

## TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

| Form name                                                         | Number of respondents | Number of responses per respondent | Total responses | Average burden per response (in hours) | Total burden hours |
|-------------------------------------------------------------------|-----------------------|------------------------------------|-----------------|----------------------------------------|--------------------|
| National Marrow Donor Program Patient Support Center Survey ..... | 1,000                 | 1                                  | 1,000           | 0.075                                  | 75                 |
| Total .....                                                       | 1,000                 | 1                                  | 1,000           | 0.075                                  | 75                 |

HRSA specifically requests comments on: (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the burden of the information collection.

**Maria G. Button,**

*Director, Executive Secretariat.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Modification of Living Organ Donation Reimbursement Program Eligibility Guidelines in Response To Honor Our Living Donors Act

**AGENCY:** Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

**ACTION:** Notice of final Living Organ Donation Reimbursement Program guidelines.

**SUMMARY:** On July 1, 2026, HRSA published a notice in the **Federal Register** to solicit comments on proposed modifications to the Living Organ Donation Reimbursement

Program (LODRP or Program) eligibility guidelines in response to the Honor Our Living Donors (HOLD) Act. The HOLD Act, enacted in February 2026, prohibits consideration of an organ recipient's household income in determining a living organ donor's eligibility for reimbursement. This notice responds to the comments received and finalizes the Program Eligibility Guidelines.

#### FOR FURTHER INFORMATION CONTACT:

Allison Hutchings, Division of Transplantation, Health Systems Bureau, Health Resources and Services Administration, 5600 Fishers Lane, Rockville, MD 20857; 240-290-2179 or [livingdonorsupport@hrsa.gov](mailto:livingdonorsupport@hrsa.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Overview of the Living Organ Donation Reimbursement Program (LODRP)

Under section 377 of the PHS Act, as amended,<sup>1</sup> Congress gives the Secretary of Health and Human Services specific authority to reimburse eligible living donors and donor candidates for qualifying expenses incurred toward living organ donation, with a preference for individuals who the Secretary determines are more likely to be otherwise unable to meet such expenses. Since 2007, HRSA's LODRP has fulfilled this function, reimbursing eligible living organ donor candidates and donors for qualifying non-medical expenses, including travel, meals, lost wages, and child and elder care. Eligible donors may receive reimbursement of up to \$6,000 per organ donated for qualifying travel, lost wage, child-care,

and elder-care expenses associated with donor evaluation, the donation surgery, and follow-up care occurring within two years of the procedure, or beyond that period in exceptional circumstances. Since the program's inception, LODRP (currently operated by Mayo Clinic Arizona and the National Living Donor Assistance Center, also known as NLDAC, via a cooperative agreement) has received more than 21,000 applications, approving nearly 89 percent of them. During this timeframe, LODRP facilitated over 12,000 living organ donations.

##### II. Summary of Comments Received

On July 1, 2026, HRSA published a notice<sup>2</sup> in the **Federal Register** requesting comments on proposed modifications to the LODRP eligibility guidelines to implement the HOLD Act, which prohibits consideration of an organ recipient's household income in determining a living organ donor's eligibility for reimbursement.<sup>3</sup>

The proposed guidelines established a donor-centered eligibility framework consisting of a first priority category for donors with household incomes (HHI) at or below 350 percent of the HHS Poverty Guidelines, a second priority category for donors with HHIs above 350 but no more than 500 percent of the HHS Poverty Guidelines (which would open mid-project period, subject to available funding), and a capped financial hardship waiver for donors with HHIs above 500 but no more than 750 percent of the HHS Poverty Guidelines.

#### 2026 ANNUAL HOUSEHOLD INCOME THRESHOLDS<sup>4</sup>

| Household size                     | 48 Contiguous states and Washington, DC | Alaska   | Hawaii   |
|------------------------------------|-----------------------------------------|----------|----------|
| <b>500% HHS Poverty Guidelines</b> |                                         |          |          |
| 1 .....                            | \$79,800                                | \$99,750 | \$91,800 |
| 2 .....                            | 108,200                                 | 135,250  | 124,450  |

<sup>1</sup> 42 U.S.C. 274f.

<sup>2</sup> HHS, HRSA. "Modification of Living Organ Donation Reimbursement Program Eligibility Guidelines in Response to Honor Our Living Donors Act." **Federal Register**, vol. 91, no. 125, 1 July 2026, pp. 40005-40009, FR Doc. No. 2026-13250,

[www.federalregister.gov/documents/2026/07/01/2026-13250/modification-of-living-organ-donation-reimbursement-program-eligibility-guidelines-in-response-to](https://www.federalregister.gov/documents/2026/07/01/2026-13250/modification-of-living-organ-donation-reimbursement-program-eligibility-guidelines-in-response-to).

