

**DEPARTMENT OF LABOR****Occupational Safety and Health Administration****29 CFR Parts 1910, 1915, 1917, 1918, 1926, and 1928****[Docket No. OSHA–2021–0009]****RIN 1218–AD39****Heat Injury and Illness Prevention in Outdoor and Indoor Work Settings; Extension of Comment Period****AGENCY:** Occupational Safety and Health Administration (OSHA), Department of Labor.**ACTION:** Advance notice of proposed rulemaking (ANPRM); extension of comment period.

**SUMMARY:** OSHA is extending the period for submitting comments by 30 days to allow stakeholders interested in the ANPRM on Heat Injury and Illness Prevention in Outdoor and Indoor Work Settings additional time to review the ANPRM and collect information and data necessary for comment.

**DATES:** The comment period for the ANPRM that was published at 86 FR 59309 on October 27, 2021, is extended. Comments on any aspect of the ANPRM must be submitted by January 26, 2022.

**ADDRESSES:**

*Written comments:* You may submit comments and attachments, identified by Docket No. OSHA–2021–0009, electronically at [www.regulations.gov](http://www.regulations.gov), which is the Federal e-Rulemaking Portal. Follow the online instructions for making electronic submissions. The Federal e-Rulemaking Portal at [www.regulations.gov](http://www.regulations.gov) is the only way to submit comments on this ANPRM.

*Instructions:* All submissions must include the agency's name and the docket number for this rulemaking (Docket No. OSHA–2021–0009). All comments, including any personal information you provide, are placed in the public docket without change and may be made available online at [www.regulations.gov](http://www.regulations.gov). Therefore, OSHA cautions commenters about submitting information they do not want made available to the public or submitting materials that contain personal information (either about themselves or others), such as Social Security Numbers and birthdates.

*Docket:* To read or download comments or other material in the docket, go to Docket No. OSHA–2021–0009 at [www.regulations.gov](http://www.regulations.gov). All comments and submissions are listed in the [www.regulations.gov](http://www.regulations.gov) index; however, some information (e.g.,

copyrighted material) is not publicly available to read or download through that website. All comments and submissions, including copyrighted material, are available for inspection through the OSHA Docket Office. Documents submitted to the docket by OSHA or stakeholders are assigned document identification numbers (Document ID) for easy identification and retrieval. The full Document ID is the docket number plus a unique four-digit code. OSHA is identifying supporting information in this ANPRM by author name and publication year, when appropriate. This information can be used to search for a supporting document in the docket at <http://www.regulations.gov>. Contact the OSHA Docket Office at 202–693–2350 (TTY number: 877–889–5627) for assistance in locating docket submissions.

**FOR FURTHER INFORMATION CONTACT:**

*Press inquiries:* Contact Frank Meilinger, Director, Office of Communications, U.S. Department of Labor; telephone: (202) 693–1999; email: [meilinger.francis2@dol.gov](mailto:meilinger.francis2@dol.gov).

*General and technical information:* Contact Andrew Levinson, Directorate of Standards and Guidance, U.S. Department of Labor; telephone: (202) 693–1950.

**SUPPLEMENTARY INFORMATION:** On October 27, 2021, OSHA issued an ANPRM to initiate rulemaking to protect indoor and outdoor workers from hazardous heat and to obtain additional information about the extent and nature of hazardous heat in the workplace and the nature and effectiveness of interventions and controls used to prevent heat-related injury and illness.

The public comment period for the ANPRM was to close on December 27, 2021, 60 days after publication of the ANPRM. However, OSHA received requests from stakeholders to extend the comment period by an additional 30 days (Document ID 0145) or 60 days (Document ID 0101, 0133, 0141, 0143, 0144, 0148, 0152, 0159). These stakeholders explained that they need additional time to carefully review the questions in the ANPRM, obtain input from members, and provide comments (see, e.g., Document ID 0101).

OSHA agrees to an extension of the public comment period and believes a 30-day extension is sufficient and appropriate in order to balance the agency's need for timely input to inform how the agency will proceed with the rulemaking with these stakeholder requests. Therefore, OSHA is extending the public comment period until January 26, 2022.

**Authority and Signature**

Douglas L. Parker, Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, 200 Constitution Avenue NW, Washington, DC 20210, authorized the preparation of this document pursuant to the following authorities: Sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657); Secretary of Labor's Order 8–2020 (85 FR 58393 (Sept. 18, 2020)); 29 CFR part 1911; and 5 U.S.C. 553.

Signed at Washington, DC, on November 24, 2021.

**Douglas L. Parker,***Assistant Secretary of Labor for Occupational Safety and Health.*

[FR Doc. 2021–26269 Filed 12–2–21; 8:45 am]

**BILLING CODE 4510–26–P****DEPARTMENT OF HEALTH AND HUMAN SERVICES****Centers for Medicare & Medicaid Services****42 CFR Chapter IV****[CMS–3409–NC]****RIN 0938–AU55****Request for Information; Health and Safety Requirements for Transplant Programs, Organ Procurement Organizations, and End-Stage Renal Disease Facilities****AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.**ACTION:** Request for information.

**SUMMARY:** This request for information solicits public comments on potential changes to the requirements that transplant programs, organ procurement organizations, and end-stage renal disease facilities must meet in order to participate in the Medicare and Medicaid programs. These providers and suppliers are integral to the transplant ecosystem in the United States and to the health of patients across the Nation. We are seeking public comment that will help to inform potential changes that would create system-wide improvements, which would further lead to improved organ donation, organ transplantation, quality of care in dialysis facilities, and improved access to dialysis services.

**DATES:** To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on February 1, 2022.

**ADDRESSES:** In commenting, refer to file code CMS–3409–NC.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the “Submit a comment” instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-3409-NC, P.O. Box 8010, Baltimore, MD 21244-8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-3409-NC, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

**FOR FURTHER INFORMATION CONTACT:**

Diane Corning, (410) 786-8486; James Cowher, (410) 786-1948; Jeannine Cramer, (410) 786-5664; Lauren Oviatt, (410) 786-4683; or Alpha-Banu Wilson, (410) 786-8687.

**SUPPLEMENTARY INFORMATION:**

*Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that website to view public comments. CMS will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the individual will take actions to harm the individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

**I. Background**

The organ donation and transplantation system (known and referred to herein as the transplant ecosystem) in the United States comprises a vast network of institutions

dedicated to ensuring that patients are evaluated and, if appropriate, placed onto the organ transplant waitlist, and that those on the organ transplant waitlists receive lifesaving organ transplants. These entities include organ procurement organizations (OPOs), charged with identifying eligible donors and procuring organs from deceased donors; transplant programs, located within transplant hospitals, that perform transplantation procedures from living and deceased donors; and donor hospitals that notify OPOs of the imminent death of potential donors and assist the OPO in the management of the donor and the procurement of the donor’s organs. OPOs, donor hospitals, and transplant programs rely on a close collaborative relationship to ensure that organs are successfully procured and appropriately placed with transplant programs. Further, OPOs rely on families or next-of-kin, or the deceased donor themselves (if they made the decision to donate prior to death), who voluntarily make the choice to save lives and become donors. OPOs also have the role of compassionately discussing donation issues with donor families and educating the public on organ donation. In calendar year 2020, there were a total of 39,034 transplants.<sup>1</sup> These transplants resulted from 12,587 deceased donors and 5,725 living donors. For deceased donors, this represents about a 6 percent increase over 2019.<sup>2</sup> However, there continues to be a chronic substantial unmet need for transplantable organs as the number of people who need an organ transplant increases in the United States. As of November 2, 2021, there are 106,712 patients waiting for organ transplants.

On the other side of the care spectrum and prior to transplantation, end-stage renal disease (ESRD) facilities, also known as dialysis facilities, are charged with delivering safe, adequate dialysis to patients with ESRD. ESRD facilities also educate patients on their treatment options, including kidney transplantation, and ultimately refer patients to transplant programs for

evaluation and potential kidney transplantation. ESRD is complete kidney impairment that is irreversible, permanent and requires either a regular course of dialysis or kidney transplantation to maintain life. In the United States, approximately 37 million patients suffer from chronic kidney disease (CKD)<sup>3</sup> and more than 785,000 have ESRD.<sup>4</sup>

We have made changes to the existing CMS regulations with the goal of making impactful changes to the transplantation ecosystem and improving patient health, safety, and outcomes in transplant programs, OPOs, and ESRD facilities. On September 30, 2019, we published the final rule, “Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction; Fire Safety Requirements for Certain Dialysis Facilities; Hospital and Critical Access Hospital (CAH) Changes To Promote Innovation, Flexibility, and Improvement in Patient Care” (84 FR 51732) and finalized changes to the transplant program regulations by eliminating the data, clinical experience, and outcome requirements for re-approval of transplant programs. This action removed disincentives to transplantation by encouraging the use of organs that may be perceived as being less than ideal, but could still be used for transplantation with improved outcomes over traditional therapies such as dialysis. On December 2, 2020, in response to Executive Order 13879, which aimed to increase the utilization of available organs, we published a final rule entitled, “Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations (85 FR 77898),” which revised the OPO conditions for coverage (CfCs) by replacing the previous outcome measures with new transparent, reliable, and objective outcome measures. While these regulatory changes recently went into effect with the goal of creating improvements in the performance of these entities and the delivery of care to patients additional system-wide improvements may be necessary to further improve patient health and safety and outcomes in transplant programs, OPOs, and ESRD facilities. In

<sup>1</sup> U.S. Health Resources and Services Administration. Organ Procurement and Transplantation Network—DATA. <https://optn.transplant.hrsa.gov/data/>. Accessed January 13, 2021. <https://optn.transplant.hrsa.gov/data/>. Accessed January 13, 2021.

<sup>2</sup> U.S. Health Resources and Services Administration. Annual record trend continues for deceased organ donation, deceased donor transplants. <https://optn.transplant.hrsa.gov/news/annual-record-trend-continues-for-deceased-organ-donation-deceased-donor-transplants/>. Published January 11, 2021. Accessed January 13, 2021. <https://optn.transplant.hrsa.gov/news/annual-record-trend-continues-for-deceased-organ-donation-deceased-donor-transplants/>. Published January 11, 2021. Accessed January 13, 2021.

