossmatch, and the time spent in providing biological materials and conducting the physical crossmatch causes a considerable delay in case times. We have also found that if the kidney has been transported to the transplant center prior to physical crossmatch, especially if that center is located far from the OPO, there is a high likelihood of organ discard if the crossmatch is positive and the transplant center cannot transplant the kidney.

We have seen a pattern of late declines due to an unintended outcome of the OPTN policy (5.6.C Organ Offer Acceptance Limit) permitting a transplant center to accept more than one organ offer for any one candidate at a time (two offer acceptances). Transplant centers may accept an organ and then rescind

that offer acceptance at the last minute due to a "better" organ offered from another donor. In efforts to mitigate loss of an organ due to late declines, OPOs will back up the organ with offers to subsequent candidates on the Match Run. OPTN policy (5.4.D Backup Organ Offers) states that transplant centers must treat backup offers like actual organ offers. It is our experience that backup offers are not "treated as a primary offer," and when a late decline is received the backup offer(s) fall through due to transport logistics for both or either the transplant team or the intended candidate. We recommend that CMS implement data collection on backup offers, possibly through DonorNet Match Run data, for transparency and performance monitoring to reduce organ discard.

We have also seen late declines increase as a result of the pandemic (omicron variant), as transplant candidates are testing positive for Covid-19 at an alarming rate causing transplant centers to decline organs very late in the process; pre-OR or post OR recovery. This trend is illustrated in our data from January 1 through January 31, 2002; five kidney late declines and three liver late declines occurred due to the potential transplant recipient testing positive for COVID-19 and all required reallocation.

Organ discard metrics associated with donors that yielded other organs that were transplanted should be separate from the measures surrounding the organ discard rate from zero organ donors. A zero organ donor illustrates that the OPO was fulfilling its responsibility to optimize donation by pursuing a medically complex donor, which unfortunately resulted in transplant centers determining that no organs were suitable for transplant. Having a very low discard rate may infer that the OPO may not be as aggressive with medically complex donors as they could be; conversely, a high discard rate may mean the OPO needs to reevaluate what it considers donor potential.

What has contributed to the recent rapid increase in DCD organ donation? What challenges do OPOs face from stakeholders regarding DCD donation and how do some OPOs overcome these challenges? Are there requirements that CMS should establish that may facilitate greater acceptance of DCD donation while ensuring patient rights and protections?

There have been several factors contributing to the increase of DCD donation. Transplant center acceptance of DCD organs has changed drastically over the years; kidneys were previously the only organ able to be transplanted from DCD donors but due to clinical advancements all organs are now considered viable for transplant in DCD donors. Advancements in warm and cold perfusion technology and availability post recovery, increased post-transplant data, and public acceptance of DCD have also contributed to the rapid increase in DCD donation.

Common challenges faced by OPOs in working with potential donor families are typically around the timing of the donation conversation in relation to when hospitals begin the process of conducting grave prognosis conversations. Time is a key factor for many families making the decision to withdraw life sustaining therapies. OPOs may receive the initial notification of a patient meeting defined clinical triggers in a timely manner. However, a challenge develops when plans of care quickly pivot to de-escalation of care and plans to withdraw life sustaining therapies, and the plan of care update to the OPO is late in the process. These are difficult clinical and communication challenges all increased by time compression and of course, grief the family is experiencing.

Another challenge is the time limit that transplant centers will consider the organ viable once care is withdrawn to pronouncement. Usually defined internally by the transplant center, it is typical in the U.S.

for that time limit to be 60 or 90 minutes while in Europe that time is typically 120 minutes or longer. We've provided recommendations on page 4 to address the challenge of finding a hospital physician/designee to pronounce death for a DCD donor, and on pages 12-13 to monitor late declines to improve the reallocation of organs when they are declined in the OR, which is more prevalent in DCD donation due to the fact that the organ was recovered after cardiac death and has cold ischemic time. We also recommend CMS should encourage innovation for effective recovery and acceptance of DCD donors, such as normothermic regional perfusion, providing an environment without time restraints.

How are OPOs sharing information related to best practices in DCD donation and what barriers limit progress in this area?

Over the last few years there has been an increase in overall education and training for DCD. The Alliance provided three courses since March of 2020. ASTS offered a day course in December 2020. UNOS implemented a DCD Collaborative Improvement project to increase DCDs, of which last April 26 OPOs joined and has now increased to 30 OPOs participating in the second phase https://unos.org/news/30-opos-project-increase-dcd-donors/. LifeGift routinely provides DCD education to hospitals and this effort has been aided by use of virtual outreach.

Are there ways to better align the CfCs with the current environment for DCD donation? How well do the CfC's complement requirements from the OPTN related to donation?

OPTN policy and the CfCs are not conflicting as CMS does not currently address requirements for DCD ("We did not include any requirements for donation after cardiac death in our proposed rule." And "…to facilitate our oversight of donation after cardiac death, not specifically to encourage OPOs to recover organs from cardiac dead donors.") We believe CMS should require both hospitals and OPOs to support DCD by having policies and procedures in place to facilitate DCD and no longer permit an OPO or hospital to opt out of participating in DCD donation. We ask CMS to support DCD by also ensuring hospitals provide the appropriate resources for declaration of death and the time period that must elapse prior to initiation of recovery, as discussed on page 4.

To what level have OPOs developed their own tissue banks and is this currently standard practice across OPOs?

