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Dr. Mehmet Oz, CMS Administrator
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Ave., SW.
Washington, D.C. 20201
March 31, 2026

Dear Dr. Oz,

The National Kidney Foundation (NKF) appreciates the opportunity to offer our perspectives on the proposed rule, Organ Procurement Organizations (OPO) Conditions for Coverage Revisions (CMS-3409-P). The National Kidney Foundation supports the proposed rule, and ongoing efforts across the Department of Health and Human Services (HHS) to make procurement, donation, and transplant accountable to patients and the public.

We note that our support for improved accountability for procurement and donation should not be taken in a vacuum. We offer comments on this rule in conjunction with recently submitted comments on the Increasing Organ Transplant Access (IOTA) Model. NKF's position is consistent that OPOs must be held to the highest possible standard for the safe and high-quality procurement of all organs available for transplant **and** transplant centers must be held to the highest possible standard for their use on behalf of waiting patients.

We aim to advance a holistic policy strategy that drives whole system accountability to the entire transplant system to the people it serves: patients waiting on a kidney transplant, those who receive one, potential candidates for transplant that will never be evaluated and listed, the 170 million American registered to be organ donors, and the selfless patients and families who leave a legacy through organ donation.

Background

A kidney transplant is the optimal treatment for most individuals with kidney failure, yet a relatively small proportion of individuals with kidney failure receive one. It is commonly stated that the kidney transplant waitlist and the 13 patients who die on it each day is a morally distressing problem of scarcity: there are not enough kidneys from deceased and living donors to meet the demand for them.

Our commitment to patients, made through our Transplants for All initiative, is a kidney for every patient who needs one. That commitment stems from the mission statement of the National Kidney Foundation to eliminate the kidney transplant waitlist. That there is no single silver bullet solution to the kidney transplant waitlist does not mean that we should not deploy every tool in our respective arsenals to address it. We look with optimism towards a future where the waitlist is much diminished by the availability of xenotransplanted and bioengineered kidneys, and where regenerative medicine may not only preserve but recondition deceased donor organs. Each day, these technologies become more like practical realities and less like science fiction, ***and they are not yet here***. As we write this, 90,000 people are enduring the crucible of waiting for the chance at a lifesaving kidney transplant.

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A policy intervention like OPO accountability is no less important to the project of reducing the waitlist because, relative to a hypothetical silver bullet solution, it is more complex and incremental. As attenuated as the public debate over organ procurement and donation has become, we note that in 2020 when the first OPO rule was proposed, the procurement and donation landscape was much different than it was today. Most donors were brain dead donors. The U.S. had 58 government contracted OPOs with widely variable rates of procuring brain dead donors, little of which could be explained by variation in population. As an organization whose mission statement is to eliminate the transplant waitlist, our support for the rule was simple: if one OPO could consistently recover more organs in one region or from one population, why couldn't another do the same? Case reports from that time demonstrated that rapid improvement in an OPOs performance was possible. In an environment of scarcity where that scarcity was the bottleneck for patients waiting on a transplant and those who would never get a chance at transplant, we could not countenance leaving kidneys behind.

After the OPO rule was finalized in 2021, organ procurement dramatically increased, though that increase happened on the backdrop of the Public Health Emergency (PHE), the implementation of Kidney Allocation System (KAS) 250, and the growth in donation after cardiac death (DCD), and was largely ignored. Implementation of the tiered accountability structure was further confounded by lack of support for the CMS policy, leaving OPOs without performance reports, data, or any kind of meaningful guardrails as they worked to meet the new donation and transplant metrics.

We are now familiar with the consequences of this patchwork approach to implementation. Rather than having access to data and quality improvement support that would allow OPOs to close population-level gaps in donation after brain death, OPOs pursued DCD donors with increasing aggressiveness, leading to striking patient care failures. Allocation out of sequence continued to grow as heterogeneity in transplant center acceptance practice led OPOs to preferentially divert organs to centers more likely to use them, some OPOs exploited the policy whereby pancreata procured for transplant count towards the donation rate metric, and families endured instances of intrusive interactions with OPO staff.

