

DISCUSSION DRAFT JANUARY 17, 2023
“THE LIVING ORGAN VOLUNTEER ENGAGEMENT (LOVE) ACT” NATIONAL
LIVING KIDNEY DONATION PROGRAM LEGISLATION

To Amend the Public Health Service Act to Create a National Living Kidney Donation Program, and for other purposes.

The Public Health Services Act is hereby amended to add the following new section: §275.

National Living Kidney Donation Program

(a) Establishment

The Secretary shall establish and maintain a national living kidney donation program (referred to in this section as the "Program"), to improve and increase the number of living donor kidney transplants for recipients suitably matched to biologically related and unrelated donors of kidneys; to ensure that kidneys donated by living donors are accessible to those in need irrespective of rural location, race, or ethnicity; and to ensure the availability of donor navigators and other support and assistance to potential and actual living kidney donors. The Secretary may award one or more separate contracts to perform each of the major functions of the Program described in subsections (b), (c), (d) and (e) of this section to operate an effective and efficient system that will improve and increase kidney donations by living donors.

(b) Living Kidney Donation information and education

(1) Information and education regarding recruitment; testing and enrollment

(A) In general

The Program shall carry out informational and educational activities, in coordination with organ donation public awareness campaigns operated public and not for profit entities, transplant hospitals, and other entities designated by the Secretary, for purposes of educating individuals to consider serving as kidney donors. Such information and educational activities shall include the following:

(i) Making information available to the general public, including information describing the needs of patients on or potentially eligible to be on the kidney transplant waiting list with respect to kidney donors;

(ii) Educating and providing information to individuals who may be willing to serve as potential kidney donors, including family members of potential kidney transplant recipients;

(iii) Training individuals (including individuals who have already donated a kidney) to discuss living kidney donation with others; and

(iv) Coordinating with the Living Organ Donation Reimbursement Program and Existing KPD Programs on educational and other programmatic activities.

(2) Recruitment; priorities

(A) The Program shall carry out activities for the recruitment of kidney donors for living kidney donations. Such recruitment program shall identify populations that are underrepresented (by race, ethnicity, rural location, age, and other factors to be designated by the Secretary) among donors enrolled with the Program, and shall give priority to carrying out activities under this part to increase representation for such populations in order to enable a member of such underrepresented population in need of a kidney transplant, to the extent practicable, to have a probability of finding a suitable unrelated recipient that is comparable to the probability that an individual who is not a member of an underrepresented population would have.

(B) Each transplant hospital shall have a recipient advocate to identify potential living donors from among family members and others with a relationship or connection to individuals in need of a transplant, who may be eligible to serve as a living kidney donor.

(3) Transplantation as treatment option

In addition to activities regarding recruitment, the recruitment program under subparagraph (2) shall provide information to physicians, other health care professionals, chronic kidney disease and dialysis patients, dialysis centers, and the public regarding kidney transplants from related and unrelated donors as a treatment option.

(4) Implementation

The requirements of this subsection shall be carried out by the entity that has been awarded a contract by the Secretary under subsection (a) of this section to carry out the functions described in subsections (b) and (c) of this section.

(c) Identifying, Recruiting and Supporting Living Kidney Donors (1) The Program shall—

(A) operate a national system to assist in identifying, recruiting and supporting living kidney donors; overseeing and facilitating the clinically appropriate use of kidneys donated by non-directed living kidney donors;

(B) create and operate a system to equitably use non-directed living donor and unmatched pair kidneys consistent with paragraph (2);

(C) provide for a patient navigator system through the Office established under subsection (c) of this section; and

(D) ensure the activities enumerated above are undertaken in a manner by which underserved individuals in need of a kidney transplant will have increased access to living donor kidneys, and that such activities address barriers to living donation based upon race, ethnicity, geography, disability, gender and other demographics.

