

Pursuant to the authority vested in the Commissioner of Health by Section 4371 of the Public Health Law, a new Part 1005 of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York (NYCRR) is hereby created within Chapter XIII, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

Part 1005 – Living Donor Support Program

Section 1005.1 shall read as follows:

1005.1 Supporting Living Donors. Qualified living donors, subject to an application and approval by the Department of Health or its designee, may seek reimbursement for eligible expenses, compensated in line with rates determined by the department, up to a maximum of \$14,000 dollars for any single living donor.

(a) Eligible expenses. The following list shall be deemed eligible expenses, provided they are directly associated with a living donation as defined by section 4370 of the Public Health Law:

- (1) either lost wages including demonstrated lost non-employment income or the economic value of sick or vacation days expended. This category of eligible expenses shall not exceed four weeks unless special circumstances are demonstrated, such as the nature of physical labor required for the living donor's employment provided that the total period shall in no event exceed eight weeks;
- (2) travel, food and lodging;
- (3) child or other dependent care expenses;
- (4) elder care expenses;

(5) costs of medications and care associated with the living donation surgery that are not covered by health insurance including the medical assistance program; and

(6) support person costs.

(b) Process for applying and submitting claims. Applicants shall submit a program eligibility application, request for preauthorization and claims for reimbursement using a form(s) and following a process designated by the department or its designee.

(c) The department or its designee shall review and if applicable, approve or disapprove the eligibility application, request for preauthorization and claims for reimbursement.

(d) In the event an application is withdrawn by the applicant, the application will be considered withdrawn. In the event an applicant does not respond to requests for additional information in a timely manner, the department may deem that application withdrawn.

(e) The department or its designee, may conduct ongoing reviews and audit a participant or provider's conduct, and recover funds as appropriate.

(1) Any person who receives reimbursement under this section for which they are not legally entitled, shall be liable to the department for such compensation plus interest as set forth in section 5004 of the Civil Practice Law and Rules.

(2) Good faith efforts by persons to seek reimbursement of eligible living donor expenses shall not be subject to recovery by the department.

REGULATORY IMPACT STATEMENT

Statutory Authority:

Public Health Law (PHL) Article 43-B Organ Procurement and Donor Support, Title 2 Living Organ Donation, Section 4371 directs the Commissioner to issue regulations to establish eligible living donor expenses that are eligible for reimbursement under the Living Donor Support Program and make regulations to implement the program.

Legislative Objectives:

The legislative objective of PHL Section 4371 is to reduce financial disincentives to living donation and reimburse eligible living donor expenses.

Current Requirements:

This is a new provision. There is no pre-existing requirement.

Needs and Benefits:

The purpose of the Living Donor Support Act is to remove the financial disincentives and barriers to living organ donation, increase the number of organ transplants in New York State (NYS) and decrease the number of deaths among those living with organ failure waiting for a transplant. Currently there are approximately 8,000 people on the NYS organ transplant waiting list and about 7,000 of those persons are waiting for a kidney. Approximately 500 living donor transplants occurred in NYS in 2024 with the majority of them being between a New York donor and a New York recipient.

Living organ donors incur expenses. Most often these expenses are related to lost wages and donation-related travel and lodging. Less often living donors incur expenses related to child, dependent and/or elder care or due to unreimbursed costs of medication or medical care. There are few sources to assist living donors with these costs including employer-based insurance coverage and/or benefits, private insurance plans, assistance from private not-for-profit organizations and in the last few years, from the National Living Donor Assistance Center. The Federal rules associated with the national program do not allow them to reimburse living donors who have or should have received reimbursement from a state reimbursement program. In 2024, approximately 100 New York living organ donors who donated to a NYS living organ recipient received reimbursement from the national program. It is unknown whether the other 400 or so living donors in New York in 2024 received any kind of financial assistance. We do know that many people who may have considered making a living donation rule themselves out because they cannot or are not willing to incur the expenses associated with the living donation.

The proposed rule identifies expenses that are eligible for reimbursement by the NYS Living Donor Support Program and sets forth that living donors applying for Program participation and seeking reimbursement from the program must complete an eligibility application as well as reimbursement related forms in accordance with a State designated process(es).

COSTS:

Costs to Private Regulated Parties:

There is no anticipated cost to regulated parties.

Costs to Local Government:

There are no anticipated costs to local government.

Costs to the State and Department of Health:

It is estimated that in a full year up to 500 people could make application to the Department for reimbursement through the Living Donor Support Program. As a result, it is anticipated that the cost to the Department could be as high as \$7.0 million based on a maximum reimbursement of \$14,000 per applicant allowed by the law. The experience of other entities providing reimbursement to living kidney donors suggests that their reimbursement requests have averaged about \$6,500.00. It is expected that most applicants to the Program will be seeking reimbursement of living kidney donation related expenses. The 2023-24 and the 2024-25 enacted State budgets appropriated 1 million dollars for reimbursement of living organ donors through the NYS Living Donor Support Program, based on estimates of a slow start up with between 70 and 100 applicants in the early years of the program and not all applicants requesting reimbursement of the maximum amount allowed by the law. The Department also anticipates a budget of 1 million dollars to be included in the 2025-26 State budget for living donor reimbursement.