<sup>3</sup> Chronic Kidney Disease Initiative. <https://www.cdc.gov/kidneydisease/basics.html#:~:text=About%2037%20million%20US%20adults,dialysis%20treatment%20for%20kidney%20failure>. Accessed November 4, 2021.

<sup>4</sup> Kidney Disease: The Basics. National Kidney Foundation. <https://www.kidney.org/news/newsroom/fsindex>.

addition, CMS is actively working to identify and address disparities and inequities across these programs. We discuss the inequities that exist in organ donation, transplantation, and dialysis and ask questions regarding how the CoPs/CfCs can address and improve these issues later in this RFI. We are soliciting comments on ways to:

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

In addition, we are soliciting information related to opportunities, inefficiencies, and inequities in the transplant ecosystem and what can be done to ensure all segments of our healthcare systems are invested and accountable in ensuring improvements to organ donation and transplantation rates.

## II. Solicitation of Public Comments

### A. Transplant Programs

#### 1. Background

Transplant programs, located within a hospital that has a Medicare provider agreement, provide transplantation services for one or more specific organs. Transplant programs must comply with the Medicare transplant program conditions of participation (CoPs) regulations at 42 CFR 482.68 through 482.104, and with the hospital CoPs at §§ 482.1 through 482.58. There are several types of CMS-approved transplant programs including heart, lung, liver, kidney, intestine, pancreas, and multi-organ. The transplant program CoPs were finalized and effective in 2007 and updated again in 2019 (84 FR 51732).

While we have made refinements to the transplant program CoPs over the years, more work is still necessary to improve the transplantation ecosystem. As evidenced through several studies and Organ Procurement and Transplantation Network (OPTN) data, the number of organs discarded continues to be high and we believe that this number could be significantly reduced. For example, in 2018, there

were 37,852 organs recovered from deceased donors. Of these, 5,085 organs were discarded, with 3,755 of those organs being kidneys, 278 being pancreata, 707 livers, 3 intestines, 23 hearts, and 319 lungs.<sup>5</sup> Transplant programs must play an important role in reducing the organ discard rate and can do so by accepting and utilizing more organs that are deemed “marginal”, thus ensuring that more patients on the waitlist receive lifesaving transplants. Research indicates that many of the organs deemed as “marginal” that are denied are later transplanted successfully into patients at other transplant centers or they are discarded despite having similar or better quality characteristics to organs that are successfully transplanted elsewhere (see discussion in section II.C.5).<sup>6,7</sup> We are requesting the public’s input on issues pertaining to potential changes to the transplant program CoPs, transplant recipient patient’s rights, and equity in organ transplantation, in order to achieve these goals.

#### 2. Transplant Program CoPs

We are seeking public comments on the following questions:

1. For patients and their families: Are transplant programs meeting your specific needs and are you satisfied with the care that you have received? Specifically, what type of information are you receiving from your transplant program or transplant surgeon?
2. Do transplant programs adequately protect the health and safety of living donors and transplant patients? Please provide data, research, studies, or firsthand accounts that would be illustrative of how transplant programs are performing with regards to adequately protecting patient health and safety.
3. How can the current transplant program CoPs be improved in order to incentivize and ensure performance quality in organ transplantation?

<sup>5</sup> OPTN/SRTR 2018 Annual Data Report: Deceased Organ Donation.

<sup>6</sup> Husain SA, King KL, Pastan S, Patzer RE, Cohen DJ, Radhakrishnan J, Mohan S. Association Between Declined Offers of Deceased Donor Kidney Allograft and Outcomes in Kidney Transplant Candidates. *JAMA Network Open*. 2019 Aug 2;2(8):e1910312. doi: 10.1001/jamanetworkopen.2019.10312. Erratum in: *JAMA Network Open*. 2019 Oct 2;2(10):e1914599. PMID: 31469394; PMCID: PMC6724162.

<sup>7</sup> Husain SA, King KL, Pastan S, Patzer RE, Cohen DJ, Radhakrishnan J, Mohan S. Association Between Declined Offers of Deceased Donor Kidney Allograft and Outcomes in Kidney Transplant Candidates. *JAMA Network Open*. 2019 Aug 2;2(8):e1910312. doi: 10.1001/jamanetworkopen.2019.10312. Erratum in: *JAMA Network Open*. 2019 Oct 2;2(10):e1914599. PMID: 31469394; PMCID: PMC6724162.

4. Do the initial approval requirements at § 482.80 create barriers to the establishment of new transplant programs? Do they require an excessive amount of hospital resources at program launch, resulting in hospitals retaining lower performing transplant programs? What alternatives for ensuring quality and oversight should be considered?

5. 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. 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?<sup>8</sup> What are the impacts of these duplicative requirements on organ utilization and transplant program/ ESRD facility/OPO quality and efficiency?

6. 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?

7. 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?

8. The industry as a whole has acknowledged that changes cannot be made solely to one part of the transplantation system. 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? For a meaningful evaluation of transplant program outcomes from the recipient point of view, please comment on meaningful outcome measures that should be included in the transplant outcomes evaluations.

9. In the context of organ shortage and expanded use of marginal, suboptimal quality organs, and transplantation into

<sup>8</sup> Organ Procurement and Transplantation Network website. <https://optn.transplant.hrsa.gov/governance/>

standard and high-risk recipients, we are seeking public comments from the recipient perspective and expectations on meaningful measures including but not limited to graft survival benefit, shorter waiting list time, frailty improvement and quality of life after transplant, and other transplant benefits.

10. How can CMS meaningfully measure transplant outcomes without dis-incentivizing transplantation of marginal organs or dis-incentivizing performing transplants on higher risk patients?

### 3. Transplant Recipient Patient Rights

Section 482.102 “Patient and living donor rights” provides specific rights for the patients on the waiting lists and transplant recipients. However, these enumerated rights do not address transparency regarding organ offers made for the patient on a transplant program’s waiting list. There is no requirement for the transplant center or surgeon to notify a patient on the waiting list that there has been an organ offered for them.

Research has shown that less than 16 percent of deceased donor kidneys are accepted without being declined at least once.<sup>9</sup> In addition, as discussed later in this RFI, there are concerns that kidneys may be declined for reasons other than organ quality. We believe that there should be some degree of transparency between the transplant program or surgeon and the patient on the waiting list. Although we believe there should be some degree of transparency and accountability, we want to avoid causing the patient undue anxiety. Therefore, we are seeking comments on the degree of transparency that we should require of programs to ensure that transplant patients on the wait list receive the information they need to make decisions about their care and ensure that transplant programs and surgeons are accountable and transparent in their decisions to decline organs.

Specifically, we are seeking public comments on the following question:

1. How can transplant programs facilitate greater communication and transparency with patients on their waiting list regarding organ selection while limiting undue delays or undue anxiety to their patients?

We are also requesting feedback from individuals who are on a waiting list or who have received a transplant, their families, advocates, and caregivers

<sup>9</sup>Mohan S. “Kidney Transplantation: Good intentions and missed opportunities leave patients behind.” Centers for Medicare & Medicaid Grand Rounds. June 13, 2019.

regarding patient education, support, and information on transplantation. We are interested in understanding how the CoPs/CfCs, in particular the patient and transplant recipient rights requirements, could be revised to ensure that transplant programs, ESRD facilities, and OPOs are providing appropriate education and information to patients and their families on organ transplantation. This would ensure that patients, particularly those in underserved communities, are aware of their ability to access a lifesaving organ transplant, which will lead to better long-term health outcomes. While we use the term “transplant program,” please include any communication or information that you have received from other health care providers such as physicians or hospitals in your responses.

Specifically, we are seeking public comments on the following questions:

1. Did the transplant program provide you with information specific to your unique needs, medical situation, and potential transplant outcomes?

2. Did the transplant program provide you with any information about waiting times specific to your type of organ transplant? If so, what was the waiting time estimate that the transplant program gave you?

3. Did the transplant program or transplant surgeon provide you with any information on organ offers that were made for you and were declined by the transplant program or surgeon? If so, was the reason for a decline explained to you?

4. What is/was the most helpful information about organ transplantation you received? From which source did you receive this information? Did you receive other helpful information from other sources? If so, what were those sources?

5. Are you satisfied with the communication and support you have received from your transplant program? What information from your transplant program did you find helpful in making your decision?

6. For patients who are or were on dialysis, what information did you receive on organ transplantation from your dialysis center? Do you believe the dialysis center supported organ transplantation? Why or why not?

### 4. Equity in Organ Transplantation and Organ Donation

On January 20 through January 21, 2021, President Biden issued three executive orders addressing issues of health equity:

- Executive Order On Advancing Racial Equity and Support for Underserved Communities Through the Federal Government (E.O. 13985, 86 FR 7009, January 20, 2021);
- Executive Order on Preventing and Combating Discrimination on the Basis of Gender Identity or Sexual Orientation

(E.O. 13988, 86 FR 7023, January 25, 2021); and

- Executive Order on Ensuring an Equitable Pandemic Response and Recovery (E.O. 13995, 86 FR 7193, January 26, 2021).

We are committed to supporting the President’s Executive Orders by “advancing equity for all, including people of color and others who have been historically underserved, marginalized, and adversely affected by persistent poverty and inequality”.<sup>10</sup> Such efforts extend to ensuring equity within the organ transplantation and donation system for all populations, including racial and ethnic minorities and people with disabilities. Organ transplantation and donation in the United States remains highly inequitable amongst racial and ethnic minorities as compared to White Americans. As one study notes regarding kidney transplants, “racial disparities were observed in access to referral, transplant evaluation, waitlisting and organ receipt” and “SES [socioeconomic status] explained almost one-third of the lower rate of transplant among black versus white patients, but even after adjustment for demographic, clinical and SES factors, blacks had a 59 percent lower rate of transplant than whites”.<sup>11</sup> In addition, Black/African Americans, Hispanics/Latinos, Asian Americans, and other minorities are at a higher risk of illnesses that may eventually lead to kidney failure, such as diabetes and high blood pressure.<sup>12</sup> “Black/African Americans are almost 4 times more likely and Hispanics or Latinos are 1.3 times more likely to have kidney failure as compared to White Americans.”<sup>13</sup> Yet those Black/African American and Hispanic/Latinos patients on dialysis are less likely to be placed on the transplant waitlist and also have a lower likelihood of transplantation.<sup>14</sup> In particular, Black/African Americans make up the largest group of minorities in need of an organ transplant and yet the number of organ transplants performed on Black/African Americans

<sup>10</sup>Executive Order on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government, January 20, 2021.