(2) Single point of coordination

The Secretary shall create an electronic system to equitably distribute organs from non-directed living kidney donors through a single database to include all information relevant to matching non-directed living kidney donor candidates and incompatible donor-recipient pairs to patients in need of a transplant. The Secretary, through the Program, shall coordinate with the Organ Procurement and Transplantation Network and each transplant hospital receiving federal funds to develop and participate in a national comprehensive registry of kidneys from living donors available for potential transplant, subject to living donor designations as provided for in subsection (4). Each transplant hospital and other Existing KPD Program (provided for in subsection (3)) shall provide such matching information, other information contained in its database and tracking processes with the single point of coordination created under this paragraph. The Organ Procurement and Transplantation Network and each participating transplant hospital shall, on an ongoing basis, provide the identity and medical information of any potential donors available to participate in living kidney donation to the Program in a timely manner.

(3) Simplifying enrollment; standard data and donor convenience The Secretary shall establish:

(A) default standards for medical evaluation, donation qualification and medical testing criteria consistent with those developed by the Organ Procurement and Transplantation Network Standards for Living Donation (which shall not preclude a transplant center or physician from requiring additional medical information before determining whether to proceed with a living donor transplant);

(B) donor selection criteria, based on established medical criteria, to protect both the donor and the recipient and to prevent the transmission of potentially harmful infectious diseases such as hepatitis B, hepatitis C, HIV and COVID;

(C) procedures to ensure the proper testing of donors and collection and transportation of kidneys donated under the Program;

(D) procedures to ensure the convenient testing of donors in their homes or other preferred locations, to the extent medically appropriate. To further advance the convenient testing of donors, the Secretary shall certify one or more laboratories

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as qualified for the analysis of such donor tests, consistent with the standards of the Organ Procurement and Transplantation Network;

The Secretary shall coordinate with all participating transplant centers to report to the Program a standard dataset of medical information regarding potential donors, including acceptance rates and reasons for not accepting a potentially offered kidney under the Program.

(4) Existing KPD Programs and Encouraging Innovation

Any not-for-profit organization or transplant center that, as of the date of enactment, is engaged in the process of living donor kidney donation exchange shall be deemed to be eligible for participation in the Program, in such manner to be determined by the Secretary. Any Existing KPD Program may continue to utilize its existing point of access and standard data criteria for its program for each new potential living donor for a period of one year to match such living donor to a person in need of a transplant. [In the event that such new potential living donor is not matched with a person in need of a transplant within one year from the date the new potential living donor is first identified by the organization, such new potential living donor shall be included in the Program.] Except as otherwise provided in this Section, the Secretary and each Existing KPD program shall take all reasonable efforts to coordinate and facilitate access to the Program and to ensure the exchange of all data collected by the Program and each Existing KPD Program, as determined by the Secretary pursuant to rulemaking. The Secretary will take all reasonable measures to preserve and utilize any qualifying Existing KPD Organization and ensure that such organizations continue to innovate in the field of living kidney donations.

(5) Respecting Wishes of Living Kidney Donors and Physician-Donor Relationship

The Program shall not interfere with:

(a) the wishes of a living kidney donor that the donor's organ be transplanted to a particular person or individual within a group or community of persons (such as family member, specified recipient, member of religious group, active-duty service member, veteran, or such other person, or within a geographic area); and

(b) The medical judgment and advice of the treating physician, surgeon or nephrologist, or other physician-specialist with a physician-patient relationship to the living donor.

(6) Role of Transplant Hospitals, Transplant Surgeons, Nephrologists and other Physician Specialists

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(a) The Secretary shall take into account the role of the transplant hospital and the transplant surgeon in performing living donations, including the relationship between the transplant center and the kidney donor, the additional costs of performing testing, surgery and other care for living kidney donors as required by this Act, and maintenance of the relationship between the transplant surgeon and the living donor. The Secretary shall, to the maximum extent possible, ensure that transplant hospital reimbursement is sufficient for all care provided or related to a living kidney donor.