There has been an investment in staffing of the Living Donor Support Program by the Department. It is expected that additional staff will be needed as the program grows. This cost will be around \$750,000 /year. Finally, there will need to be an investment into contracted services and/or information technology services, which has been estimated to be approximately \$1.5 million and included in a program submitted budget proposal for inclusion in the 2025-26 State budget.

Costs to Other State Agencies:

There are no anticipated costs to other State agencies.

Local Government Mandate:

There are no anticipated mandates to local government.

Paperwork:

There are no anticipated paperwork issues. Applicants will be given simplified paperwork to complete. Other private parties will not need to make application.

Duplication:

There are no other provisions that duplicate this one.

Alternatives:

One alternative would be to create further detailed regulations. This alternative was considered and not further pursued as it was thought to be better to start by proposing minimum necessary regulations that could be enhanced in response to public comment if needed, and at a later time, if necessary, as experience in implementing the Program is gained. The Department has developed and is working to refine more detailed guidance documents on specific components of the Living Donor Support Program including the application and reimbursement processes and requirements to complement Program regulations.

Federal Standards:

The proposed regulations do not duplicate or conflict with any Federal regulations.

Compliance Schedule:

The regulations will be effective upon publication of a Notice of Adoption in the New York State Register.

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**STATEMENT IN LIEU OF
REGULATORY FLEXIBILITY ANALYSIS
FOR SMALL BUSINESSES AND LOCAL GOVERNMENTS**

No regulatory flexibility analysis is required pursuant to section 202-(b)(3)(a) of the State Administrative Procedure Act. The proposed amendment does not impose an adverse economic impact on small businesses or local governments, and it does not impose reporting, record keeping or other compliance requirements on small businesses or local governments.

**STATEMENT IN LIEU OF
RURAL AREA FLEXIBILITY ANALYSIS**

A Rural Area Flexibility Analysis for these amendments is not being submitted because the amendments will not impose any adverse impact or significant reporting, record keeping or other compliance requirements on public or private entities in rural areas. There are no professional services, capital, or other compliance costs imposed on public or private entities in rural areas as a result of the proposed amendments.

STATEMENT IN LIEU OF JOB IMPACT STATEMENT

No job impact statement is required pursuant to section 201-a(2)(a) of the State Administrative Procedure Act. No adverse impact on jobs and employment opportunities is expected as a result of these proposed regulations.

ASSESSMENT OF PUBLIC COMMENT

A Notice of Proposed Rule Making was initially published in the State Register on May 28, 2025. During the public comment period for the Notice of Proposed Rule Making, the New York State Department of Health (“Department”) received comments from a not-for-profit organ donation organization.

Comment: Use of affidavits to prove expenses. The commenter stated that though there is guidance on proof of residency documentation and types of expenses covered under the program, there does not appear to be guidance or rules on acceptable proof for reimbursement of expenses. The commenter suggested that the Department accept affidavits of expenses incurred as proof rather than requiring receipts when seeking reimbursement of expenses.

Response: The Department will provide further information about requirements for proof of residency and expenses incurred that are covered by the Living Donor Support Program in guidance documents. No changes were made to the regulation as a result of this comment.

Comment: Inclusion of support organizations. The commenter recommended explicitly authorizing support organizations, vetted through a registration process, to assist donors under the program. The commenter further requested that such support organizations be authorized to seek compensation from the Department.

Response: The proposed regulations, implementing the Living Donor Support Program, identify expenses associated with a support person as an expense eligible for reimbursement under the Program. For the purpose of the Program, a support person is defined as someone the donor may choose to accompany them to the evaluation, surgery, or follow-up appointments, or a combination of these to assist them through the donation process. The statutory provisions establishing the Living Donor Support Program require it to be the payer of last resort and do not

contemplate reimbursement of third-party support organizations. No changes were made to the regulation as a result of this comment.

Comment: Flexibility in costs. The commenter recommended the Department eliminate caps on individual types of expenses while maintaining the overall cap on expenses reimbursed per donor at the statutory limit or alternately, clarify whether dependent care authorized expenses are per dependent or overall, recommending reimbursement be per dependent and that the Department consider substantially raising the caps on dependent care reimbursement.

Response: The Department appreciates this comment; however, this issue is outside of the scope of the proposed regulations. The Department will take this comment into consideration as we further refine our guidance documents that will accompany the Living Donor Support Program regulations. No changes were made to the regulation as a result of this comment.