<sup>3</sup> United States Congress, House. *Consolidated Appropriations Act, 2026*. H.R. 7148, 119th

Congress, 2nd Session. Signed into law 3 Feb. 2026. Public Law 119-75. [www.congress.gov/bill/119th-congress/house-bill/7148/text](https://www.congress.gov/bill/119th-congress/house-bill/7148/text).

2026 ANNUAL HOUSEHOLD INCOME THRESHOLDS<sup>4</sup>—Continued

| Household size                     | 48 Contiguous states and Washington, DC | Alaska  | Hawaii  |
|------------------------------------|-----------------------------------------|---------|---------|
| 3 .....                            | 136,600                                 | 170,750 | 157,100 |
| 4 .....                            | 165,000                                 | 206,250 | 189,750 |
| 5 .....                            | 193,400                                 | 241,750 | 222,400 |
| 6 .....                            | 221,800                                 | 277,250 | 255,050 |
| 7 .....                            | 250,200                                 | 312,750 | 287,700 |
| 8 .....                            | 278,600                                 | 348,250 | 320,350 |
| <b>750% HHS Poverty Guidelines</b> |                                         |         |         |
| 1 .....                            | 119,700                                 | 149,625 | 137,700 |
| 2 .....                            | 162,300                                 | 202,875 | 186,675 |
| 3 .....                            | 204,900                                 | 256,125 | 235,650 |
| 4 .....                            | 247,500                                 | 309,375 | 284,625 |
| 5 .....                            | 290,100                                 | 362,625 | 333,600 |
| 6 .....                            | 332,700                                 | 415,875 | 382,575 |
| 7 .....                            | 375,300                                 | 469,125 | 431,550 |
| 8 .....                            | 417,900                                 | 522,375 | 480,525 |

HRSA requested comments on four specific topics related to the proposed Program guidelines:

(1) The proposed donor HHI eligibility thresholds and priority categories;

(2) The proposed financial hardship waiver cap for donor applicants with HHIs between 501 and 750 percent of the HHS Poverty Guidelines;

(3) The proposed categories of donors' financial hardship expenses; and

(4) Recommendations for forums, resources, and venues to distribute information about LODRP and the new eligibility guidelines, including suggestions for community-based outreach and education.

HRSA received a total of 44 comments from the public, including from prior living donors, transplant centers, organ procurement organizations, professional and patient stakeholder organizations, and other interested parties. No commenters opposed the overall shift from a recipient-income-based framework to a donor-income-based framework. Comments addressing each of the four numbered topics, as well as those outside the scope of the specific requests, are summarized below, along with HRSA's responses.

### III. Comments on Proposed Donor HHI Eligibility Thresholds and Priority Categories

#### HHI Eligibility Thresholds

Thirty-four commenters expressed explicit support for a shift to a donor-centered eligibility framework, with

many noting that the change corrects a longstanding barrier under which a donor's eligibility depended on a recipient's finances rather than the donor's own need. Seven commenters found the proposed thresholds (at or below 350 percent of the HHS Poverty Guidelines for Priority Category 1 and 351 to 500 percent for Priority Category 2) reasonable as written.

Others raised concern that a uniform, nationwide income threshold (*i.e.*, HHS Poverty Guidelines) would not account for significant differences in cost of living across geographic regions and recommended that HRSA incorporate regional cost-of-living adjustments into the HHI thresholds. Four commenters recommended that HRSA eliminate income thresholds and means-testing altogether so that all donors qualify for reimbursement regardless of income, and one of these four further recommended flat-dollar income thresholds in place of HHS Poverty Guidelines percentages, which vary by household size and may cause confusion.

**HRSA Response:** In response to the comments recommending elimination of income thresholds and means-testing altogether for all donor applicants, HRSA notes that the authorizing statute requires the Program to give preference to individuals who are "more likely to be otherwise unable to meet such expenses."<sup>5</sup> This requirement makes it necessary to impose income eligibility parameters on applicants.

Regarding comments recommending regional cost-of-living adjustments,

HRSA acknowledges that a uniform, nationwide HHS Poverty Guidelines-based threshold does not account for cost-of-living differences across regions and that donors in high-cost areas may face hardship at income levels above the proposed thresholds. Given the magnitude of administrative changes entailed, HRSA does not believe it would be feasible to develop and implement a reliable geographic adjustment mechanism or flat-dollar income thresholds at this time; however, in collaboration with the LODRP cooperative agreement recipient, HRSA will continue to evaluate whether income eligibility adjustments are warranted in a future revision of the Program's eligibility guidelines. In the interim, donors in high-cost areas facing financial hardship notwithstanding their household income may apply for the financial hardship waiver described in Section VII of this notice.

#### Priority Categories—Phased Opening of Priority Category 2

Nine commenters objected to HRSA's proposal to activate Priority Category 2 only upon determination of available program resources rather than at the outset of the project period.