<sup>11</sup> Patzer, RE, Perryman, JP et. al. The Role of Race and Poverty on Steps to Kidney Transplantation in the Southeastern United States. *American Journal Transplant.* <https://pubmed.ncbi.nlm.nih.gov/22233181/>.

<sup>12</sup> <https://www.kidney.org/atoz/content/minorities-KD>, Race, Ethnicity, & Kidney Disease.

<sup>13</sup> <https://www.kidney.org/atoz/content/minorities-KD>, Race, Ethnicity, & Kidney Disease.

<sup>14</sup> Social Determinants of Health: Going Beyond the Basics to Explore Racial Disparities in Kidney Transplantation. [https://journals.lww.com/transplantjournal/Fulltext/2020/07000/Social\\_Determinants\\_of\\_Health\\_Going\\_Beyond\\_the.9.aspx](https://journals.lww.com/transplantjournal/Fulltext/2020/07000/Social_Determinants_of_Health_Going_Beyond_the.9.aspx). Access.

in 2020 was 28.5 percent of the number of Black/African Americans currently waiting for a transplant. The number of transplants performed on White Americans, however, was 40.4 percent of the number currently waiting.<sup>15</sup>

U.S. TRANSPLANT WAITING LIST—CANDIDATES BY RACE/ETHNICITY

Organ	All candidates	Number of Black candidates	Black percent of all candidates	Number of White candidates	White percent of all candidates
All Organs .....	106,666	30,421	28.5	43,054	40.4
Kidney .....	90,235	28,365	31.4	32,377	35.9
Liver .....	11,704	836	7.1	7,865	67.2
Heart .....	3,531	990	28.0	2,004	56.8
Lung .....	922	118	11.9	661	66.6

TRANSPLANTS PERFORMED IN THE U.S. BY RECIPIENT ETHNICITY, 2020

	Number	Percentage of total 2020 transplants
Black .....	8,414	21.6
White .....	20,997	53.8
Total Transplants .....	39,036	100

Source: HRSA. U.S. Organ Procurement and Transplantation Network (OPTN). Based on OPTN data as of August 23, 2021. <https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/>. Tables from <https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlid=27>.

There are many theories that have been posited as to why these racial and ethnic inequities in transplantation exist. A person’s social determinants of health (those additional social and economic factors that are driven by systemic racism and social policies) affect a wide range of health and quality of life risks and outcomes.<sup>16</sup> These can therefore be contributing factors that lead to inequities in transplantation and impact a patient’s access to dialysis and placement on the waitlist. In addition, low health literacy, lack of healthcare coverage, and lack of economic, environmental, and other social opportunities can contribute to poorer health outcomes in general. However, studies have also shown that medical practices can contribute to inequities in transplantation. Delays in referrals to kidney transplantation, in particular, may be due “. . . in part, to clinicians’ implicit or explicit biases, including physician misperceptions about the benefits of transplants for Black individuals or discordant and inaccurate beliefs regarding causes or prevalence of these disparities”.<sup>17</sup> Another contributing factor to inequities in transplantation could also be due to the widespread use of the Chronic

Kidney Disease Epidemiology (CKD–EPI) equation used by kidney transplant programs, which measures kidney function and includes an adjustment for race (Black/African American) that often under-identifies chronic kidney disease in Black/African Americans and denies them equitable appropriate intervention, which in turn could have an impact on the time a patient waits for a kidney transplant. The use of race in the calculation of the estimated glomerular filtration rate (eGFR) has been questioned recently and the OPTN has solicited public feedback on reassessing the inclusion of race in eGFR equations.<sup>18</sup>

In addition, inequity exists for people with disabilities who similarly need access to organ transplantation. A 2019 National Council on Disability report found that people with disabilities are frequently denied equal access to receive organ transplants based solely on their disability status.<sup>19</sup> Providers and transplant centers also often assume that people with disabilities, especially those with intellectual disabilities, will have worse outcomes after transplantation. A survey conducted in 2008 of pediatric transplant centers determined that “43 percent always or

usually consider intellectual disabilities an absolute or relative contraindication to transplant due to assumptions about quality of life, concerns regarding ‘compliance or long-term self-care’ ‘financial concerns’, and ‘the functional prognosis of the delay itself’”.<sup>20</sup> However, individuals with disabilities can have equally positive outcomes, and the disability should have very limited impact on the individual’s ability to adhere to post-transplant care, if they receive adequate support.<sup>21</sup> These individuals must be afforded equal access to transplantation services in accordance with federal civil rights laws, and the value of their lives are no less than those individuals who are without disabilities. This inequity exists despite numerous federal and state prohibitions on discrimination on the basis of race, color, national origin, and disability.

As the discussion on inequity for racial and ethnic minorities and people with disabilities demonstrates, there remain outstanding issues, including those that lead to inequities in transplantation. It is imperative that racial and ethnic minorities as well as those with disabilities are afforded the same opportunities to receive a life-

<sup>15</sup> Organ Donation and African Americans—The Office of Minority Health ([hhs.gov](https://hhs.gov)). Accessed June 10, 2021.

<sup>16</sup> <https://www.cdc.gov/socialdeterminants/index.htm>.

<sup>17</sup> Systemic Kidney Transplant Inequities for Black Individuals: Examining the Contribution of Racialized Kidney Function Estimating Equations | Health Disparities | JAMA Network Open | JAMA Network. January 14, 2021.

<sup>18</sup> Reassess Inclusion of Race in Estimated Blomerular Filtration Rate (eGFR) Equation. <https://optn.transplant.hrsa.gov/governance/public-comment/reassess-inclusion-of-race-in-estimated-glomerular-filtration-rate-egfr-equation/>.

<sup>19</sup> Organ Transplant Discrimination Against People with Disabilities: Part of the Bioethics and Disability Series, National Council on Disability, September 25, 2019. <https://ncd.gov/publications/2019/bioethics-report-series>.

<sup>20</sup> Organ Transplant Discrimination Against People with Disabilities: Part of the Bioethics and Disability Series, National Council on Disability, September 25, 2019. <https://ncd.gov/publications/2019/bioethics-report-series>.

<sup>21</sup> Organ Transplant Discrimination Against People with Disabilities: Part of the Bioethics and Disability Series, National Council on Disability, September 25, 2019. <https://ncd.gov/publications/2019/bioethics-report-series>.

saving organ transplant as their non-disabled, white counterparts. Further, addressing these issues in transplantation will have intersectional impacts for individuals that belong to more than one group.

We acknowledge that this and other critical improvements cannot, and will not, be achieved only through revisions to the transplant CoPs, OPO CfCs alone, or the ESRD facility CfCs. Thus, we are asking the public for specific ideas on advancing equity within the organ transplantation ecosystem, as they pertain to changes to the health and safety standards for transplant programs and OPOs. Specifically, we are seeking public comments on the following questions:

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

2. 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? Social determinants of health are those conditions in the places where people live, learn, work, and play that affect a wide range of health and quality-of-life risks and outcomes.<sup>22</sup> Obtaining consent for donation is vital to increasing the number of organs available for transplantation. However, studies have demonstrated that African Americans are half as likely as Whites to agree to donate a loved one's organs.<sup>23</sup> In addition, studies have shown a "lower donation rate among racial/ethnic minorities, specifically including Blacks, Hispanics, and Asians".<sup>24</sup> There are many factors that contribute to these differences, including medical mistrust and differing opinions on organ donation and transplantation. OPOs have a key role in educating the public on organ donation and reaching out to those in underserved populations to address concerns or misconceptions regarding organ donation. They must also obtain consent from families in underserved communities with cultural sensitivity, awareness, and empathy. In order to ensure that more organs are available for transplant to those in underserved populations that need them the most, we are therefore asking what role CMS can play to ensure that OPOs can better build trust and awareness in historically underserved populations and communities (including racial and ethnic minorities).

<sup>22</sup> Social Determinants of Health. Know What Affects Health. <https://www.cdc.gov/socialdeterminants/index.htm>.

<sup>23</sup> Goldberg, David, et al. Rejecting Bias: The case against race adjustment for OPO performance in communities of Color. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1831604/>. March 17, 2020.

<sup>24</sup> Siminoff, Laura, et al. Racial Disparities in Preferences and Perceptions Regarding Organ Donation. <https://onlinelibrary.wiley.com/doi/full/10.1111/ajt.15865>. September 21, 2006.

3. 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? This would include ways that CMS can hold OPOs accountable for their outreach and communication to those underrepresented communities while maintaining cultural competency, such as awareness of various religious beliefs surrounding organ donation. Comments should include considerations of how to address issues pertaining to medical mistrust, disadvantageous social and economic factors, and the effects of systemic racism and discrimination on underserved populations.

4. 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?

5. What changes can be made to the current requirements to ensure that transplant programs ensure equal access to transplants for individuals with disabilities?

6. What changes can be made to the current requirements to address implicit or explicit discrimination, such as decisions made based on faulty assumptions about quality of life and the ability to perform post-operative care?

## B. Kidney Health and End-Stage Renal Disease Facilities

### 1. Background

On September 29, 2020, we published a final rule entitled, "Medicare Program; Specialty Care Models To Improve Quality of Care and Reduce Expenditures" (85 FR 61114), hereinafter referred to as the Specialty Care Models final rule. Among other things, the Specialty Care Models final rule finalized the End-Stage Renal Disease (ESRD) Treatment Choices (ETC) Model, which is designed to encourage greater use of home dialysis and kidney transplants for Medicare beneficiaries with ESRD, while reducing Medicare expenditures and preserving or enhancing the quality of care furnished to beneficiaries with ESRD. As described in the Specialty Care Models final rule, both of these modalities have support among health care providers and patients as preferable alternatives to in-center hemodialysis, but utilization has been less than in other developed nations (85 FR 61263).