These unintended consequences are not evidence that the regulatory framework for OPOs should not have been promulgated. NKF continues to support accountability for the organ procurement industry that maximizes the supply of deceased donor kidneys for waiting patients. That the number of available organs for transplant has increased and the number of OPOs in Tiers 1 and 2 have increased shows that the framework is generally working. Rather, unintended consequences are evidence that careful attention to implementation is essential to ensure success of a policy in the larger context in which it touches lives of people who interact with the organ donation system, including patients at the end of life, donors, families, those registered to be donors, people on the transplant waitlist, and hospital and OPO staff.

NKF thanks our colleagues at CMS and in the Health Resources and Services Administration (HRSA) for this proposed rule, which provides much needed clarity to OPOs as they enter the last performance year prior to the upcoming decertification cycle. We are also gratified to see the cross-government approach to holistic system improvement that addresses and preempts further unintended consequences. The actions identified below are components of a strategy that will push OPOs to procure the maximum number of available organs for transplant in a manner that is

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consistent with high quality medical practice, honoring both the patient who provided the organ and the patient who will receive it, while working to drive placement of those organs with a waiting patient consistent with the OPTN's kidney allocation policy and a shared decision-making model that puts the patient at the center of acceptance decisions.

- The implementation of the Ventilated Patient Form (VPF), which will provide insight into process variation among OPOs, providing targeted and meaningful data to support quality improvement that will help OPOs to continually improve their performance and avoid decertification.
- Advancing a donation after circulatory death (DCD) policy proposal to improve the safety of DCD and the quality of information shared with families.
- Work through the modernization of the OPTN to develop and implement national safety and quality standards for OPOs.
- Releasing CMS guidance that clarifies the responsibilities of OPOs and hospitals in providing medical care regardless of donor status and allowing families to make decisions without coercion.
- Securing adherence to OPTN organ allocation policy, which ensures that OPOs and transplant centers cannot take advantage of open offers to place organs at the expense of transparency and fairness.
- Implementing the IOTA model, which will test payment incentives to drive increased utilization of organs at risk to drive increases in the transplant rate.

Finally, as a general matter, we support a donation and transplant system that is accountable to the outcomes that are important to patients, as well as to other aspects of the procurement and donation processes that interact with the patient experience. A high performing OPO as identified by the donation and transplant metrics can still have quality gaps that are important to understand and address. We are especially interested in accountability for the interaction between the family and the OPO during the process of authorization. For example, an OPO that performs well on the donation rate measure but is aggressive with a family may be a high performing OPO but not a high quality one. This distinction is particularly important as CMS proposes to reinterpret its authority to allow the Secretary to authorize new OPOs. Organizations eager to enter the OPO market will "play to the test." Prior to opening the market, CMS must have a firm understanding of what defines quality and the tools in hand to ensure it. Efforts to better define and standardize quality will and should intersect with the work to set national safety and quality standards for OPOs. These standards will become another tool available to ensure quality, no matter if the organization ultimately contracted with CMS to provide procurement and donation services. CMS could complement this effort by using its own authorities to set the Conditions for Coverage for OPOs and hospitals to require an independent advocate, for example, a hospital chaplain, to support a family through procurement, donation, and aftercare. CMS could also consider the use of a tool like the Consumer Assessment of Healthcare Providers & Systems (CAHPS) survey, though CMS is already familiar with the limitations of the survey. The CAHPS survey has not been validated for use in the donor family population, and there needs to be an opt-out mechanism for families that do not want further outreach from the OPO.

Patient Story: *As a donor mother, I carry both a deep sense of purpose and heavy grief. When my two-year-old son passed, my husband and I decided to donate his organs, one of the hardest*