These commenters expressed concern that a delayed or phased opening of Priority Category 2 could create inequitable outcomes for donors with similar financial circumstances depending solely on the timing of their application or donation, could discourage or delay donation while a recipient's health continues to decline, and could create administrative confusion for transplant programs counseling prospective donors. Five commenters recommended that all priority categories be open to

<sup>4</sup> HHS, Office of the Assistant Secretary for Planning and Evaluation. "2026 Poverty Guidelines." <https://aspe.hhs.gov/sites/default/files/documents/b1bfa16b20ae9b89d525bc35de7c1643/detailed-guidelines-2026.pdf>.

<sup>5</sup> Reimbursement of Travel and Subsistence Expenses Incurred toward Living Organ Donation. 42 U.S.C. 274f. Office of the Law Revision Counsel, U.S. House of Representatives, <https://www.govinfo.gov/link/uscode/42/274f>.

applications from the start of the funding period by default, with categories closed only if and when necessary to preserve funding for higher-priority applicants. Three of these commenters cited historical program data indicating that LODRP funds have not been fully expended in past years and that a substantial share of previously approved applicants (variously cited as approximately 41 percent) would fall within the proposed Priority Category 2 income range, suggesting sufficient funding may exist to open all priority categories simultaneously. Two commenters recommended that HRSA establish a fixed annual eligibility schedule or provide advance notice (at least 60 days, per one commenter) before any change in category status, and two other commenters recommended that previously granted approvals be protected if a priority category later closes.

**HRSA Response:** After careful consideration of the comments received, HRSA has modified the proposed guidelines to enable applicants to apply to all priority category areas from the start of the project period, rather than delaying the opening of lower priority categories. HRSA, in collaboration with the LODRP cooperative agreement recipient, will monitor application volume and Program expenditures for each Priority category on a regular basis and provide participating transplant centers and the public with direct and advance notice if there is insufficient funding for Priority Categories 2 and 3.

HRSA agrees with the commenters that starting each project period with all priority categories open and then closing Priority Categories 2 and 3 if HRSA and the cooperative agreement recipient determine that there is insufficient funding to reimburse applicants in Priority Category 1 would reduce confusion among applicants and filers, particularly since this is how the Program has de facto operated since its inception. However, in response to commenters who expressed concerns that a delayed opening of lower priority categories would negatively affect applicants with higher HHIs, HRSA notes that these applicants would face similar outcomes should the Program need to close lower priority categories due to funding limitations.

#### *Priority Categories—Hardship Waiver as a Separate Priority Category*

Six commenters proposed restructuring the priority categories into three tiers rather than two, by separating the proposed 501 to 750 percent hardship waiver population into its own

distinct preference category, to provide administrative clarity, and to avoid subjecting lower-income Category 2 applicants to hardship documentation requirements intended for a different population. One commenter recommended that HRSA monitor and publicly report use of the new categories by geography, race and ethnicity, rurality, insurance status, and organ type to assess the framework's equity impact.

**HRSA Response:** HRSA agrees with the recommendation to create a separate, third category (Priority Category 3) for financial hardship waiver applicants (*i.e.*, those with HHIs 501 to 750 percent of the HHS Poverty Guidelines) to ease administrative burden and reduce confusion among applicants and application filers. Going forward, HRSA, in collaboration with the cooperative agreement recipient, will closely monitor application data and plan to publicly report these and other program data.

#### **IV. Comments on Proposed Capped Financial Hardship Waiver for Applicants With HHIs 501 to 750 Percent of the HHS Poverty Guidelines**

Fourteen of the 43 commenters supported a financial hardship waiver capped at or near the proposed 750 percent of HHS Poverty Guidelines threshold, with several citing HRSA's estimate<sup>6</sup> that the majority of current applicants (approximately 92 percent) fall at or below this threshold. One commenter recommended that HRSA periodically reassess the hardship waiver ceiling after implementation, while another recommended eliminating the income ceiling for the hardship waiver altogether. One commenter urged HRSA to decouple waiver eligibility from Priority Category 2's open/closed status, so the waiver would remain available whenever the Program is accepting applications generally and recommended that waiver denials include a written basis and an opportunity for reconsideration upon additional documentation. Another commenter suggested that HRSA replace the proposed hardship waiver mechanism—under which a donor's documented donation-related expenses must reduce their effective HHI below 500 percent of the HHS Poverty

Guidelines to qualify—with an alternative approach that would reimburse applicants with HHIs above 501 percent of the HHS Poverty Guidelines for qualifying expenses exceeding the current \$6,000 reimbursement cap, up to the program maximum (\$6,000). Finally, several commenters noted a typographical error in the original **Federal Register** request for comment, whereby the hardship waiver income threshold criteria was listed as 501 to 570 percent of the HHS Poverty Guidelines, instead of 501–750 percent.