Interventions that can slow progression of CKD include early identification of the disease, controlling blood pressure, controlling blood glucose, reducing albuminuria, eating a healthy diet, and maintaining a healthy lifestyle. We would like to learn what patient, clinician and system factors would help patients maintain or improve their health. We are also interested in knowing various

approaches to identifying those at risk of developing CKD and ways to improve CKD detection rates. Additionally, we are interested in actions that aim to close health equity gaps in CKD detection, education and care and would like to learn about these and other health equity concerns among this patient population. Feedback on ways to increase interventions and awareness of health inequities may further improve patient centered ESRD health and safety CfCs, or may impact future CfCs for health equity. To that end, we request the public's help in answering the following questions:

1. How can CMS increase the use of nutritional, lifestyle, and medical management interventions to improve health care and decrease the progression of CKD?

2. What are the barriers to access for routine and preventive health care? To what extent does low health literacy and cultural and attitudinal beliefs impact access to care?

3. How can we better educate patients about behaviors (such as diet and exercise) that may affect CKD progression? What is working? What is not working? How can pre-dialysis education and prevention programs be improved?

4. How can we increase awareness of known racial, ethnic, gender, sexual orientation, and economic disparities in care for CKD?

5. How can primary care providers (PCPs) better support their patients in prevention and slowing progression of CKD? What can be done to increase screening of at-risk individuals and how can we ensure that PCPs provide timely referrals to nephrologists for individuals with poor or declining kidney function?

6. How can we improve health literacy among the general population, and individuals at higher risk about the prevention of CKD?

7. How can individuals facing complete kidney failure be informed and empowered to make choices about their care?

Transition to dialysis is too often a surprise, with as many as half of all new dialysis patients having never previously seen a nephrologist. We are interested in learning about how patients with CKD receive appropriate information on kidney health and modality options, including transplantation. Transitional care units are specialized programs offered by dialysis facilities that provide medical and psychosocial support during the peridialysis initiation period. The goal of these units is to improve awareness of all aspects of renal replacement therapy, including modalities, access, transplantation options, and nutritional and psychosocial aspects of the disease enabling patients to make informed decisions regarding their care. In addition, we would like more information on transitional units.

1. To improve long-term outcomes and quality of life, how can we support and promote transplantation prior to the need for dialysis (preemptive transplantation)?

2. For people beginning dialysis, how can CMS support a safe transition?

3. Are there concerns regarding the location or quality of care of the transitional care units?

4. How can these care transitions be equitably provided?

## 2. Home Dialysis

Under the current CfCs at 42 CFR 494.70(a)(7) the patient has the right to be informed about all treatment modalities and settings, including but not limited to, transplantation, home dialysis modalities (home hemodialysis, intermittent peritoneal dialysis, continuous ambulatory peritoneal dialysis, continuous cycling peritoneal dialysis), and in-facility hemodialysis. Once they are stable on a specific modality, patients are infrequently aware that they are able to change modalities. In 2018, 72 percent of Black or African-American patients with ESRD received in-center hemodialysis versus only 57 percent of White patients. This data point may indicate that more White ESRD patients receive home dialysis than Black or African-American patients.<sup>25</sup> We would like information on the following questions:

1. What are patient barriers to dialysis modality choice? How can we overcome barriers to ensure patients understand their options and have the freedom to choose their treatment modality?

2. What are reasons for differing rates of home dialysis by race/ethnicity? How can we address any barriers in access to home dialysis to improve equity in access to home dialysis?

3. With regard to home dialysis, how can CMS ensure adequate safety standards such as appropriate infection control behaviors and techniques are enforced?

4. What can CMS do to increase availability and use of home support resources with regard to home dialysis as described in 42 CFR 494.100(a)((3)(iv)? Given the increase in home dialysis patients, is there a need to revise the current standards § 494.100, including but not limited to updating and revising training and care delivery requirements?

5. If more patients choose home dialysis, would there be systems and infrastructure in place to support this? Were more patients to choose home dialysis, what other supports, systems or infrastructure might be necessary?

6. To what degree does telehealth and remote monitoring technology impact decisions of home dialysis use? Would allowing physicians to leverage evolving telehealth and remote monitoring technology for their patients increase the selection of and

uptake of home dialysis as a modality? What are best practices in this area that would facilitate the delivery of safe and quality care?

## 3. Dialysis in Alternative Settings

### a. Dialysis in Nursing Homes

There are several means by which dialysis services are currently provided to nursing home residents, including transporting a resident to a local dialysis facility, dialysis facilities located on the campus of a nursing home, qualified dialysis facility staff that comes to the nursing home, or trained nursing home staff that provides dialysis services. The population of dialysis patients who receive home dialysis care in nursing homes is small, but it is an especially high-risk population. Our internal analysis shows that the percentage of dialysis patients in a nursing home was approximately 17 percent (89,568) in 2018. Most dialysis facilities (93 percent) had at least one patient in a nursing home. Only a small fraction of these dialysis patients (<1 percent) appear to receive dialysis treatment in a nursing home setting annually. There are no limitations to the number of agreements a dialysis facility may have with nursing homes to provide home dialysis services. We have received reports where some nursing homes are over 100 miles away or across the state from the dialysis facility where the agreement to provide care exists. We are concerned that this poses concerns for oversight of the dialysis care and services in providing timely support services and patient assessments as well as necessary equipment & supplies. We must ensure that these patients are receiving safe and appropriate dialysis care. We seek answers to the following questions:

1. Should dialysis facilities have geographical limitations for distance between the certified dialysis facility and nursing homes where they provide home dialysis services? Would health and safety issues be mitigated if there were some type of geographical limitation? Are there areas where placing a geographical limitation could create access issues where there are no dialysis facilities near the nursing home? If so, why, and how could these issues be mitigated?

2. Should there be a limit to the number of agreements that a given dialysis facility can have to provide home dialysis services in nursing homes? Why or why not?

3. Should CMS enhance protections for dialysis in institutional settings in the CfCs, such as including a written agreement to outline the roles and responsibilities of the dialysis facility and nursing home when home dialysis services are provided to residents, have protections for residents incapable of self-care, including clarifying staff roles, responsibilities, safety, and

supervision when the home dialysis services are not administered by the dialysis facility staff?

### b. Alternative Types of Dialysis Treatment Facilities Including Mobile Dialysis

We are also seeking information on the potential certification and safe use of alternate types of facilities that can provide dialysis treatments outside of an individual's home or resident care facility, such as mobile units. Mobile dialysis units are not currently defined or certified by CMS.

1. Should the use of mobile dialysis be limited to emergency circumstances and enrollment as a Special Purpose Renal Dialysis Facility?

2. How can mobile dialysis be used? Should these units be independently certified or used as an extension to an existing facility if approved outside of emergency circumstances?

3. What are the oversight considerations of these mobile dialysis units if units do not have a brick and mortar location and are moving among various locations? If used outside of an emergency circumstance, should there be geographical limitations?

4. Should mobile units have separate/different physical environment requirements compared to a brick and mortar building?

5. What health and safety standards are necessary to ensure a safe physical environment in mobile units?

6. What are the concerns related to equipment handling and maintenance related to mobile units that are different from brick and mortar facilities?

7. How can CMS ensure appropriate staffing roles, responsibilities and oversight of patient's dialysis care and needs by interdisciplinary team members for mobile units? Would these units require different staffing mix or requirements than a stationary dialysis unit?

8. What other alternative types of dialysis treatment facilities should we consider?

9. What should be the appropriate use of alternative types of facilities, such as only for emergency situations?

10. How should CMS certify these alternative types of facilities?

11. Are these facilities able to meet current patient safety and equipment standards?

12. Given the importance of water quality for dialysis, how do we ensure safe water standards with facilities that do not have water treatment centers?

13. Do patients in Medicare Advantage plans have a choice whether or not to dialyze at one of these alternative facilities?

14. What kind of emergency plans would be appropriate for mobile units or other alternative settings?

### c. Alternate Models of Care

We have received significant public interest and questions related to staff-assisted home dialysis, which is not a separately paid service, but is covered as part of the ESRD Prospective Payment System (PPS) bundled

<sup>25</sup> National Kidney Foundation. <https://www.kidney.org/news/newsroom/fjsindex>. Accessed 11/15/2021.

payment. A dialysis facility may provide qualified staff members in the patient's home to assist them in performing their home dialysis treatments as long as the facility provides Home Training and Support services specified at (42 CFR 494.100(a)). The dialysis staff member functions in the role of the patient's caregiver and monitors the patient throughout the dialysis treatment. The dialysis facility maintains overall responsibility and oversight to ensure appropriate, qualified staff are assigned and trained and provides supervision of staff members as indicated. Employees performing staff assisted dialysis must meet the personnel qualification requirements at § 494.140. In addition, staff who provide staff-assisted home dialysis must meet any state scope of practice requirements and any other applicable state laws.

1. Should there be two sets of guidelines for staff-assisted home dialysis in residential homes and staff-assisted home dialysis in alternative settings; and if so, how should they differ?

2. What factors should be taken into consideration for establishing different guidelines?

### C. Organ Procurement Organizations (OPOs)

#### 1. OPO Assessment and Recertification and Competition

CMS recently revised the OPO performance metrics that will be implemented in the 2022 through 2026 recertification cycle (85 FR 77898). The changes were made to improve upon the current measures by using objective and reliable data that will incentivize OPOs to ensure all viable organs are transplanted, apply greater oversight to OPOs while driving higher performance, and as a result, save more lives. We implemented a tiered approach based on thresholds set prior to the performance period using a previous year's data, while also using a median rate for assessing OPOs. We will assign OPOs to tiers based on whether performance exceeded these thresholds. OPOs assigned to tier 1 are those OPOs with performance rates for both measures (donation rate and transplantation rate) that are not statistically below the lowest rates among the highest 25 percent of all OPOs. These OPOs are automatically recertified after successfully complying with the remaining Conditions for Coverage and can compete for other open areas (provided they meet all other requirements). OPOs assigned to tier 2 are those whose performance for both measures statistically meet or exceed the median rates for all OPOs but do not

meet tier 1 requirements for both measures. The designated service areas (DSAs) for these OPOs will be opened for competition and these OPOs must compete to retain their DSA. Additionally, these OPOs can compete for other open areas (provided they meet all other requirements). OPOs assigned to tier 3 are OPOs whose performance rate for either measure is statistically below the respective median rate for all OPOs. These OPOs will be decertified and their areas opened for competition. If no OPO applies to compete for the area, CMS may select a single OPO to take over the entire open area or may adjust the service area boundaries of two or more contiguous OPOs to incorporate the open area.