decisions we have ever faced, but also one of the most meaningful. In the midst of unimaginable loss, we wanted to
honor his life by helping others. However, as we moved through the donation process, we felt overwhelmed and uncertain at times. Information came quickly, and not always in a way that felt clear or compassionate. In those moments, the way details were explained, the tone, the timing, and the approach mattered deeply. Those interactions did not just shape our understanding of the process; they became part of the memories we carry as his parents.
Looking back, our donation experience could have been strengthened with more consistent and supportive communication. At times, we spoke with different individuals, making it difficult to know whom to turn to for questions or concerns. Having a single, trained point of contact to guide us through each step would have brought a sense of stability during an incredibly fragile time. We also needed more space to process information, ask questions, and fully understand what to expect. Families like mine are making decisions in the middle of despair, and even small improvements in communication and transparency can have a lasting impact. Creating structured opportunities for families to share feedback after the process also helps ensure these experiences are heard and used to improve care for others.
What stayed with me long after the donation was complete was not just the decision we made but how supported we felt afterward. Grief does not end when the process is over, especially when you are grieving a child. In many ways, that is when the reality truly begins. Donor families should be more intentionally connected to grief resources, including counseling, peer support, and ongoing follow-up. A simple check-in, a resource, or a connection to someone who understands can make an incredible difference in the healing journey. If we truly want a system that honors the gift of donation, we must also honor the families behind that gift by listening to their experiences, supporting them through their grief, and ensuring their voices help shape a more compassionate and accountable process for those who come after us.

In Appendix I, we list several questions that are being asked of donor families in a study being conducted by an organ donation researcher. We offer these as examples of the type of questions that could allow a family to provide insights into the experience of organ donation.

III. Provisions of the Proposed Regulations

A. Definitions (§ 486.302)

The National Kidney Foundation (NKF) generally supports the revisions to the definitions proposed in this section. NKF especially supports the proposed definition of the term “donor” to close the loophole that allowed OPOs to count pancreatas procured but not actually used for research as donated organs for purposes of certification and re-certification. The intent of the Public Health Service (PHS) Act is to provide an incentive for OPOs to procure pancreatas and ensure they are used for a clinically meaningful purpose of islet cell transplantation or research. We support the proposed policy that would ensure pancreatas procured for transplant are used for the purposes intended by the statute. We appreciate CMS’ thoughtfulness in accounting for the ability to cryopreserve pancreatic islet cells and the collaboration between CMS and HRSA that will enable enhanced OPO data reporting on how pancreatas are used for transplantation or research.
Adverse Event**:** The National Kidney Foundation supports the proposal to move the examples of possible adverse events to to § 486.348(c), QAPI requirements. We note that even with the best of

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intentions, the general public has a great deal of difficulty understanding the meaning of federal regulations. CMS may want to consider other mechanisms to express what it hopes to communicate its understanding of an adverse event, that a non-exhaustive list of examples are provided with the regulatory definition of QAPI requirement, and that further specifics are provided either in memos or the State Operations Manual. Stated simply, communication errors are usually a function of believing communication has happened. Clarity is especially important as CMS considers authorizing new OPOs.

Donor: NKF supports the proposed definition of the term "donor" to close the so-called pancreas loophole. The use of pancreatas for islet cell transplantation and research are both important goals for patients. We support ensuring that pancreata that are procured are used for these true purposes.

Organ: NKF supports the proposal to revise the definition of the term "organ" such that it would no longer include pancreatas used for islet cell research, unless the research is islet cell transplantation that occurs under a research protocol. As stated elsewhere, we support the closure of the pancreas loophole in a manner that incentivizes the procurement of pancreata for the clinically meaningful purposes of transplantation or research, provides "credit" when the pancreata is transplanted into a recipient on the OPTN waitlist, and retains the incentive for OPOs to place organs for transplant that are genuinely used for transplantation.

Medically Complex Organs and Donors: The National Kidney Foundation is a longtime supporter of policies that improve the procurement and utilization of kidneys procured from "medically complex donors." We have been consistent in our position that not every kidney must be "perfect" to have value to a waiting patient, and that placing shared decision-making at the heart of the transplant system will give more patients the chance at a better quality of life relative to dialysis. We note for CMS' consideration that the terms "medically complex organs" and "medically complex donors" are so broad that their understanding by an OPO could include the majority of donors and organs. For example, "elevated KDPI" may well be interpreted in 55 different ways by 55 different OPOs. In addition, the definition of "medically complex organ" is changing all the time, adding to the complexity of its interpretation. We would also note that organs procured from DCD donors are rising as organs procured from brain dead donors are falling, suggesting that OPOs do not need further incentive to procure organs from more complex donors.