**HRSA Response:** HRSA appreciates the strong support expressed for the proposed capped financial hardship waiver.

In response to comments recommending that HRSA eliminate the income ceiling on hardship waiver eligibility, or replace the waiver mechanism with an alternative reimbursement model, HRSA continues to believe that a capped hardship waiver, set at 750 percent of the HHS Poverty Guidelines, best targets the Program's limited resources to donors with demonstrated financial need while minimizing administrative burden relative to an uncapped waiver or a more complex alternative reimbursement structure.

The aforementioned creation of a *Priority Category 3* for hardship waiver applications allows HRSA and the recipient of the cooperative agreement to open, close, or otherwise manage hardship waiver applications independently of *Priority Category 2*, directly addressing the comment recommending HRSA decouple *Priority Category 2* from the hardship waiver.

HRSA will evaluate and consider the recommendation for a modified waiver denial and appeal process in future Program guidance and operational procedures developed in coordination with the LODRP cooperative agreement recipient. The recommendation to require a written basis for waiver denials and to permit applicants to submit additional documentation for hardship waiver would constitute a change to how the Program currently operates and requires further evaluation by HRSA and the cooperative agreement recipient.

HRSA concurs with the comment recommending periodic reassessment of the hardship waiver ceiling following implementation. In collaboration with the recipient of the cooperative agreement, HRSA will monitor application volume, approval rates, and other relevant data to evaluate whether the 750 percent threshold continues to appropriately balance program access

<sup>6</sup> As cited in HHS, HRSA. "Modification of Living Organ Donation Reimbursement Program Eligibility Guidelines in Response to Honor Our Living Donors Act." **Federal Register**, Vol. 91, No. 125, 1 July 2026, pp. 40005–40009, FR Doc. No. 2026–13250, [www.federalregister.gov/documents/2026/07/01/2026-13250/modification-of-living-organ-donation-reimbursement-program-eligibility-guidelines-in-response-to](http://www.federalregister.gov/documents/2026/07/01/2026-13250/modification-of-living-organ-donation-reimbursement-program-eligibility-guidelines-in-response-to).

with availability of Program resources and will consider adjustments in future Program eligibility guideline revisions as warranted.

Finally, HRSA acknowledges the typographical error identified by several commenters in the original request for comment, which referenced a hardship waiver income range of 501 to 570 percent, rather than 501 to 750 percent, of the HHS Poverty Guidelines. HRSA confirms that 501 to 750 percent of the HHS Poverty Guidelines reflects its intended proposal and has corrected this error in the final guidelines (see Section VII below).

#### **V. Comments on Proposed Categories of Donors' Financial Hardship Expenses**

Five commenters supported the four proposed expense categories as sufficient and appropriate without recommending changes. Additionally, several commenters recommended adding pet care (boarding or in-home care during recovery) as a qualifying expense, and two of these commenters also recommended adding care for disabled adults, broadening the existing "child-care and elder-care" language to cover dependents more generally. Four commenters recommended including a donor household's broader out-of-pocket medical expenses, not limited to donation-related costs, as a qualifying hardship expense category; one of these four commenters also recommended including legally obligated support payments to a family member outside the household, such as child support. One commenter recommended explicitly excluding normal ongoing living expenses (such as routine housing, groceries, and utilities) as duplicative of the income-based eligibility criteria, while another commenter recommended including those types of expenses in the hardship waiver application.

Other comments focused on the burden of applying for hardship, with one commenter raising concerns about the administrative burden associated with itemized documentation of numerous expense categories, particularly for hourly or project-based workers, and recommending that HRSA consider standardized or flat allowances for certain expense types (for example, lost wages keyed to State median wage, or mileage reimbursement modeled on the Federal per diem or IRS mileage rate structures), with itemized documentation required only above the standard allowance or in the event of an audit. One commenter urged HRSA to avoid a detailed, prescriptive expense list altogether and instead rely on attestations from an authorized

transplant center representative, such as a social worker, to establish a donor's effective household income for hardship purposes. Finally, another commenter recommended that HRSA work with the U.S. Department of the Treasury and the Internal Revenue Service to ensure LODRP reimbursement is not treated as taxable income to the donor.

*HRSA Response:* In response to the comments received, HRSA has expanded the proposed hardship waiver application categories to explicitly include consideration of pet care and disabled adult care expenses in the determination of hardship. Additionally, HRSA will modify the out-of-pocket medical expenses category in the proposed hardship waiver application to include out-of-pocket medical expenses (not limited to those related to the donation process) for the whole household. Finally, HRSA will add a hardship category for regular, legally mandated payments to support a family member who is not part of the household, such as child support. HRSA agrees that each of these expenses is non-discretionary and can have significant effects on a household's income and thus an individual's ability to proceed with living donation. Finally, HRSA notes that the proposed qualifying hardship waiver expenses are merely categories of expenses and that HRSA will work with the LODRP cooperative agreement recipient to provide clarity to applicants on the specific expenses that fall within each category.