Although we believe our new assessment approach will incentivize OPO performance, resulting in clustering of rates close to the highest performers, eventually the margin between the top 25 percent and the median will begin to narrow. Once OPO performance on the outcome measures reaches this level, CMS will need to consider other factors that differentiate highly functioning OPOs from those that are less highly functioning. We are interested in exploring what factors CMS may consider in this regard and ways to measure performance in these areas.

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

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

3. Should CMS consider additional metrics, such as those that measure equity in organ donation or an OPO's success in reducing disparities in donation and transplantation, and how should this be measured?

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

We are interested in ensuring our processes for the assessment of OPO performance are continually evolving and reflective of current industry standards and technological capabilities while providing the necessary incentives and rewards based on the dynamics within the OPO community and organ donation-transplantation ecosystem. We seek public comment to facilitate fair and equitable oversight of OPOs while ensuring we continually drive performance to ensure more lifesaving organs are available to individuals on transplant waitlists.

In addition, we are assessing ways that we can improve the current recertification and competition

processes. We ask the public for specific information on how these CfCs can be modified to ensure that OPOs are recertified and competition occurs in such a manner that would allow for the seamless determination of recertification for an OPO at the end of the recertification cycle, or the assignment of a new OPO to an open DSA. Therefore, we are asking the following questions:

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

2. 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.

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

4. 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?

5. 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?

6. What would be the anticipated impact from consolidation or expansion of the OPO community? Would consolidation or expansion of OPOs facilitate increased competition and improved performance or have a negative impact?

7. Any other helpful information that could inform potential changes to the current recertification and competition processes.

#### 2. Organ Transport and Tracking

While many organs are transported to recipients with organ recovery teams, some organs need to be transported independently via common or commercial carrier in order to reach the intended recipient at a transplant hospital. A recent media report of organs being lost or delayed in transport, mainly through commercial airlines, have raised concern regarding the risks associated with unaccompanied organ transport. The tracking of these organs during transport is often subpar, using outdated methods.<sup>26</sup> Lost or delayed organs lead to the unnecessary discards and missed opportunities for those waiting for a lifesaving organ transplant. Ensuring

<sup>26</sup> Kaiser Health News. How Lifesaving Organs for Transplant Go Missing In Transit. <https://khn.org/news/how-lifesaving-organs-for-transplant-go-missing-in-transit/>.



that organs arrive at the transplant hospital in a timely manner is of the utmost importance.

Recovered organs that are ready for transplant must first be preserved, packed, stored, and transported to the transplant hospital. The OPTN has specific policies for the transport of organs including requirements for packaging, labeling, shipping and storage of organs and vessels.<sup>27</sup> Such processes are extremely important in reducing errors and help ensure that donated organs are matched correctly and efficiently with the identified recipient. However, there are currently no specific requirements, such as real-time tracking, for OPOs that utilize organ transport via common or commercial carriers. An OPO may choose a transport and tracking method that it believes is most appropriate based on the particular circumstances; however, these choices sometimes have resulted in lost opportunities for transplantation. Therefore, we are asking the public the following questions:

1. Are there best practices regarding the arrangement of organ transportation between an OPO and a transplant program?

2. 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?

3. Can the OPO CfCs address the issue of organs that are lost during transport to a transplant program?

4. Are there other ways HHS can incentivize creation or use of additional mechanisms to reduce the likelihood organs will be lost or damaged after procurement but before transplantation?

### 3. Donor Referral Process

Under the OPO CfCs, OPOs are required to have agreements with 95 percent of the Medicare and Medicaid participating hospitals and critical access hospitals in its DSA that have both a ventilator and an operating room and have not been granted a waiver by CMS to work with another OPO. The agreement must describe the responsibilities of both the OPO and hospital or critical access hospital in regards to organ donation. Hence, the first step in the organ donation process is for the donor hospital to timely notify the appropriate OPO of all deaths and imminent deaths in the hospital (42 CFR 482.45(a)(1)).

The notification and timing of referrals to OPOs is critical to ensure the

identification of potential donors and availability of organs for transplantation. The failure to make this referral is a significant reason a potential donor who is medically suitable for organ donation does not become a donor.<sup>28</sup> This should be done as soon as possible to give the OPO time to evaluate the person to determine if he or she is a potential donor and, if so, obtain consent and begin managing the potential donor's care to maximize the chances of organ recovery. CMS does not define "imminent death" or "timely referral" but requires that these terms be defined in the agreement between the OPO and the hospital (42 CFR 486.322(a)).

Some members of the OPO community have advocated for invasive mechanical ventilation to be a clinical trigger that would require a referral to the OPO. Most of the potential donors will be on invasive mechanical ventilation. A person being assessed for brain death criteria will be on invasive mechanical ventilation due to their inability to breathe. In addition, potential donation after cardiac death (DCD) donors will most likely be on invasive mechanical ventilation prior to any decision to discontinue life support due to devastating injuries. If the decision has been made to withdraw life support, it is critical that the OPO know of these individuals before invasive mechanical ventilation is withdrawn to give the OPO time to evaluate the potential donor and obtain consent for donation.

Since CMS does not specifically define "imminent death" or "timely referral," it has been suggested that this may result in variable performance in this requirement due to lack of any national standards. Some have indicated that reporting timelines vary from hospital to hospital and the demands of patient care can cause unintended delays in this process. One recommendation to reduce the variation in timeliness of reporting is automating real time donor referral thereby removing the subjective element of identifying potential organ donors and reducing the variation in timeliness of reporting.<sup>29</sup>

CMS is interested in learning more about the capabilities hospitals and OPOs may currently have for transmitting and receiving automated referrals. We are particularly interested in the experience of OPOs and donor

hospitals that have successfully piloted or implemented the use of automated donor referral systems.

1. What specific patient events, clinical triggers, or subsets of clinical information are used to send notifications to OPOs?

2. 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 (for example, should the reason for placement on invasive mechanical ventilation be considered for a potential exclusion from the trigger or should the trigger be automatic for all patients)?

3. Could the referral to the OPO be made by someone other than a doctor or nurse, such as a respiratory therapist?

4. What is the minimum information necessary to facilitate notification to the OPO and what additional clinical information, if any, may also be beneficial?

5. Do donor hospitals that are making electronic referrals leverage the existing admission, discharge, and transfer elements in electronic medical record systems to transfer information to OPOs, and if so, how is this information utilized? We are interested to learn if there is any standardization in the industry for transmitting and receiving this information as well as any common data sets that are currently collected.

6. 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?

7. 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?

8. Are there opportunities for OPOs to use electronic health record (EHR) application program interfaces (APIs) to facilitate key information transfer between the hospital and OPO?

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. We would like to better understand what technical requirements are necessary and how any changes can be duplicated across hospital EHR systems nationally with minimal burden to the industry.

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

<sup>28</sup> Dominguez-Gil, B, et al. The critical pathway for deceased donation: Reportable uniformity in the approach to deceased donation. *Transplant International*. 24 (2011): 373–378.

<sup>29</sup> <https://unos.org/news/media-resources/5-ways-to-automate-real-time-donor-referral/>.

<sup>27</sup> UNOS. [https://optn.transplant.hrsa.gov/media/1200/optn\\_policies.pdf](https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf).

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.

#### 4. Organ Recovery Facilities

Organs from deceased donors are nearly always recovered in donor hospitals. However, OPOs have pointed out that there can be numerous challenges in recovering organs in this setting, and the overall process of organ procurement is often time consuming and logistically challenging. Unless an organ(s) is going to be recovered and transplanted in the same hospital, transplant surgeons must often travel to the donor hospital to surgically recover the organ(s). This procedure is complex and time-sensitive, especially for extrarenal organs. Depending upon the organs intended to be procured from the donor, multiple teams of recovery surgeons may need to travel to the donor hospital. Due to competing priorities in a donor hospital, donors often receive lower priority for operating room time and may experience delays in special tests, such as echocardiograms, biopsies, or cardiac catheterizations. These delays may result in increased costs for procurement of the organ(s) or in not being able to procure organs from a donor due to medical complications during a protracted timeframe while on mechanical ventilation. Additionally, OPOs are responsible for all costs for donor evaluation and medical management once declaration of death and consent for donation occurs. These costs are reimbursed by transplant hospitals, other OPOs and Medicare for Medicare beneficiaries. Donor evaluation and management tasks can include a range of laboratory, imaging, and diagnostic procedures that OPOs report they may complete at a fraction of the cost they pay for these services at donor hospitals.

CMS is aware of at least 10 OPOs that have developed dedicated facilities to recover organs from donors. These facilities are independent of the donor hospital location from which the donor was referred. These facilities do not provide routine medical care but they may provide a range of services to facilitate donor evaluation and management and organ recovery. In addition, the only potential donors who would be transferred to these facilities would have been declared dead by brain death criteria and the OPO would have already received appropriate consent for organ donation.

There are few published studies evaluating the effectiveness of organ recovery facilities.<sup>30 31</sup> While these studies highlight the potential benefits, the practice has not been universally adopted by OPOs and growth of these facilities is relatively slow. Federal oversight of tissue collection is provided under the Public Health Service Act (PHS Act) and FDA regulations on human cells, tissue, and cellular and tissue-based products, or HCT/Ps (21 CFR part 1271). However, organ recovery facilities are not specifically addressed in the OPO CfCs and Medicare does not currently compensate OPOs for some activities associated with operation of these facilities, such as transportation of the donor to the OPO's facility.

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. We are requesting public comments that provide evidence-based conclusions, such as additional peer-reviewed literature, that we should consider to inform any future rulemaking. Additionally, we are requesting that commenters share any experiences in operating or interacting with staff from OPOs with organ recovery facilities. Finally, we are particularly interested in the experience of donor families and patient advocates and seek comments from these individuals and any organizations representing donor families. While much of the information reviewed by CMS highlights the benefits of organ recovery facilities, we are also interested in learning of specific risks or adverse outcomes associated with these facilities.

