

# PUBLICATION

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## CMS Considers Comprehensive Changes to Organ Donation and Transplantation System Through RFI

Authors: Tenia L. Clayton, Melodie Hengerer

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As part of its continuing efforts to improve the organ donation and transplantation system, the Centers for Medicare and Medicaid Services (CMS) recently issued a Request for Information (RFI) seeking public comments on potential changes to the requirements that transplant programs, organ procurement organizations (OPOs), and end-stage renal disease (ESRD) facilities must meet to participate in the Medicare and Medicaid programs. Additionally, the RFI requests responses related to racial disparities in the organ donation and transplantation system, particularly as these issues may relate to inequities in access to referral, transplant evaluation, waitlisting, and organ receipt. Via this comprehensive RFI, CMS aims to create system-wide changes to improve organ donation, transplantation, quality of care in dialysis facilities, and improved access to dialysis services. See our article "[CMS Organ Transplant Proposal Must Balance Reform, Access.](#)"

Through the RFI, CMS generally seeks to accomplish the following goals:

- Continue to improve systems of care for all patients in need of a transplant
- Increase the number of organs available for transplant for all solid organ types
- Encourage the use of dialysis in alternate settings or modalities over in-center hemodialysis where clinically appropriate and advantageous
- Ensure that CMS and Department of Health and Human Services (HHS) policies appropriately incentivize the creation and use of future new treatments and technologies, and
- Harmonize requirements across government agencies to facilitate these objectives and improve quality across the organ donation and transplantation ecosystem

Due to the broad scope of information requested and the potential for significant regulatory changes as a result of the information gathered, CMS seeks input from all relevant stakeholders including transplant programs, OPOs, ESRD facilities and dialysis providers (including in-home and nursing home dialysis providers), donor hospitals, transplant recipients and families, and organ donor families. A summary of some of the specific issues on which CMS seeks comments is provided below.

With regard to **Transplant Centers** and CMS Conditions of Participation, CMS seeks information related to the following:

- Data, research, or anecdotal information illustrating transplant center performance with regard to patient safety
- Suggestions incentivizing and ensuring quality in organ transplantation
- Input on whether current CMS regulations create barriers to the establishment of new transplant programs
- Suggestions on streamlining the regulation of all transplantation partners, including ESRD facilities and OPOs, including how to structure performance metrics for both transplant centers and OPOs
- Suggestions for reducing organ discards and expanding use of "suboptimal" organs

- Suggestions for reducing disparities in organ transplantation, including reducing mistrust of the medical community
- For patients and families, information regarding satisfaction of care, quality of patient education, and waitlist transparency

With specific regard to **ESRD Facilities**, CMS seeks information as follows:

- Suggestions for increasing health care and decreasing the progression of kidney disease, including reducing barriers to routine and preventative health and increasing education
- Suggestions for reducing racial, ethnic, gender, sexual orientation and economic disparities in caring for patients with kidney disease
- Suggestions for empowering these patients and improving long-term outcomes
- Information regarding the reasons for differing rates of home dialysis by race/ethnicity
- Suggestions on improving patient safety for **in-home dialysis**
- Suggestions regarding necessary infrastructure support, including telehealth and remote monitoring technology, in order to elevate the patient experience
- For **nursing homes providing dialysis**:
  - Input regarding whether dialysis facilities should have geographical limitations for the distance between the dialysis facility and the nursing home where the dialysis is provided
  - Input regarding whether a dialysis facility should be limited to a certain number of agreements with nursing homes providing home dialysis services
  - Suggestions regarding whether CMS should revise the Conditions for Coverage to require a written agreement between dialysis facilities and nursing homes
- For **mobile dialysis units** (currently undefined or certified by CMS):
  - Input regarding general oversight considerations, geographical limitations, health and safety standards, and staffing

With regard to **OPOs**, CMS seeks the following information:

- Input regarding additional qualitative or quantitative indicia of excellent OPO performance for recertification purposes
- Suggestions regarding whether and how equity in organ donation should be considered when measuring performance
- Suggestions related to whether other factors should be considered when determining which OPOs should be considered for "open" designated service areas (DSAs), including level of performance for new OPO, contiguity of an OPO to an open DSA and challenges and disincentives to OPO DSA takeovers
- Input on whether the current CMS regulations regarding OPO governance are adequate
- Input on whether and how the OPO Conditions for Coverage can or should address the issue of lost organs or organ tracking
- Suggestions regarding the donor referral process from donor hospitals, in particular as related to clinical triggers for OPO notification and use of electronic health record interface technology in order to facilitate ease of information-sharing between hospitals and OPOs
- Input on the OPO's use of organ recovery facilities and any impact on **donor hospitals, transplant centers, tissue banks and donor families**
- Input on whether and to what extent the sharing of data on organ offer and acceptance is helpful in minimizing zero organ donors or organ discards and whether CMS should consider an acceptable baseline rate of organ discards

- Suggestions on ways to continue to increase donation after cardiac death (DCD) and perhaps incentivize DCD through revisions to the Conditions for Coverage
- Input regarding ways to improve the **OPO/hospital/tissue bank** relationship in order to increase tissue donation and to what extent OPOs that operate tissue banks conflict or affect the OPO's primary mission organ procurement
- Input on whether additional incentives are needed to provide organs for research, and whether CMS should consider other methods of assessing procurement of pancreata for islet transplantation and research
- Input on whether VCAs should be counted as organs for OPO performance measures and whether CMS should implement additional safety requirements for VCA transplantation

Finally, CMS seeks information with regard to **nephrology joint ventures** as follows:

- Suggestions on whether CMS should collect information on such joint ventures as part of Medicare enrollment in order to support analysis of the impact of these arrangements on the quality of care furnished to Medicare beneficiaries
- Input on whether a dialysis facility or nephrologist should be required to disclose information on joint venture arrangements to patients
- Input on whether such joint ventures affect resource use, patient care and/or modality choice

### **Key Takeaways and Next Steps**

While the RFI seeks input from key stakeholders meant to address disparities and improve equity in the organ donation, transplantation, and dialysis space, the majority of substantive requests to which CMS seeks responses are focused largely on consideration of specific processes and performance improvements across a wide range of providers and OPOs. Many of the requests also relate to issues previously raised by these same stakeholders during the CMS rulemaking process for the OPO Conditions for Coverage Final Rule and the FY 2022 IPPS Proposed Rule as reviewed in our article "[CMS Continues to Consider Organ Acquisition Cost Rule Changes](#)". Accordingly, and as CMS continues to focus on transforming the system, transplant programs, donor hospitals, OPOs, and dialysis facilities should take this opportunity to be heard on these critical issues by [submitting public comments](#). Comments to the RFI must be received by February 1, 2022.

For more information, please contact [Melodie Hengerer](#), [Tenia Clayton](#) or any member of the Baker Donelson Health Law Team.