HRSA does not agree with the recommendation to include ongoing household expenses as a hardship waiver category, as these expenses are already embedded in the HHS Poverty Guideline thresholds. Therefore, including them in the hardship waiver application would be duplicative.

In response to comments recommending a reduction or removal of documentation requirements related to the financial hardship waiver, HRSA reiterates the need for standardized and well-documented hardship expense categories, not only to promote consistent eligibility requirements for applicants across transplant centers, but also to support the Program's ability to withstand audit and ensure appropriate stewardship of Federal resources. For this reason, HRSA is not adopting the recommendation to forgo a defined expense list in favor of reliance on transplant center attestation alone, nor is HRSA adopting standardized or flat expense allowances in place of itemized documentation at this time. Finally, HRSA will consult with Treasury and the Internal Revenue Service to evaluate

whether it is feasible for LODRP reimbursement to be treated as non-taxable income for the donor once the new Program eligibility guidelines take effect.

#### **VI. Comments on Outreach and Education**

Thirteen of the 44 commenters addressed forums, resources, or venues for disseminating information about LODRP and the new eligibility guidelines. Ten of these commenters recommended that HRSA and its cooperative agreement recipient pursue outreach through professional and clinical channels, including transplant center evaluation visits, independent living donor advocates, nephrology and dialysis practices, transplant social workers and financial coordinators, and professional societies and associations. Four commenters recommended that educational materials be multilingual and culturally appropriate, and four commenters specifically recommended that outreach be targeted to reach medically underserved and minority communities, which some of these commenters noted face documented disparities in living-donation rates.

Several of these commenters also recommended that donor financial assistance information be incorporated into standard informed consent and intake processes for both donors and recipients, since donors often raise practical questions with intended recipients before contacting a transplant center, and recommended that outreach materials prominently and clearly communicate the elimination of the recipient household income requirement so that donors and recipients who previously assumed they were ineligible are made aware of the change. One commenter recommended that LODRP-related outreach incorporate general messaging about deceased organ donation, given overlapping community channels and audiences for donation-related education. Other commenters recommended specific outreach tools, including a short, plain-language eligibility screening tool and a publicly available, regularly updated status page showing which priority categories and the hardship waiver are currently open.

*HRSA Response:* HRSA appreciates the suggestions received regarding outreach and education and will coordinate with the Public Education for Living Organ Donation Reimbursement Program (PE-LODRP) and LODRP cooperative agreement recipients, as well as each recipient's Advisory Board, to ensure that information about the Program is widely

available and accessible to patients, transplant professionals, and the general public.

## VII. Other/Out-of-Scope Comments

### *Non-Directed Donor Impact*

Five commenters raised concerns specific to non-directed living donors, who by definition do not have or may not have access to an identified recipient's financial information. Four of these five commenters recommended that the final guidelines explicitly state that non-directed donors are exempt from recipient-related eligibility criteria and may apply without an identified recipient, consistent with existing program practice, to avoid an unintended barrier for this donor population.

**HRSA Response:** HRSA agrees that the eligibility guidelines should clearly reflect the Program's existing treatment of non-directed donors. In response to these comments, HRSA has revised the final guidelines to expressly state that non-directed donors are exempt from recipient-related eligibility criteria and documentation requirements and may apply for reimbursement without an identified recipient, consistent with current Program practice.

### *Privacy and Program Integrity*

Five commenters raised privacy or program-integrity concerns. Four of these five recommended that HRSA collect the recipient's estimated household income directly from the recipient, rather than from the donor, to protect clinical boundaries and improve data accuracy. One commenter raised concern about the risk of the Program being used to facilitate impermissible payment for organs, and recommended informed consent disclosures regarding financial scrutiny, explicit privacy protections, and an opt-in application process kept separate from the transplant care team.

**HRSA Response:** HRSA appreciates the concerns raised regarding the collection of recipient household income data and the importance of maintaining clear clinical and ethical boundaries between donors, recipients, and the transplant care team. As described in the original **Federal Register** notice, HRSA will continue to collect limited, high-level information on recipient household income to monitor the Program's impact on recipients' access to living organ transplants. HRSA intends to submit a separate Paperwork Reduction Act package for Office of Management and Budget review, public comment, and clearance that will specify the

demographic and other information the recipient of the cooperative agreement will be required to report to HRSA regarding the donors, donor candidates, and recipients benefiting from the Program. Consistent with its role in administering the Program, the recipient of the cooperative agreement will be responsible for determining a feasible and accurate method for collecting this information, which may include collecting recipient household income directly from the recipient rather than the donor. HRSA encourages the recipient of the cooperative agreement to consider this recommendation, among other approaches, in developing its data collection procedures.