##### *Effectiveness:*

1. What benefits and risks may OPOs experience in regards to cost-effectiveness, organ yield, and organ

quality from operating an organ recovery facility?

2. Are there particular benefits to securing organs from marginal or extended criteria donors while at an organ recovery facility?

3. Are OPOs able to achieve better placement of these organs relative to organs recovered at donor hospitals?

##### *Operations:*

1. What medical evaluation diagnostic procedures are commonly performed in these organ recovery facilities?

2. What special equipment needs, such as laboratory and imaging, are necessary?

3. What supplies, such as pharmaceuticals, should be considered?

4. Which professional staff are needed and what are their qualifications for operating an organ recovery facility?

5. What specific risks may be associated with operating a facility for the recovery of organs outside a donor hospital?

6. What state or local requirements apply to the currently existing facilities, including health and safety and fire?

##### *Impacts on other stakeholders:*

1. Are there any negative impacts or disincentives to donor hospitals or transplant centers?

2. How does having an organ recovery facility impact tissue recovery and the relationships with tissue banks in the DSA?<sup>32</sup>

##### *Impacts on Donor Families:*

1. Were you satisfied with the request for donation discussion by the OPO representative and how did this affection your decision for donation?

2. How does organ donation at organ recovery facilities impact donor families?

3. Does the process for transfer to organ recovery facility 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?

4. What are the reasons why donor families reject transfer from the donor hospital to an organ recovery facility? If you have personal experience with this issue, what reasons led you and your family to the decision to reject transfer?

5. 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?

<sup>30</sup> Doyle, M., et al. Organ Donor Recovery Performed at an OPO-Based Facility Is an Effective Way to Minimize Organ Recovery Costs and Increase Organ Yield." *Journal of the American College of Surgeons*, April 2016 (Vol. 222, Issue 4, pp. 591–600).

<sup>31</sup> Marslais, P., et al. The First 2 Years of Activity of a Specialized Organ Procurement Center: Report of an Innovative Approach to Improve Organ Donation. *American Journal of Transplantation* 2017; 17: 1613–1619.

<sup>32</sup> Establishments that manufacture human cells, tissues, and cellular and tissue-based products (HCT/Ps) regulated solely under section 361 of the PHS Act are commonly referred to as "tissue establishments" within FDA terminology but are commonly referred to as "tissue banks" within the CMS regulations.

6. What aspects do donor families find particularly beneficial and which are challenging for them?

##### 5. “Zero Organ Donors” and Discarded Organs

In response to our recent rulemaking (85 FR 77898), some commenters raised concerns about the new definition of “donor,” which excludes “zero organ donors.” While there is no commonly accepted definition of a “zero organ donor,” it is generally interpreted to mean a situation where the donation process was initiated but no organ was transplanted. Our internal analysis during this rulemaking indicated that in 2018, there were 1,255 organs procured from 593 “zero organ donors,” but never transplanted. Commenters claimed that excluding “zero organ donors” from the donation rate may discourage OPOs from pursuing extended criteria or marginal and complex donors, which is inconsistent with our goal of increasing organ donation.

More recent data indicates that the number of “zero organ donors” is increasing significantly. A recent internal analysis indicates that “zero organ donors” increased by 31 percent between 2019 and 2020 (746 to 977) and 76 percent from 2017 through 2020 (555 to 977). In 2017, these donors represented 5 percent (555) of all deceased donors and 25 percent (1,215) of all discarded organs. In 2020, “zero organ donors” increased to 8 percent (977) of all deceased donors and 31 percent (2,051) of all discarded organs. During the past decade, the rate of “zero organ donors” ranged from a low of 5.3 percent to a high of 8.5 percent in 2020 with an average annual rate of 6.0 percent.

In addition to “zero organ donors” where no organs from a donor are transplanted, there are many donors that have organs recovered and transplanted while other organs from the same donor are discarded. The number of all organ discards (including organs from zero organ donors) has increased steadily over the past 15 years. There were 3,553 discarded organs (including kidney, liver, heart, pancreas, lung, and intestine) in 2005, 3,878 discarded organs in 2010 (increase of 9.1 percent), 4,439 discarded organs in 2015 (increase of 14.5 percent), and 6,512 discarded organs in 2020 (increase of 31.8 percent). Overall, there were a total of 71,335 discarded organs in the 16-year period inclusive of the years 2005 to 2020. The rate of organ discards increased from 10.5 percent to 13.4 percent during this same period highlighting the increased frequency of discarding organs. Historically, kidney

discards represent the largest number of discarded organs accounting for 77.6 percent (5,051) of all organ discards in 2020 despite over 91,000 candidates registered on the waitlist for a kidney transplant.<sup>33</sup> The Scientific Registry of Transplant Recipients (SRTR) data indicate that many organs that are not recovered or are discarded are a result of failure to locate a recipient for the organs. Additionally, many of these organs have a disposition reason code of “other” despite a range of options for categorizing the organs.<sup>34</sup> While there may be many medically appropriate reasons for organ discards or non-recovery, such as infection, organ trauma, poor organ function and anatomical abnormalities, we are concerned with the increasing number of organs that go unused and are subsequently discarded. We are interested in ways to better understand and identify these issues and incentivize a reduction in these numbers through policy options.

The elimination of outcome measures for recertification of transplant programs was intended to eliminate provider disincentives for performing transplantations, improve organ procurement for transplantation, and increase organ utilization through increased acceptance of organs that previously may have been declined. Since the change in the transplant program outcome measures was only implemented in 2019, we only have 1 year of data to assess at this time. However, data from 2020 demonstrates a continued increase in the number of “zero organ donors” and discarded organs suggesting the policy change may not be achieving the desired outcome indicating other factors may be impacting placement of organs. While we acknowledge the complexity that is involved in the placement of organs, we are seeking information on additional factors to consider and methods that may facilitate improvements in this area through OPO and transplant center collaboration.

Recent research indicates that factors beyond organ quality impact acceptance behavior by transplant centers. These factors may include donor characteristics, geographic area, characteristics of the organ donation-transplantation environment within a DSA, and timing such as interruptions caused by weekends and holidays.<sup>35</sup>

<sup>33</sup> OPTN National Data. Accessed 2/18/2021.

<sup>34</sup> SRTR/OPTN 2018 Annual Data Report; Discarded Organ Donors: [https://srr.transplant.hrsa.gov/annual\\_reports/2018/DOD.aspx](https://srr.transplant.hrsa.gov/annual_reports/2018/DOD.aspx).

<sup>35</sup> Mohan S, Foley K, Chiles MC, Dube GK, Patzer RE, Pastan SO, Crew RJ, Cohen DJ, Ratner LE. The

This often results in missed opportunities for many patients on the waitlist and frequently leads to organ discards. Some of these organs are initially rejected only to later be accepted at other centers and successfully transplanted in patients lower on the waitlist. Recent studies have found that many kidneys that were discarded had similar or better quality characteristics to those that had been successfully transplanted.<sup>36 37</sup> Additionally, candidates for transplantation are frequently not aware of organs being declined on their behalf and may not be informed of the reason for the decline. Center-level organ acceptance practices eliminate a patient-centered approach to involvement in decision making on the advantages and disadvantages to organ acceptance versus continuation of existing care while remaining on a waitlist.<sup>38</sup> This may result in significant negative quality of life impacts for potential organ recipients, and even death, while waiting for a better organ after many potentially acceptable offers were declined on behalf of the patient. The net effect is the discard of lifesaving organs, frequently without potential recipient involvement in the decision-making process, while there is a shortage of organs for over 106,000 individuals.<sup>39</sup>

Given the impact from reducing the number of organ discards, CMS is interested in exploring policy options that may assist in this effort. We are seeking information that we can act upon to strengthen requirements as well

weekend effect alters the procurement and discard rates of deceased donor kidneys in the United States. *Kidney Int.* 2016 Jul; 90(1):157–63. doi: 10.1016/j.kint.2016.03.007. Epub 2016 May 12. PMID: 27182001; PMCID: PMC4912390.

<sup>36</sup> Aubert O, Reese PP, Audry B, Bouatou Y, Raynaud M, Viglietti D, Legendre C, Glotz D, Empana JP, Jouven X, Lefaucheur C, Jacqueline C, Loupy A. Disparities in Acceptance of Deceased Donor Kidneys Between the United States and France and Estimated Effects of Increased US Acceptance. *JAMA Intern Med.* 2019 Aug 26;179(10):1365–74. doi: 10.1001/jamainternmed.2019.2322. Epub ahead of print. PMID: 31449299; PMCID: PMC6714020.

<sup>37</sup> Mohan S, Chiles MC, Patzer RE, Pastan SO, Husain SA, Carpenter DJ, Dube GK, Crew RJ, Ratner LE, Cohen DJ. Factors leading to the discard of deceased donor kidneys in the United States. *Kidney Int.* 2018 Jul;94(1):187–198. doi: 10.1016/j.kint.2018.02.016. Epub 2018 May 5. PMID: 29735310; PMCID: PMC6015528.

<sup>38</sup> Husain SA, King KL, Pastan S, Patzer RE, Cohen DJ, Radhakrishnan J, Mohan S. Association Between Declined Offers of Deceased Donor Kidney Allograft and Outcomes in Kidney Transplant Candidates. *JAMA Network Open.* 2019 Aug 2;2(8):e1910312. doi: 10.1001/jamanetworkopen.2019.10312. Erratum in: *JAMA Netw Open.* 2019 Oct 2;2(10):e1914599. PMID: 31469394; PMCID: PMC6724162.

<sup>39</sup> Organ Procurement and Transplantation Network (OPTN) website. Accessed 10/27/2021.

as information where additional burden reduction may facilitate improvement. 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.

1. 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?

2. 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?

3. Should this type of collaboration between OPOs and transplant programs be incorporated into quality assurance performance improvement (QAPI) requirements for OPOs and transplant centers?

There are many quality improvement tools and initiatives available to OPOs and transplant centers through the OPTN, and potentially within the industry itself that may foster improvements in reducing the number of “zero organ donors” and organ discards. OPOs and transplant programs that do not take full advantage of the resources available to improve performance may continue to unnecessarily waste these lifesaving organs.