(b) In implementing the Program, the Secretary shall also consider the role of community nephrologists and other physician specialists in supporting living kidney donors through the donation process.

(d) Office of Donor Navigation (1) In general

The Program shall establish and maintain an office of Donor Navigation (in this subsection referred to as the "Office") to provide living donors with support through each stage of the donation process, beginning at the initial expression of interest from an individual to be a living kidney donor through an appropriate period following a donation.

(2) General functions

The Office shall meet the following requirements:

(A) The Office shall be headed by a director.

(B) The Office shall be staffed by individuals with expertise in kidney medicine, kidney transplantation, and living kidney donation covered under the Program.

(C) The Office shall provide donor navigators to coordinate with transplant hospitals. Such donor navigators shall serve patients who have expressed an interest in, are in the process of, or who have completed a living kidney donation, consistent with subsection (3).

(D) A transplant hospital operating a donor navigator program meeting the standards of this subsection may continue such program in place of the services provided by the Office.

(3) The Office shall establish minimum standards for donor navigation that shall include:

(A) a donor navigator assigned to each prospective donor by the Office (or by an appropriate transplant center) to assist in referral, triage, and support and to provide health care information throughout the transplant process;

(B) assistance in evaluation and testing for prospective donors (including scheduling of such testing), at an appropriate location (including when possible

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the home), prioritizing clinical sites most convenient for the donor to the extent possible;

(C) services related to the donation process, services related to the recovery following surgery, and services related to monitoring, and evaluation and medical care directly related to the donation or any effects of the donation on the donor for five years following kidney donation; and

(D) such other navigator services deemed appropriate by the Secretary, using care models developed in the non-profit, public and private sectors.

(4) The Office shall utilize the services of living kidney donors who have donated a kidney to the extent feasible and appropriate. To the extent an approved transplant center directly provides such donor navigation services as required by this paragraph, such costs shall be reimbursed through the hospital cost report or similar reimbursement methodology consistent with reimbursement for pre-transplant services.

(5) The Office shall establish a training and certification program for individuals to serve as donor navigators.

(e) Donor expenses and future care

(1) Living Organ Donation Reimbursement Program

(A) The Office shall coordinate with the Living Organ Donation Reimbursement Program to establish a program to reimburse all direct and indirect costs associated with donation. The following elements shall be included in any such cost reimbursement in implementing this subsection:

1. (i) Direct costs, which shall include all medical care and diagnostic testing necessary for a donation, including costs before, during and after the donation, and any follow up care for a period of ten years following the donation if such medical care after the date of the donation is directly related to the donation or any effects of the donation on the donor;
2. (ii) Indirect costs, which shall include all reasonable lost wages of up to \$2,500 per week, which shall be indexed to inflation, for up to eight weeks (except such amounts and periods may be extended under appropriate circumstances as determined by the Secretary), travel, dependent-care and other caregiver expenses, and other related expenses as determined reasonable by the Secretary without regard to the financial capacity of the donor or recipient;

(iii) Comprehensive life, health and disability insurance for any loss, health care expense, or disability related to the donation or donation process; and

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(iv) The Organ Donation and Recovery Improvement Act, P.L. 108-216, 42 U.S.C. § 274f-1, is amended as follows:

1. By deleting section 274f(d)(3); and
2. ADD OTHER CONFORMING AMENDMENTS

(2) In addition to the support offered by the Living Organ Donation Reimbursement Program, the Secretary shall ensure that any donor experiencing kidney failure following a donation shall be given the highest possible priority for a transplant under any program administered by the Secretary, and in appropriate circumstances to be determined by the Secretary pursuant to rulemaking, provide one or more (not to exceed five) vouchers to any individual in need of a kidney transplant, as directed by the living kidney donor following donation to be prioritized to receive a kidney donation.