In response to the comment expressing concern that the Program could be used to facilitate impermissible payment for organs, HRSA notes that the existing eligibility criteria already require both the donor and the recipient to certify that they understand and are in compliance with Section 301 of the National Organ Transplant Act (42 U.S.C. 274e), which prohibits the transfer of any human organ for valuable consideration affecting interstate commerce. HRSA believes this certification requirement, in conjunction with the transplant center's certification of good standing with the Organ Procurement and Transplantation Network, provides an appropriate safeguard against use of the Program for impermissible payment. HRSA will continue to evaluate whether additional informed consent disclosures or privacy protections are warranted as it gains further experience administering the Program under the revised eligibility guidelines.

### *Out-of-Scope Comments*

Commenters also raised a number of issues outside the scope of the four numbered requests for comment. Four commenters recommended that HRSA raise the Program's maximum reimbursement amount, which has remained at \$6,000 since 2007, with some recommending an increase to \$10,000. Two commenters recommended extending the post-donation reimbursement window for living liver donors, whose recovery period is longer than for other donor types, from the current 4 weeks to 6 or 8 weeks. Three commenters proposed alternative or supplemental funding mechanisms to support living donors, including a proposal that insurers contribute a fee to the Program when a covered member's transplant results in removal from dialysis, and a proposal for a larger flat reimbursement amount

available to all donors without means-testing.

Five commenters recommended that HRSA conduct or support research, data collection, or enhanced Congressional reporting on the Program's impact, including actual donation-related costs, sources of reimbursement other than the Program, and the experience of donors who forgo reimbursement. Three commenters recommended ongoing program monitoring for access, equity, and outcomes following implementation, particularly with respect to expanding access among lower-income and historically underserved communities.

Finally, two commenters submitted brief, general statements of support for the proposed shift to a donor-centered eligibility framework without addressing a specific numbered request for comment.

**HRSA Response:** HRSA appreciates this additional feedback but notes that the comments are out-of-scope for the present proposal. However, HRSA will consider these recommendations in future revisions to the Program's eligibility guidelines. With respect to the comments urging ongoing program monitoring, HRSA intends to work collaboratively with the recipient of the LODRP cooperative agreement to analyze the effects of the eligibility guideline modifications implemented in response to the HOLD Act and will propose further revisions to the guidelines as needed.

## VIII. Final Living Organ Donation Reimbursement Program (LODRP) Eligibility Guidelines, as Amended

*Note: These guidelines apply to all applications reviewed on or after September 30, 2026. Applications reviewed before this date will be processed according to the current Program guidelines outlined in the September 2020 **Federal Register** Notice.<sup>7</sup>*

As provided for in the statutory authorization, LODRP is authorized to provide reimbursement only in those circumstances when payment cannot reasonably be covered by other specified sources of reimbursement. The recipient of the cooperative agreement, under Federal law, cannot provide reimbursement to any living organ

<sup>7</sup> HHS, HRSA. "Reimbursement of Travel and Subsistence Expenses Toward Living Organ Donation Program Eligibility Guidelines." **Federal Register**, vol. 85, No. 184, 22 Sept. 2020, pp. 59530–59534, FR Doc. No. 2020–20805, [www.federalregister.gov/documents/2020/09/22/2020-20805/reimbursement-of-travel-and-subsistence-expenses-toward-living-organ-donation-program-eligibility](http://www.federalregister.gov/documents/2020/09/22/2020-20805/reimbursement-of-travel-and-subsistence-expenses-toward-living-organ-donation-program-eligibility).

donor for listed qualifying expenses if the donor can receive reimbursement for these expenses from any of the following sources:

- Any State compensation program, an insurance policy, or any Federal or State health benefits program; or
- An entity that provides health services on a prepaid basis.

All persons who wish to become living organ donors are eligible to receive reimbursement for their qualifying expenses if they cannot receive reimbursement from the sources outlined above and if all the requirements outlined in the *Criteria for Donor Reimbursement* section below are satisfied. However, because reimbursement is subject to the availability of funds, prospective living organ donors who are most likely not able to cover these expenses will receive priority. The ability to cover these expenses is determined based on an evaluation of (1) the donor's HHI in relation to the HHS Poverty Guidelines and (2) financial hardship. As a general matter, income refers to the donor's total household income.

#### *Criteria for Donor Reimbursement*

The following criteria must be met in order for a donor to be eligible for reimbursement under LODRP:

- Any individual who in good faith incurs travel and other qualifying expenses toward the intended donation of an organ.
- Donor and recipient of the organ are U.S. citizens or lawfully present in the United States.
- Donor and recipient have primary residences in the United States or its Territories.
- Travel originates from the donor's primary residence.
- Donor and recipient certify that they understand and are in compliance with Section 301 of National Organ Transplant Act (42 U.S.C. 274e) which states in part that it shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation if the transfer affects interstate commerce.
- The transplant center where the donation procedure occurs certifies to its status of good standing with the Organ Procurement Transplantation Network.

