

Pursuant to the authority vested in the Commissioner of Health by Section 4371 of the Public Health Law, a new section 1010 of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York (NYCRR) is hereby created, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

Section 1010 shall read as follows:

1010. Supporting Living Donors. Qualified living donors, subject to an application and approval by the Department 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 event as defined by the Department:

(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(d) In the event an application is withdrawn by the applicant, the application will be considered withdrawn.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does not respond to requests for additional information in a timely manner, the Department may deem that application withdrawn.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 investigate potential fraud or abuse in a participant or provider's conduct and recover funds as appropriate.

(1) Any person who, with intent to defraud, presents for allowance or payment any false or fraudulent claim for reimbursement of living donor expenses, or knowingly submits false information for the purpose of obtaining reimbursement or greater reimbursement than that to which they are legally entitled for reimbursement of living donor expenses, or knowingly submits false information for the purpose of obtaining authorization for reimbursement for living donor expenses under this title, shall be liable to the department for any compensation unjustly received, plus interest.

(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) § 4371 authorizes the Commissioner to issue regulations, to implement the purposes and provisions of PHL Section § 4371, and to establish requirements for reimbursement of living donor expenses.

Legislative Objectives:

The legislative objectives of PHL § 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 was to remove the financial disincentives to living organ donation, increase the number of organ transplants in New York State 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. 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 Department of Health:

It is estimated that in a full year 500 people will make application to the Department for reimbursement. It is anticipated that the cost to the Department will be approximately \$7.0 million based on a maximum reimbursement of \$14,000 per applicant. This work will also require an investment of staffing by the Department. 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 could be approximately \$1.5 million.

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 was considered and not further pursued as this would allow feedback and experience from the sector to inform guidance published by the Department.

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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**REGULATORY FLEXIBILITY ANALYSIS
FOR SMALL BUSINESSES AND LOCAL GOVERNMENTS**

Effect of Rule:

The proposed regulatory provisions do not impact small businesses and local government.

Compliance Requirements:

There are no regulatory compliance requirements.

Professional Services:

There are no professional service requirements.

Compliance Costs:

There are no compliance costs.

Economic and Technological Feasibility:

This proposal is economically and technically feasible.

Minimizing Adverse Impact:

There is no adverse impact.

Small Business and Local Government Participation:

These parties were not consulted as there would be no impact to them.

RURAL AREA FLEXIBILITY ANALYSIS

Types and Estimated Numbers of Rural Areas:

This rule applies uniformly throughout the state, including rural areas. Rural areas are defined as counties with a population less than 200,000 and counties with a population of 200,000 or greater that have towns with population densities of 150 persons or fewer per square mile. The following 44 counties have a population of less than 200,000 based upon the United States Census estimated county populations for 2020 (<https://www.census.gov/quickfacts/>).

There are 55 general hospitals in rural areas.

Allegany County	Greene County	Schoharie County
Broome County	Hamilton County	Schuyler County
Cattaraugus County	Herkimer County	Seneca County
Cayuga County	Jefferson County	St. Lawrence County
Chautauqua County	Lewis County	Steuben County
Chemung County	Livingston County	Sullivan County
Chenango County	Madison County	Tioga County
Clinton County	Montgomery County	Tompkins County
Columbia County	Ontario County	Ulster County
Cortland County	Orleans County	Warren County
Delaware County	Oswego County	Washington County
Essex County	Otsego County	Wayne County
Franklin County	Putnam County	Wyoming County
Fulton County	Rensselaer County	Yates County
Genesee County	Schenectady County	

The following counties have a population of 200,000 or greater and towns with population densities of 150 persons or fewer per square mile. Data is based upon the United States Census estimated county populations for 2020.

Albany County	Niagara County	Orange County
Dutchess County	Oneida County	Saratoga County
Erie County	Onondaga County	Suffolk County

Monroe County

Reporting, Recordkeeping, Other Compliance Requirements and Professional Services:

The proposed regulation is applicable to individuals in rural areas and is expected to impose minimum policies and procedures related to various operational requirements. This should help to minimize the administrative burden.

Costs:

There are no costs to rural communities or providers within those communities.

Minimizing Adverse Impact:

The regulations are carefully tuned to minimize adverse impact.

Rural Area Participation:

Rural areas were not consulted as there would be no impact to them

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.