(f) Data Coordination

The Office shall coordinate with the Scientific Registry of Transplant Recipients and the National Institutes of Diabetes and Digestive and Kidney Diseases to ensure that data, on a patient de-identified basis, is made available to all living kidney donors, kidney transplant recipients, and the public regarding the living donation process. The Office shall publish statistics for each transplant hospital regarding the number of potential living donor candidates identified, evaluated, the number that served as a living donor, and other outcomes (for the donor and recipient) of those donations. The Office shall conduct surveys of living donors (or family members, physicians and other health professionals, or other individuals acting on behalf of patients) to determine the extent of satisfaction with the system for patient navigation under this subsection, and to identify ways in which the system can be improved to best meet the needs of patients.

(g) Kidney criteria, default standards, and procedures

The Secretary shall establish through rulemaking, for participating entities, including the Program, living kidney donor registries, and transplant hospitals—

(1) standards for the system for patient navigation operated under subsection (c) of this section;

(2) standards that—

(A) require the establishment of a system of strict confidentiality to protect the identity and privacy of donors and patients in accordance with Federal and State law; and

(B) prescribe the purposes for which the records described in subparagraph (A) may be disclosed, and the circumstances and extent of the disclosure; and

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(3) in the case of an organ procurement organization, transplant hospital, or other entity participating in the Program, procedures to ensure the establishment of a method for integrating donor files, searches, and general procedures of the center or registry with the Program. The Secretary shall also develop and make available for use (at their option) by transplant programs tools to facilitate the collection of data to support the activities under this subsection and the data reporting requirements under this Section.

The requirements of this subparagraph shall apply to Existing KPD Programs, except to the extent such Existing KPD Programs desire to coordinate with the Program under terms to be mutually agreed with the Secretary.

(h) Consultation

In developing policies affecting the Program, the Secretary shall consult with the Advisory Council, the National Marrow Donor Program, the Department of Defense, Existing KPD Programs, and the board of directors of each entity awarded a contract under this section.

(i) Contracts

(1) Application

To be eligible to enter into a contract under this section, an entity shall submit to the Secretary and obtain approval of an application at such time, in such manner, and containing such information as the Secretary shall by regulation prescribe. The Secretary shall promulgate such regulations on an expedited basis, but in no event in more than nine months following enactment of this Act.

(2) Considerations

In awarding contracts under this section, the Secretary shall give consideration to the continued safety of living kidney donors and recipients and other factors deemed appropriate by the Secretary. The Secretary shall enter contracts with separate vendors for: (A) the operation of the Program, and (B) licensing of technology to operate the matching program.

(3) Limitations

Any organization under contract with the Health Resources and Services Administration for the operation of the Organ Procurement and Transplantation Network or any entity certified or decertified as an Organ Procurement Organization shall be ineligible to operate the Program. Any programs operated by the Organ Procurement and Transplantation Network addressing living kidney donations shall be transferred by the Secretary to the Program as soon as practicable and no later than six months following the creation of the Program; and

(4) Living Organ Donation Reimbursement Program 8

The Living Organ Donation Reimbursement Program shall continue to be operated through its existing contract with the Health Resources and Services Administration, except that responsibility for that contract shall be transferred to the Program for continued operations and contract renewals or bidding.

(5) Eligibility

Entities eligible to receive a contract under this section shall include not for profit entities.

(j) Records

(1) Recordkeeping

Each recipient of a contract or subcontract under subsection (a) of this section shall keep such records as the Secretary shall prescribe, including records that fully disclose the amount and disposition by the recipient of the proceeds of the contract, the total cost of the undertaking in

connection with which the contract was made, and the amount of the portion of the cost of the undertaking supplied by other sources, and such other records as will facilitate an effective audit.

(2) Examination of records

The Secretary and the Comptroller General of the United States shall have access to any books, documents, papers, and records of the recipient of a contract or subcontract entered into under this section that are pertinent to the contract, for the purpose of conducting audits and examinations.