As CMS is proposing for the definition of "adverse event," we would recommend that CMS increase the specificity of what it means by "medically complex organ" and "medically complex donor" and include these specific examples at § 486.348(c), QAPI requirements if CMS would like this to be an area for quality improvement. With regard to "medically complex organs" we are most interested in QAPI requirements that focus on the placement of procured organs consistent with the match run, i.e., on the transplant rate component of the accountability structure. A data-driven and systematic understanding of the factors that lead to non-utilization aggregated by center would be a powerful means to drive improvements in system-wide utilization practice and could provide improved data relative to OPTN refusal codes. Conversely, it would be important, for the purposes of disseminating best practices, to know where placement of a specific "medically complex organ" was successful.

Unsound Medical Practice: NKF supports clarification of the definition of unsound medical practices. CMS and OPOs should have an explicit understanding of the circumstances that can lead to "urgent

need" decertification. As we note elsewhere in this letter, specificity is important. We wonder if CMS may find it has a similar problem to the one noted in the rule preamble of OPOs seeing examples as exhaustive rather than as a sample of unsound medical practices. For both the benefit of OPOs and CMS, we recommend being specific and clear, while leaving flexibility for circumstances that CMS cannot yet anticipate that could lead to the need for urgent need decertification.

B. Requirements for Certification

The National Kidney Foundation (NKF) cautiously supports the ability of the Secretary to authorize new OPOs. As CMS is aware, market consolidation in the OPO industry is already taking place and is expected to accelerate. Like in other areas of healthcare, the line between hypothetical efficiency and performance gains from consolidation and an industry that becomes difficult to regulate is very fine. As far as NKF is aware, there is no current consensus on how many OPOs are needed to secure safe, high quality, and efficient procurement and donation activities. Given that this number is likely less than 55 but more than one, it is wise to start now to equip the Secretary with the ability to certify new OPOs.

As CMS knows, procurement and donation are highly nuanced areas of healthcare, and becoming more nuanced as the proportion of DCD donors increases and procurement and donation interact with end-of-life care for patients. In general terms, we would like a clear understanding of both the criteria and process used to make the determination about an organization's ability to serve as an OPO, understanding that these criteria naturally must differ from the criteria used by CMS when designating an OPO for an open service area, as stated at § 486.316(d), specifically: (1) performance on the outcome measures at § 486.318, (2) relative success in meeting the process performance measures and other conditions at §§ 486.320 through 486.348 as modified pending finalization of this rule, (3) success in identifying and overcoming barriers to donation within its own service area and the relevance of those barriers to barriers in the DSA that is open for competition, and (4) contiguity to the open service area.

In general we agree that the questions posed by CMS are the right ones and we regret that we do not have more specific suggestions to offer. As CMS is aware, there are several options under standard procurement policies outlined in the Federal Acquisition Regulation (FAR) that CMS could leverage to "pilot" potential OPOs before expanding their contracts, for example designating a potential OPO with task orders under a Indefinite Delivery / Indefinite Quantity (IDIQ) structure, or the use of a short base period followed by the addition of option years to cover a recertification cycle if CMS deems the performance and quality acceptable.

We would note that as implementation of the rule continues, the types of organizations that may wish to enter the OPO market will become apparent. For example, the US market for machine perfusion is small but growing. Medical device companies like Organ Recovery Systems, Transmedics, Paragonix and others are already embedded in OPO workflows and logistics. Variations on the business model, like 34Lives, provide organ reconditioning services in standalone lab facilities. Several Normothermic Regional Perfusion (NRP) vendors support organ recovery activities, providing perfusionists, specialized technologies, and logistics support. Any of these business models could expand into the scope of traditional organ procurement. To be clear, NKF's position is not that any of these companies are prepared to be or should be OPOs. We recommend that CMS closely observe these

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and other emerging industries in the transplant space. CMS should use those observations to assess what these companies are doing that is consistent with existing Conditions for Coverage, and how CMS would assess performance in those areas. We suggest that efforts towards national safety and quality standards for OPOs and further use of the Secretary's authority to collect data from OPTN members will be exceptionally important to understand the quality and performance of organizations that might one day look to become OPOs.

D. OPO Designation to Donation Service Areas (DSAs)

The National Kidney Foundation (NKF) supports the proposal to provide further guidance on the management of multiple DSAs by a single OPO. We support the ability of an OPO to assume responsibility for separate DSAs, thereby maintaining some geographic diversity in the market. We also support allowing OPOs the flexibility to determine how best to extend operations. We note that finalizing this proposal alone will not be sufficient to maintain competition and that CMS should also proceed with clarifying its authority and the process by which it intends to certify new OPOs.