Currently 31 of the 57 OPOs are registered with the American Association of Tissue Banks (AATB) as being accredited to perform some aspect of tissue banking, with most being responsible for screening and recovery and only a few involved in the processing and distribution of donated tissue. Additional OPOs recover tissue but are not AATB accredited, with the remaining OPOs having recovery agreements with third party tissue bank recovery agencies to evaluate and recover tissue in their donation service area (DSA). We highly encourage CMS and other applicable agencies to require AATB accreditation or similar accreditation as a condition of participation in the tissue recovery to ensure patient safety and consistent high-quality processes. LifeGift does not own or have any ownership interest in any tissue recovery agency.

Are there areas for improvement in the relationship between OPOs, hospitals, and tissue banks that would facilitate increasing the collection of useable tissue?

The addition of non-OPO affiliated tissue banks introduces complexity into the OPO referral process which can lead to confusion between the OPO, non-affiliated tissue bank, referral hospitals, and the next-of-kin. This complexity can have a negative impact on the organ referral process within the hospital leading to the potential of negative impact for organ donation.

For OPOs that do have active tissue banks, how does this service impact or intersect with the OPOs primary mission of recovering and distributing organs?

OPOs with in-house tissue banks take advantage of the OPO infrastructure, hospital relationships, medical examiner relationships, and referral processes to increase the donor potential for all hospitals including those with low organ donor potential, increasing the overall awareness of donation across the DSA. OPOs with in-house tissue banking coordinate education with the referral hospitals and have a unified public education initiative and more streamlined referral processes that promote both organ and tissue donation compared to those OPOs operating with non-OPO affiliated tissue banks.

Data on organs submitted for research is self-reported by OPOs and there is currently no method to independently verify this information on a regular basis limiting utility in annual performance measures. Are there other methods CMS should consider that would be effective? We are interested to know if there are currently sufficient incentives to provide organs for research absent a metric or process measure for this purpose. If an incentive is needed in this area, how should OPOs be assessed on this aspect of its operations?

As previously stated, there is a role for CMS to consider OPO participation in research programs as an additional factor in evaluating the high performance of an OPO compared to OPOs not participating in organ research. It is also important for CMS to know that organs for research are now being used for regenerative medicine, cellular therapy and drug toxicity testing as examples of broader use of appropriately authorized organs that are not transplantable.

How can CMS implement an approach that both incentivizes OPOs and is not excessively burdensome through enforcement?

Please see previous comments on page 6 where we commented on research and innovation as related to OPO CMS recertification.

Given the decline in islet transplantation research, are there other methods CMS should consider to assess pancreata procured for islet transplantation and research that can be used for certification and recertification purposes?

Due to the paucity of actual islet cell transplant programs and research and transplant groups not using perfectly transplantable pancreas, it has become impractical in our opinion to consider this as an indicator of any practice performance. We do not believe pancreas for islets (research) should be included in any of the metrics but rather be considered as an additional qualitative factor by CMS when evaluating OPOs, especially as a possible tie-breaker at tier boundaries. This will be enough incentive in this new environment.

CMS would like to determine if it is equitable to count VCAs as organs for OPO performance measures. Would certain OPOs be disproportionately advantaged or disadvantaged from such a change?

The OPTN added VCAs to the definition of "organ" because it is vascularized, similar to solid organ transplants, and reflects the critical clinical advances in transplantation. Recovery of VCAs incurs costs aligned with organ recovery costs. Historically, all OPTN regions except Region 6 and 8 (see chart below) have procured VCAs. If you consider the concept of advantages to other low volume organs, pancreas or intestine, both have significantly different volumes by OPTN regions but are included in the definition. Regardless of the advantages or disadvantages to OPOs, including VCAs in the definition of "organ" would further support and increase organ donation and transplantation and add important access to those who can benefit from VCA approaches, including uterine transplant.

	Intestines				Pancreas				Total VCA	Abdominal Wall	Head & Neck	GU Penile	GU Uterus	Upper Limb
	To Date	2021	2020	2019	To Date	2021	2020	2019	To Date	To Date	To Date	To Date	To Date	To Date
All Regions	3,286	96	91	81	9,172	143	135	143	111	20	19	2	33	37
Region 1	28	1	0	0	450	1	0	4	16	0	10	1	0	5
Region 2	981	23	26	23	1,667	16	15	24	17	0	1	1	3	12
Region 3	516	13	17	12	708	14	17	20	15	13	0	0	0	2
Region 4	15	0	0	0	320	10	9	8	24	0	1	0	22	1
Region 5	235	9	3	2	641	12	6	6	2	0	0	0	0	2
Region 6	13	1	1	2	137	0	1	0	0	0	0	0	0	0
Region 7	135	6	1	3	2,539	35	34	32	7	5	1	0	0	1
Region 8	510	6	11	6	543	9	9	10	0	0	0	0	0	0
Region 9	262	7	11	10	380	14	14	11	4	0	3	0	0	1
Region 10	532	30	20	21	1,204	20	22	20	12	1	3	0	8	0
Region 11	59	0	1	2	583	12	8	8	15	1	0	0	0	14

Data as of 01/20/2022 https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/

Given the low volume of VCA transplantation, should CMS establish specific survey and certification requirements for centers that transplant VCAs? If so, what health and safety aspects specific to VCA transplantation should be considered?

VCA transplantation is complex, and patient care management varies by the type of VCA. Basic standardized requirements should be established to ensure high quality and patient safety. Applying regulations like CMS Transplant CoP's for intestine and pancreas programs must be established in hospitals with a Medicare-approved transplant program. Oversight and monitoring of VCA programs should be established by the OPTN Contractor due to the variability of the type of VCA and what would be defined as successful outcomes.

LifeGift appreciates the opportunity to comment. We are happy to provide further information upon request.