(k) Advisory Council

The Secretary shall establish an Advisory Council to advise, assist, consult with, and make recommendations to the Secretary on matters related to the activities carried out by the Program. The members of the Advisory Council shall be appointed in accordance with the following:

(1) Each member of the Advisory Council shall serve for a term of 2 years, and each such member may serve as many as 3 consecutive 2-year terms, except that such limitations shall not apply to the Chair of the Advisory Council (or the Chair-elect) or to the member of the Advisory Council who most recently served as the Chair.

(2) A member of the Advisory Council may continue to serve after the expiration of the term of such member until a successor is appointed.

(3) In order to ensure the continuity of the Advisory Council, the Advisory Council shall be appointed so that each year the terms of approximately one-third of the members of the Advisory Council expire.

(4) The membership of the Advisory Council—

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(A) shall include as voting members a balanced number of representatives including representatives of living kidney donors and their families, kidney transplant centers, clinicians including surgeons and nephrologists, recipients of a kidney transplant, persons who require such transplants and their family members, persons with expertise in kidney transplantation, persons with expertise in organ matching, and transplant outcome data analysis, persons with expertise in the social sciences related to kidney donation, basic scientists with expertise in the biology of renal systems, and members of the general public;

(B) shall be racially and economically diverse and include persons with expertise in health equity; and

(C) shall include as nonvoting members representatives from the Department of Defense living kidney donation program, the Veterans Administration living kidney donation program, the

Division of Transplantation of the Office of the Health Resources Services Administration, the Centers for Medicare and Medicaid Services, and the National Institutes of Health.

(5) Members of the Advisory Council shall be chosen to ensure objectivity and balance and reduce the potential for conflicts of interest.

(6) The Secretary, acting through the Office of the Assistant Secretary of Health, shall submit to Congress an annual report on the activities carried out under this section.

(l) Studies

(1) Feasibility for International Expansion of the Program

The Secretary shall investigate the feasibility of conducting live and chain kidney donations across national borders and identify specific partnership opportunities with other countries to coordinate national living kidney donation programs. The Secretary shall within three years following the date of enactment, submit to Congress a report on how such international cooperation could benefit Americans, specific steps that need to be taken to pursue such cross-border cooperative efforts, recommendations for undertaking one or more such international cooperation programs, and recommendations for changes to legislation that would be required to undertake such programs.

(2) Long Term Outcomes of Living Kidney Donation

The Secretary shall study the long-term outcomes (including behavioral health outcomes) of living kidney donation for both donors and recipients. Such study shall include an evaluation of the long-term impacts of kidney donation on the health of living kidney donors, and the impact on outcomes of recipients of living kidney donations.

(m) Coordination

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The Secretary of Homeland Security and the Secretary of Health and Human Services shall coordinate to ensure the timely approval of a visa application for the purposes of a foreign living kidney donor entering the United States for the purposes of donation.

(n) Definitions

In this part:

(1) The term "Advisory Council" means the advisory council established by the Secretary under section 275(a)(1) of this title.

(2) The term "Program" means the Living Kidney Donation Program established under section 275(b) of this title.

(3) The term “donor” shall include potential donors being evaluated for donation and individuals that are actual kidney donors under the Program.

(4) The term “recipient” shall include potential and actual recipients of live kidney donations.

(5) The term “living kidney donation” means any procedure in which a living person donates a kidney to another person, including, but not limited to, paired donation, chain donation, directed giving donation, altruistic donation, non-directed donation, kidney exchange donation, cross-over kidney donation, and other living kidney donations.

(o) Authorization of appropriations

For the purpose of carrying out this part, there are authorized to be appropriated \$__,000,000 for each of fiscal years 2024 through 2028 and \$__,000,000 for fiscal years 2029 through 2032.

(p) Conforming amendments

[ADD ANY CONFORMING AMENDMENTS HERE]

(q) Program expansion

The Secretary is authorized to expand the program established by this section to include the transplant of livers at such time as the Secretary deems appropriate.