E. OPO Agreements, Non-Renewal and De-Certification

The National Kidney Foundation (NKF) supports the proposed reorganization of the conditions for coverage to further clarify CMS' intentions regarding the ongoing implementation of the OPO rule.
F. Appeals of Adverse Actions

The National Kidney Foundation (NKF) supports the proposed clarification regarding the process of appeals for OPOs in cases of involuntary termination or non-renewal of its agreement with CMS. We support the proposal to provide appeal rights in an instance where an OPO has its designation to a DSA removed without de-certification. We also support the proposal to reduce the number of days in which an OPO must request a hearing before a CMS hearing officer to 15 calendar days. We agree that avoiding disruption is of the utmost importance and that de-certification should not come as a surprise to an OPO facing involuntary termination or non-renewal of its agreement.

G. Re-Certification and Competition

The National Kidney Foundation (NKF) supports the clarification provided in this section regarding an instance where an OPO is designated to more than one DSA. The specific proposals related to re-certification and competition for OPOs serving more than one DSA are logical and consistent with policies already finalized. With regards to the criteria used to select an OPO, NKF continue to support the use of the criteria at § 486.316(d) used to designate an OPO and the overall policy that CMS will give weight to contiguity when OPOs are ranked equally. We strongly support codifying the requirement that OPOs cooperate during transitions.

H. Outcome Measures

The National Kidney Foundation (NKF) agrees that flexibility in assessing performance is important as OPOs take over new DSAs. We agree that an OPO designated to a DSA should have an additional amount of time to demonstrate improvement before being held accountable for its

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performance for the purposes of re-certification. We support the proposal that an OPO be held accountable for its performance in the new DSA once 12 months of data are available.

I. Human Resources

The National Kidney Foundation (NKF) supports the proposal that OPO staff meet minimum personnel requirements, including that OPO staff in clinical roles are legally authorized, meaning licensed, certified, or registered per the federal, state and local laws where the clinical services are provided, act in accordance with the license, certification, or registration, and that the licensure, certification, or registration are kept current at all times.

We note that regulations that codify scope of practice can quickly cross the line from protective to anti-competitive, particularly in an environment where healthcare worker staffing shortages persist and are not expected to improve. For example, an OPO that can maintain licensure, certification and registration for a large staff where clinical practice crosses state lines (i.e., the DSA covers more than one state, or the OPO is responsible for multiple DSAs covering multiple states) will always have a competitive advantage over an incumbent. NKF supports these proposed policies because poor clinical care provided by OPO staff pose such a dire threat to organ donation and the safety of donor patients overall. However, we urge CMS to remain vigilant for unintended consequences.

I. Information Management

The National Kidney Foundation (NKF) supports the proposal that OPOs maintain records for organs that are procured for research, including pancreatas used for islet cell research.

J. Quality Assessment and Performance Improvement

In general, the National Kidney Foundation (NKF) supports the requirement at CFR 486.348 that requires OPOs to develop, implement, and maintain a comprehensive, data driven QAPI program designed to monitor and evaluate performance of all donation services. We support the proposal to add additional specificity regarding the elements of the QAPI program including improved performance that pertains to potential transmission of infectious or communicable diseases, avoidable loss of a medically suitable potential donor for whom consent for donation has been obtained, and organs that are either lost or delayed and arrive too late to be transplanted or arrive in a condition incompatible with transplantation.

We reiterate our concern expressed elsewhere in this letter that the terms “medically complex donor” and “medically complex organ” are too broad to be meaningful for the purposes of QAPI programs. NKF is a longstanding champion of improving the procurement of all available organs for transplant and the use of those organs for well-selected recipients who would otherwise die on the transplant list. We encourage CMS to consider revising the terminology to be more specific to the challenge that CMS wants OPOs to address, whether that is procurement of DCD organs, or procurement or placement of high KDPI organs, or some other subset of potential organs for transplant. We recommend that this QAPI requirement focus specifically on strategies to improve placement of kidneys consistent with the match run.