Patient rights and patient-centered care are a vitally important aspect of organ donation and transplantation. Ensuring individuals have the information needed to make informed decisions about their care is essential and transparency is an important component of this process. We believe that patients and their families should have increased awareness of practices at OPOs and transplant centers. OPOs that have a high discard rate and transplant centers that have a high rate of declining organs are a concern in that many potentially life-savings organs are wasted and patients are at greater risk for dying while waiting for a transplant.

1. 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.

2. 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.

#### 6. Donation After Cardiac Death (DCD)

In the May 31, 2006 final rule entitled, “Conditions for Coverage for Organ Procurement Organizations (OPOs)” (71 FR 30982), we noted that commenters expressed concern that we did not include specific requirements related to Donation after Cardiac Death (DCD) (71 FR 30985). In this rulemaking, our intention was not to avoid addressing the issue of DCD, nor did we specifically encourage OPOs to recover organs from cardiac death donors. Rather, we stated that we believed DCD donation was addressed in three separate sections of the CFCs, specifically 42 CFR 486.322, Relationships with hospitals, critical access hospitals, and tissue banks; § 486.324, Administration and governing body; and § 486.344, Evaluation and management of potential donors and organ replacement and recovery. Therefore, we finalized the requirements to facilitate our oversight of donation after cardiac death and not disadvantage OPOs that did not pursue these donors. We indicated that we understood donation after cardiac death was an evolving practice and was not yet accepted in every area of the country. Some donor hospitals were reluctant to permit donation after cardiac death in their facilities and some transplant surgeons were unwilling to transplant organs from such donors into their patients. Thus, some OPOs were hesitant to advocate donation after cardiac death in their service areas.

CMS is interested in better understanding both the successes and the challenges that OPOs face in implementing DCD organ donation. We are interested in learning whether and to what extent the clinical, scientific, and general environment for DCD donation has changed in recent years and if commenters have specific recommendations in regards to policy options related to DCD donation that may be beneficial.

1. What has contributed to the recent rapid increase in DCD organ donation?

2. What challenges do OPOs face from stakeholders regarding DCD donation and how have some OPOs overcome these challenges?

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

4. Are there ways to better align the CFCs with the current environment for DCD donation?

5. How well do the CFCs complement requirements from the OPTN related to DCD donation?

6. Are there requirements that CMS should establish that may facilitate greater

acceptance of DCD donation while ensuring patient rights and protections?

#### 7. OPO Tissue Banking Activity and Relationships With Other Tissue Banking Organizations

CMS is interested in exploring the relationship between hospitals, OPOs, and tissue banks and how these relationships may have evolved over time, particularly since publication of the OPO final rule in 2006. Currently, hospitals are required to have an agreement with at least one tissue bank and at least one eye bank to cooperate in the retrieval, processing, preservation, storage and distribution of tissues and eyes, to assure that all usable tissues and eyes are obtained from potential donors provided these activities do not interfere with organ donation.

Additionally, regulations at § 486.322(c) require that OPOs have arrangements to cooperate with tissue banks that have agreements with hospitals and critical access hospitals with which the OPO has agreements. These regulations include cooperating on a range of potential activities to ensure that all usable tissues are obtained from potential donors. These activities may include screening and referrals; obtaining informed consent; managing tissue retrieval, processing, preservation, storage, and distribution; and providing designated requestor training. CMS does not regulate tissue banks, also known as tissue establishments. Instead, oversight over such establishments is primarily provided by FDA.

In drafting requirements for OPOs with respect to such agreements with tissue banks, in 2006, CMS considered three factors including (1) an OPO’s role as the agency that receives most referrals of deaths and imminent deaths from the hospitals in its service area (unless referrals are screened by a third-party designated by the OPO); (2) the need to show sensitivity toward the circumstances of potential organ and tissue donor families (such as ensuring that potential donor families are not approached by more than one agency unnecessarily); and (3) the statutory requirement that an OPO have arrangements to cooperate with tissue banks to assure that all useable tissues are obtained. The CFCs were intended to ensure OPOs maintain a collaborative relationship with tissue banks in their area but OPOs are only required to have agreements with those tissue banks that have agreements with hospitals in their DSA.

We noted in our 2006 final rule “Medicare and Medicaid Programs;

Conditions for Coverage for Organ Procurement Organizations (OPOs)” (71 FR 31007), that many OPOs were beginning to establish tissue banking services. We seek input on the changes that have occurred since then to better understand how this service has evolved and if changes to the existing requirements are necessary.

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

2. How has the increase in OPOs participating in tissue banking impacted the collection of useable tissues from donors?

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

4. 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?

#### 8. Organs for Research

While the primary mission of an OPO is to maximize the number of viable organs it recovers for transplantation, OPOs also serve a role in providing organs to the research community. Currently, OPOs are assessed on both these aspects of organ donation as a requirement of the outcome measures at § 486.318. During recent rulemaking revising these measures (85 FR 77898), CMS eliminated the assessment of organs for research focusing the measures on the primary mission of OPOs in providing organs for transplantation. This change is scheduled to be implemented during the next OPO certification period beginning in 2022. The one exception to this change was the inclusion of pancreata procured for islet cell transplantation or research that was included in the outcome measures in order to comply with the Pancreatic Islet Cell Transplantation Act of 2004. While this recent rulemaking accomplished our goal of developing more transparent, reliable, and objective outcome measures that will drive higher performance, it also leaves some areas that CMS may consider in future rulemaking. Specifically, CMS is interested in exploring the need for continued support for obtaining organs for research as well as possible alternative approaches to address the requirements of the Pancreatic Islet Cell Transplantation Act. Additionally, we are seeking information on approaches that align with our efforts to have transparent, reliable, and easily verifiable information while minimizing burdens associated with any potential future changes.

Providing organs for research is an important aspect for assisting

researchers in discovering new treatments for debilitating and fatal diseases. The Department of Health & Human Services defines research at 45 CFR 46.102(l). For our purpose of assessing OPO performance, we consider three categories of organs including: organs transplanted into patients with no research interventions (conventional transplants); organs that have had a research intervention that are transplanted into patients; and organs used exclusively for research purposes. In recent rulemaking (85 FR 77902), we indicated the transplant and research communities commonly described the transplantation of organs into humans using research protocols (for example, deceased donor intervention research) as both transplants and research. Generally, such research involves the transplantation of organs into transplant candidates that is generally considered clinical care while simultaneously qualifying as human subject research. Therefore, in establishing the new OPO performance measures, we consider organs used for research as applying to organs procured and used only for research purposes whereas organs transplanted into human subjects are counted as part of clinical care and included in the outcome measures. For example, in regards to assessing OPO performance in providing organs for research purposes as relating to organs that have been manipulated for research purposes but are not transplanted into a human recipient. This interpretation, used only for assessing OPOs on performance outcome measures, provides a level of demarcation for counting organs transplanted into human subjects (including those as part of a research protocol) versus those that are utilized strictly for research purposes, and aligns with our assessment of an OPO’s primary mission with data that is independently verifiable. As previously noted, pancreata procured for research are also counted in the performance measures based on statutory requirement.

Given the importance of research to continued innovation in transplant medicine, CMS is interested in exploring the issue of incentivizing the placement of organs with researchers without detracting from the OPOs primary mission of providing organs for transplantation.

1. 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?

2. 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?

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

4. 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?

#### 9. Vascular Composite Allografts

The use of vascular composite allografts (VCAs) is an evolving area of practice that involves the transplantation of multiple tissue types that may include skin, bone, muscles, blood vessels, nerves, and connective tissue. It includes body structures such as a face, limb (for example, arms, hands, fingers, legs, toes), bone, soft tissue (for example, larynxes and abdominal wall), and/or reproductive organs. According to data from the OPTN, there have been approximately 110 VCA transplantations in the United States. While VCA transplantations are relatively infrequent and the goals of surgery are restorative and life-enhancing, versus lifesaving, they can provide profound quality of life benefits for the recipient. FDA regulates human cells, tissues, and cellular and tissue-based products (HCT/Ps) under 21 CFR part 1271. Prior to 2014, VCAs were not explicitly excluded from the definition of HCT/Ps under FDA’s regulations and therefore were subject to FDA oversight, while HRSA regulated vascularized human organs through the OPTN, which sets policies related to the procurement, transplantation, and allocation of human organs, at regulations under 42 CFR part 121 (the “OPTN final rule”). In enacting the National Organ Transplant Act (NOTA) in 1984, the Congress gave the Secretary the authority to expand the definition of organ in regulation. Prior to 2013, VCAs were not included in the definition of organ and the classification of VCAs as HCT/Ps previously excluded them from regulation by HRSA. However, in 2013 the Secretary changed the definition of “organ” in the OPTN final rule to include VCAs shifting oversight responsibilities to HRSA (78 FR 40033, July 3, 2013). By including VCAs within the OPTN final rule’s definition of “organs”, transplants involving VCA are subject to the requirements of the OPTN final rule and explicitly excluded from the definition of HCT/Ps under FDA

regulations. This change became effective on July 3, 2014. The rule established specific criteria for body parts to qualify as VCAs.

In establishing the regulatory requirements for the oversight of VCAs through the OPTN, HRSA requires the body part to have specific characteristics to be considered a VCA. The characteristics include a body part that is: (1) Vascularized and requires blood flow by surgical connection of blood vessels to function after transplantation; (2) containing multiple tissue types; (3) recovered from a human donor as an anatomical/structural unit; (4) transplanted into a human recipient as an anatomical/structural unit; (5) minimally manipulated (that is, processing that does not alter the original relevant characteristics of the organ relating to the organ's utility for reconstruction, repair, or replacement; (6) for homologous use (the replacement or supplementation of a recipient's organ with an organ that performs the same basic function or functions in the recipient as in the donor; (7) not combined with another article such as a device; (8) susceptible to ischemia and, therefore, only stored temporarily and not cryopreserved; and (9) susceptible to allograft rejection, generally requiring immunosuppression that may increase infectious disease risk to the recipient.

Despite the change in the definition of organ by HRSA, CMS has not made changes to its definition of "organ" in oversight of solid organ transplantation through the CoPs at 42 CFR part 482 subpart E. However, we are seeking comment on whether or not we should revise its definition of organ to correspond to that of HRSA. We seek comment on ways to support this evolving area of practice while providing necessary health and safety oversight for transplant recipients.