#### *Non-Directed Donors*

Because non-directed donors may not have access to or knowledge of their recipient, they are exempt from recipient-related eligibility criteria and documentation requirements and may apply for reimbursement without an

identified recipient. Non-directed donors must meet all other criteria noted above for reimbursement.

#### *Priority Categories*

Non-directed and directed donors meeting the criteria for reimbursement will be given preference in the following order of priority:

- *Priority Category 1:* Donor applicants with HHIs at or below 350 percent of the HHS Poverty Guidelines<sup>8</sup> at the time of the eligibility determination in their respective States of primary residence would receive the highest priority for reimbursement under LODRP.
- *Priority Category 2:* If sufficient program resources exist, applicants with HHIs greater than 350 but no greater than 500 percent of the HHS Poverty Guidelines would also be eligible to apply for reimbursement.
- *Priority Category 3:* If sufficient program resources exist, applicants with HHIs greater than 500 but no greater than 750 percent of the HHS Poverty Guidelines would also be eligible to apply for reimbursement via a financial hardship waiver.

At the start of each budget period, the LODRP cooperative agreement recipient will accept and process applications from all three priority categories. Each month, the cooperative agreement recipient will report to HRSA with the number of applications received and the amount of donor reimbursement issued over the past 30 calendar days. If HRSA and the cooperative agreement recipient determine that funding levels are insufficient to continue accepting applicants from *Priority Categories 2 and/or 3*, the LODRP cooperative agreement recipient will notify participating transplant programs and the public in a timely fashion prior to "closing" a Priority Category.

#### *Financial Hardship Waiver*

Applicants with HHIs greater than 500 but no greater than 750 percent of the HHS Poverty Guidelines at the time of the eligibility determination may apply for a financial hardship waiver.

Financial waiver requests will be reviewed on a case-by-case basis. Determination of hardship in a particular case will be based off attestation and documentation of the following types of expenses incurred by the donor or donor candidate:

- Lost wages attributable to the donation and/or recovery period.

• Travel, lodging, and meals related to the evaluation, donation and/or follow-up appointments.

- Child, elder, or other dependent care costs (e.g., disabled adult care) incurred during the evaluation, donation, and/or recovery period.
- Out-of-pocket medical expenses incurred by the donor candidate and/or individuals in their household.<sup>9</sup>
- Pet care costs incurred during the evaluation, donation, and/or recovery period.
- Other non-discretionary household expenses (e.g., child support).

Based on a complete evaluation of the donor's financial circumstances, a transplant social worker or other appropriate transplant center representative, will submit the written waiver request on the donor's behalf to the cooperative agreement recipient, attesting that the donor has provided documentation outlining significant expenses that reduce their HHI to at or below 500 percent of the HHS Poverty Guidelines. The waiver request is then reviewed by the cooperative agreement recipient and subject to final determination by HRSA. HRSA will communicate its final determination to the cooperative agreement recipient, and its determination will not be subject to appeal.

#### *Qualifying Expenses*

The total federal reimbursement for all qualifying expenses during the donation process shall not exceed \$6,000 per potential donor evaluated and/or organ donated. For the purposes of LODRP, qualifying expenses include:

- Travel, lodging, meals and incidental expenses incurred by the donor and/or his/her accompanying person(s) as part of:
  - Donor evaluation and/or
  - Hospitalization for the living donor surgical procedure and/or
  - Medical or surgical follow-up, clinic visits, or hospitalization within 2 calendar years following the living donation procedure (or beyond the 2-year period if exceptional circumstances exist).
- Lost wages, child care, and elder care expenses incurred by the donor and/or his/her accompanying or assisting person(s) as part of:
  - Donor evaluation and/or
  - Hospitalization for the living donor surgical procedure and/or
  - Non-hospital post-surgery recovery time and/or

<sup>8</sup> HHS Poverty Guidelines for 2026, <https://aspe.hhs.gov/topics/poverty-economic-mobility/poverty-guidelines>.

<sup>9</sup> Note that recipients' health insurance generally covers all medical expenses related to donation including evaluation, surgery, and immediate follow-up care.

○ Medical or surgical follow-up, clinic visits, or hospitalization within 2 calendar years following the living donation procedure (or beyond the 2-year period if exceptional circumstances exist).

The recipient of the cooperative agreement will pay for a total of up to five trips; three for the donor and two for accompanying individuals. However, in cases in which the transplant center requests the donor to return to the transplant center for additional visits as a result of donor complications or other health related issues, the recipient of the cooperative agreement may provide reimbursement for the additional visit(s) for the donor and an accompanying person. The accompanying person need not be the same in each trip.