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Comment Solicitation and Discussion on Emerging Topics

E. Automatic Electronic Referrals

The National Kidney Foundation (NKF) appreciates CMS's request for information regarding the use of technology to support automated electronic referrals from hospitals to Organ Procurement Organizations (OPOs). Timely referral is the first step in the organ donation process and is critical to identifying potential donors and enabling the complex clinical coordination necessary for successful transplantation. NKF supports efforts to leverage health information technology (Health IT) to improve timeliness, reliability, and consistency of donor referrals. Health IT and OPO referral automation shows promise in reducing missed opportunities caused by delays or variability in hospital workflows. NKF believes automated referral systems have the potential to strengthen the organ donation system in multiple ways. Standardized clinical triggers embedded in the electronic health record system can help ensure that potential donors are consistently identified and referred, regardless of variability in the hospital setting. Preventing delays caused by staffing levels, time of day, or other dynamics in the hospital is an essential step in reducing missed donation opportunities.

NKF maintains the position that avoidance of missed referrals is particularly important to honoring the intent of the approximately 170 million Americans who have registered as organ donors. When donation opportunities are missed due to delays or inconsistent referral practices, the expressed wishes of registered donors may not be realized.

However, NKF recognizes that expanding automated referral processes raises legitimate concerns about the handling and eventual storage of sensitive patient information. Referrals often occur at the point of "imminent death" when the patient may still be living but unable to participate in the decision-making process. In these circumstances, hospitals may transmit identifiable health information of a currently living patient to OPOs so that medical suitability for donation can be assessed. If automated referrals are expanded, the timing of referral must be carefully selected to ensure patients do not commonly recover after referral while balancing maximizing time for the OPO to function. NKF believes maintaining strong protection for patient privacy is essential to sustaining public confidence in the organ donation system.

In addition to the concerns surrounding sharing identifiable information, NKF wants to bring attention to our concerns with the data storage of individuals who do not become donors. Because hospitals are required to refer all deaths and imminent deaths for the OPO to determine donor eligibility, OPOs receive referrals for nearly all deceased individuals. OPOs are then required to store referral data for 7 years. As a result, OPOs are responsible for the storage and security of identifiable information for nearly all deaths in the United States. We believe this data should instead be stored by CMS or another government entity.

While NKF does not intend to prescribe specific regulatory requirements for referral technology, we believe that practical guardrails can help achieve the balance between efficient referrals and protection of patient privacy. Such safeguards could include encryption of referral data during transmission and storage, role-based access controls that limit data visibility to trained personnel directly involved in donor evaluation, audit trails that monitor data access, and clear limitations on redisclosure or secondary use of referral data unrelated to procurement activities. Additionally,

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transparent policies governing the retention and deletion of information for individuals who do not ultimately become donors could further reinforce public trust while allowing OPOs to maintain the clinical information necessary to perform their functions.

NKF appreciates CMS's continued efforts to modernize the organ donation system through improved interoperability and digital health infrastructure. As CMS considers the role of automated referrals within the broader health IT ecosystem NKF encourages the agency to prioritize solutions that enhance referral efficiency while reinforcing the trust that underpins the nation's organ donation system.

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The National Kidney Foundation (NKF) respectfully submits these comments with gratitude for the work our colleagues at the Department of Health and Human Services (HHS) are doing to strengthen procurement, donation, and transplantation. We would welcome the opportunity to discuss. Please contact Miriam Godwin, Vice President of Health Policy, at Miriam.godwin@kidney.org.

Sincerely,

Dr. Jesse Roach
Senior Vice President,

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Appendix I.

1. How did you feel about your interactions with the Organ Procurement Organization (OPO) staff?
    - If necessary, remind the participant what the OPO is (the team that talked to you about organ donation, and determined whether your loved one was able to donate organs).
    - The person from the OPO who talked to you about organ donation is sometimes called a donation coordinator or a family support advocate.
2. I'd like to ask you about the process of authorizing donation for your loved one, meaning the time when someone talked to you about your loved one donating their organs. What do you remember about that conversation?
3. Could that process have been improved in any way?
4. Do you remember being given an opportunity to ask questions? What questions did you ask?
5. Did they give you time to think about whether you wanted to allow donation? What do you think about that amount of time? (was it enough, too little, too much)?