1. 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?

2. 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?

#### D. Nephrology Joint Ventures

The Medicare Payment Advisory Commission (MedPAC) has stated that many dialysis facilities are operated as a joint venture between a dialysis organization and physicians. Joint ventures allow participating partners to share in the management, profits, and

losses of an entity.<sup>40</sup> MedPAC has noted concerns raised in the literature that joint ventures between dialysis organizations and physicians create financial incentives for participating physicians that could inappropriately influence decisions about patient.<sup>41</sup>

The health care industry is increasingly interested in identifying Medicare-enrolled providers and suppliers and their associations with other health care groups/organizations. CMS has been working on improving provider and supplier enrollment transparency by making data available for use by the healthcare community for research and to increase awareness in the provider and supplier community about enrollment information on file with CMS.<sup>42 43</sup> Recently, CMS has received requests from the research community for data to study the business practices of dialysis facilities and the effect of joint ventures between nephrologists and dialysis facilities. These researchers have reported difficulty in performing the research due to the lack of information on these financial arrangements collected by CMS.

When a provider enrolls in Medicare, CMS collects information that is self-reported by the provider on individuals and organizations with 5 percent or greater direct or indirect ownership of, a partnership interest in, and/or managing control of the provider.<sup>44</sup> Institutional providers, such as dialysis facilities, may self-report whether their affiliation with a Chain Home Office is a joint-venture or partnership on their enrollment application.

In addition to efforts to increase transparency of Medicare enrollment information and in order to learn more about the impact of nephrology joint ventures for the purpose of these efforts, CMS is seeking information on the following questions:

<sup>40</sup> March 2021 Report to the Congress: Medicare Payment Policy [https://www.medpac.gov/document/http-www-medpac-gov-docs-default-source-reports-mar18\\_medpac\\_entirereport\\_sec\\_rev\\_0518-pdf/](https://www.medpac.gov/document/http-www-medpac-gov-docs-default-source-reports-mar18_medpac_entirereport_sec_rev_0518-pdf/) (cut and paste into browser, page 205).

<sup>41</sup> MedPAC 2021 report citing Berns, J.S., A. Glickman, and M.S. McCoy. 2018. Dialysis facility joint-venture ownership—Hidden conflicts of interest. *New England Journal of Medicine* 379, no. 14 (October 4): 1295–1297.

<sup>42</sup> Medicare Fee-For-Service Public Provider Enrollment. <https://data.cms.gov/provider-characteristics/medicare-provider-supplier-enrollment/medicare-fee-for-service-public-provider-enrollment>.

<sup>43</sup> Public Provider and Supplier Enrollment Files. <https://www.cms.gov/newsroom/fact-sheets/public-provider-and-supplier-enrollment-files>.

<sup>44</sup> Medicare Enrollment Application. Institutional Providers. <https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/cms85a.pdf>.

1. Would it be helpful for CMS to collect information on joint venture arrangements 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?

2. Should a dialysis facility or nephrologist be required to disclose information on joint venture arrangements to patients for improved transparency?

3. Do joint ventures between nephrologists and dialysis facilities have an impact on resource use, patient care, and/or choice of modality? If so, please describe how joint venture arrangements affect resource use, patient care, or choice of modality.

### III. Collection of Information Requirements

This is a request for information (RFI) only. In accordance with the implementing regulations of the Paperwork Reduction Act of 1995 (PRA), specifically 5 CFR 1320.3(h)(4), this general solicitation is exempt from the PRA. Facts or opinions submitted in response to general solicitations of comments from the public, published in the **Federal Register** or other publications, regardless of the form or format thereof, provided that no person is required to supply specific information pertaining to the commenter, other than that necessary for self-identification, as a condition of the agency's full consideration, are not generally considered information collections and therefore not subject to the PRA.

This RFI is issued solely for information and planning purposes; it does not constitute a Request for Proposal (RFP), applications, proposal abstracts, or quotations. This RFI does not commit the United States Government to contract for any supplies or services or make a grant award. Further, we are not seeking proposals through this RFI and will not accept unsolicited proposals. Responders are advised that the United States Government will not pay for any information or administrative costs incurred in response to this RFI; all costs associated with responding to this RFI will be solely at the interested party's expense. We note that not responding to this RFI does not preclude participation in any future procurement, if conducted. It is the responsibility of the potential responders to monitor this RFI announcement for additional information pertaining to this request. In addition, we note that CMS will not respond to questions about the policy issues raised in this RFI.

We will consider all input as we develop future regulatory proposals or future subregulatory policy guidance.

We may or may not choose to contact individual responders. Such communications would be for the sole purpose of clarifying statements in the responders' written responses. Contractor support personnel may be used to review responses to this RFI. Responses to this RFI are not offers and cannot be accepted by the Government to form a binding contract or issue a grant. Information obtained as a result of this RFI may be used by the Government for program planning on a non-attribution basis. Respondents should not include any information that might be considered proprietary or confidential. This RFI should not be construed as a commitment or authorization to incur costs for which reimbursement would be required or sought. All submissions become United States Government property and will not be returned. In addition, we may publicly post the public comments received, or a summary of those public comments.

*I, Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on August 4, 2021.*

**Xavier Becerra,**

*Secretary, Department of Health and Human Services.*

[FR Doc. 2021-26146 Filed 12-1-21; 4:15 pm]

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## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

#### 50 CFR Part 679

[Docket No.: 21123-0243; RTID 0648-XY119]

#### Fisheries of the Exclusive Economic Zone Off Alaska; Bering Sea and Aleutian Islands; Proposed 2022 and 2023 Harvest Specifications for Groundfish

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

**ACTION:** Proposed rule; harvest specifications and request for comments.

**SUMMARY:** NMFS proposes 2022 and 2023 harvest specifications, apportionments, and prohibited species catch allowances for the groundfish fisheries of the Bering Sea and Aleutian Islands (BSAI) management area. This action is necessary to establish harvest

limits for groundfish during the 2022 and 2023 fishing years and to accomplish the goals and objectives of the Fishery Management Plan for Groundfish of the Bering Sea and Aleutian Islands Management Area (FMP). The 2022 harvest specifications supersede those previously set in the final 2021 and 2022 harvest specifications, and the 2023 harvest specifications will be superseded in early 2023 when the final 2023 and 2024 harvest specifications are published. The intended effect of this action is to conserve and manage the groundfish resources in the BSAI in accordance with the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act).

**DATES:** Comments must be received by January 3, 2022.

**ADDRESSES:** Submit your comments, identified by NOAA-NMFS-2020-0141, by either of the following methods:

- *Electronic Submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to <https://www.regulations.gov> and enter 21123-0243 in the Search box. Click on the "Comment" icon, complete the required fields and enter or attach your comments.
- *Mail:* Submit written comments to Glenn Merrill, Assistant Regional Administrator, Sustainable Fisheries Division, Alaska Region NMFS, Attn: Records Office. Mail comments to P.O. Box 21668, Juneau, AK 99802-1668.

*Instructions:* NMFS may not consider comments if they are sent by any other method, to any other address or individual, or received after the comment period ends. All comments received are a part of the public record, and NMFS will post the comments for public viewing on [www.regulations.gov](http://www.regulations.gov) without change. All personal identifying information (e.g., name, address), confidential business information, or otherwise sensitive information submitted voluntarily by the sender is publicly accessible. NMFS will accept anonymous comments (enter "N/A" in the required fields if you wish to remain anonymous).

Electronic copies of the Alaska Groundfish Harvest Specifications Final Environmental Impact Statement (Final EIS), Record of Decision (ROD) for the Final EIS, and the annual Supplementary Information Reports (SIRs) to the Final EIS prepared for this action are available from <https://www.regulations.gov>. An updated 2022 SIR for the final 2022 and 2023 harvest specifications will be available from the same source. The final 2020 Stock Assessment and Fishery Evaluation

(SAFE) report for the groundfish resources of the BSAI, dated November 2020, is available from the North Pacific Fishery Management Council (Council) at 605 West 4th Avenue, Suite 306, Anchorage, AK 99501-2252, phone 907-271-2809, or from the Council's website at <https://www.npfmc.org/>. The 2021 SAFE report for the BSAI will be available from the same source.

**FOR FURTHER INFORMATION CONTACT:** Steve Whitney, 907-586-7228.

**SUPPLEMENTARY INFORMATION:** Federal regulations at 50 CFR part 679 implement the FMP and govern the groundfish fisheries in the BSAI. The Council prepared the FMP, and NMFS approved it, under the Magnuson-Stevens Act. General regulations governing U.S. fisheries also appear at 50 CFR part 600.

The FMP and its implementing regulations require that NMFS, after consultation with the Council, specify annually the total allowable catch (TAC) for each target species category. The sum of TACs for all groundfish species in the BSAI must be within the optimum yield (OY) range of 1.4 million to 2.0 million metric tons (mt) (see § 679.20(a)(1)(i)(A)). Section 679.20(c)(1) further requires that NMFS publish proposed harvest specifications in the **Federal Register** and solicit public comments on proposed annual TACs and apportionments thereof; prohibited species catch (PSC) allowances; prohibited species quota (PSQ) reserves established by § 679.21; seasonal allowances of pollock, Pacific cod, and Atka mackerel TAC; American Fisheries Act allocations; Amendment 80 allocations; Community Development Quota (CDQ) reserve amounts established by § 679.20(b)(1)(ii); and acceptable biological catch (ABC) surpluses and reserves for CDQ groups and Amendment 80 cooperatives for flathead sole, rock sole, and yellowfin sole. The proposed harvest specifications set forth in Tables 1 through 15 of this action satisfy these requirements.

Under § 679.20(c)(3), NMFS will publish the final 2022 and 2023 harvest specifications after (1) considering comments received within the comment period (see **DATES**), (2) consulting with the Council at its December 2021 meeting, (3) considering information presented in the 2022 SIR to the Final EIS that assesses the need to prepare a Supplemental EIS (see **ADDRESSES**), and (4) considering information presented in the final 2021 SAFE report prepared for the 2022 and 2023 groundfish fisheries.