Reimbursement for travel, lodging, meals, and incidental expenses, as appropriate, shall be provided at the Federal per diem rate, except for hotel accommodation, which shall be reimbursed at no more than 150 percent of the Federal per diem rate.<sup>10</sup>

Donors may receive up to 4 weeks of reimbursement for lost wages, and child care and elder care expenses associated with the surgery and recovery time. In addition, donors may receive reimbursement for up to 2 additional weeks for lost wages, and child care and elder care expenses if the donor requires follow-up visits and hospitalization as a result of donor complications or other health-related issues. Reimbursement for lost wages is based on the donor providing appropriate documentation, such as pay stubs, to the program. Reimbursement of lost wages is not limited to traditional wage rate income. Donors may receive reimbursement for non-traditional or irregular income, including in industries dependent on tips, through the program if they provide sufficient documentation of the expected lost wages.

To qualify for reimbursement of child care and elder care expenses, a donor shall have caretaker responsibilities for:

- A minor child;
- An elder who requires caretaker assistance.

Caretaker responsibilities are not limited to familial relationships between the donor and/or the accompanying or assisting person(s), and the aforementioned individuals. In considering requests for reimbursement for child care and elder care expenses, the recipient of the cooperative agreement is encouraged to adopt a

consistent application of “child” and “elder.” The recipient of the cooperative agreement may consider applicable laws within the jurisdiction in which the caretaker resides in reviewing requests for reimbursement for expenses for care of a “child” and, in reviewing requests for reimbursement for elder care expenses, may consider “elder” to refer to an individual age 60 and older, consistent with the Older Americans Act, 42 U.S.C. 3002(40).

Requests for reimbursement for the expenses of persons accompanying or assisting the donor for travel, housing, meals, and incidental expenses are considered under the preference categories and processed for reimbursement at the same time as requests for reimbursement for expenses incurred by the donor. Requests for reimbursement for the expenses of persons accompanying or assisting the donor for lost wages and childcare and eldercare expenses are considered under the priority categories and will be processed separately. Requests for these expenses will be processed after all requests for expenses incurred by the donor, and expenses for persons accompanying or assisting the donor for qualifying expenses for travel, housing, meals, and incidental expenses, have been processed under all four preference categories.

#### *Maximum Number of Prospective Donors Per Recipient*

For the purposes of LODRP, the maximum number of donor candidates per recipient who may receive reimbursement through the program at any given time are listed below:

- Kidney: One donor at a time, with a maximum of three donors.
- Liver: One donor at a time, with a maximum of five donors.
- Lung: Two donors at a time, with a maximum of six donors.

#### *Annual Report to Congress*

The HOLD Act requires HRSA to submit an annual report to Congress, by December 31, 2027, with the following data:

- Number of donor applicants not fully reimbursed the previous fiscal year under LODRP.
- Estimated LODRP funding needed to fully reimburse all qualifying expenses for all eligible donor applicants under LODRP.

HRSA anticipates submitting a Paperwork Reduction Act package to the Office of Management and Budget to enable the LODRP cooperative agreement recipient to collect estimates of these data from all eligible living organ donors and donor candidates with

approved applications for LODRP reimbursement.

#### *Special Provisions*

Many factors may prevent the intended and willing donor from proceeding with the donation. Circumstances that would prevent the transplant or donation from proceeding include present health status of the intended donor or recipient; perceived long-term risks to the intended donor; justified circumstances such as acts of God (major storms or hurricanes); or a circumstance when an intended donor proceeds toward donation in good faith, subject to a case-by-case evaluation by the recipient of the cooperative agreement but then elects not to pursue donation. In such cases, the intended donor and accompanying persons may receive reimbursement for qualifying expenses incurred as if the donation had been completed. The recipient of the cooperative agreement will file a form with the Internal Revenue Service reporting funds disbursed as income for expenses not incurred.

#### **IX. Paperwork Reduction Act of 1995**

The proposed changes may result in revisions to information collection requirements subject to review under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

#### **X. Regulatory Impact**

This notice is a significant regulatory action under Section 3(f) of Executive Order 12866.

#### **XI. Implementation**

The final eligibility guidelines contained in this **Federal Register** notice will apply to applications to LODRP reviewed on or after September 30, 2026.

#### **XII. Other**

This guidance aligns with statutory standards and is exempt from the Administrative Procedure Act (APA) as it pertains to a matter relating to grants/benefits (5 U.S.C. 553(a)(2)).

**Ann M. Sheehy,**

*Principal Deputy Administrator.*

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<sup>10</sup> See U.S. General Services Administration site for current Federal per diem rates: <https://www.gsa.gov/travel/plan-book/per-diem-rates>.