

Pursuant to the authority vested in the Commissioner of Health by sections 602, 603 and 619 of the Public Health Law, Subpart 40-2 of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended by adding a new section 40-2.24, to be effective upon publication of a Notice of Adoption in the State Register, as follows:

§ 40-2.24 Zika Action Plan; performance standards.

(a) By April 15, 2016, the local health department shall adopt and implement a Zika Action Plan (ZAP), in accordance with guidance to be issued by the Department, and which shall include, but not be limited to, the following activities:

(1) for all local health departments:

- (i) human disease monitoring, response and control; and
- (ii) education about Zika virus and its prevention; and

(2) in addition, for those local health departments identified by the Department as jurisdictions where mosquitoes capable of transmitting the Zika virus are currently located or may be located in the future:

- (i) enhanced human disease monitoring, response, control;
- (ii) enhanced education about Zika virus and its prevention ;
- (iii) mosquito trapping, testing and habitat inspections specific to *Aedes albopictus*, and for such other species as the Department may deem appropriate;
- (iv) mosquito control; and

- (v) identification and commitment of appropriate staff available to join State-coordinated rapid response teams, which may be deployed to those areas where the Department determines that there is the potential for transmission of Zika virus by mosquitoes.
- (b) For so long as determined necessary and appropriate by the Department, local health departments shall update their ZAPs annually, or as directed by the Department, and submit such plans to the Department as part of the Application for State Aid made pursuant to section 40-1.0 of this Part.

## **Regulatory Impact Statement**

### **Statutory Authority:**

Article 6 of the Public Health Law (PHL) sets forth the statutory framework for the Department's State Aid program, which partially reimburses local health departments (LHDs) for eligible expenses related to specified public health services. PHL §§ 602(4), 603(1), and 619 authorize the commissioner to promulgate rules and regulations to effectuate the provisions of PHL Article 6. PHL § 619 specifies that such regulations shall include establishing standards of performance for core public health services and for monitoring performance, collecting data, and evaluating the provision of such services.

### **Legislative Objectives:**

PHL Article 6 establishes a program that provides State Aid to LHDs to partially reimburse the cost of core public health services, including communicable disease control and emergency preparedness and response.

### **Needs and Benefits:**

Zika virus is newly emerging as a worldwide threat to public health, and it is spreading widely in the Western Hemisphere. Zika virus has been associated with microcephaly and potentially other birth defects. In particular, there have been reports in Brazil and other countries of microcephaly in infants of mothers who were infected with Zika virus while pregnant. Developing research appears to support this association. Zika virus may also cause Guillain-Barré Syndrome, which can cause muscle weakness and sometimes

paralysis. For these reasons, in February 2016, the World Health Organization declared the recent cluster of microcephaly and other neurological abnormalities associated with in utero exposure to the Zika virus a public health emergency of international concern.

Because 80% of cases are asymptomatic, limited control measures exist. Further, although Zika virus is transmitted primarily through the bite of a mosquito, sexual transmission has also been documented.

To date, the Department's Wadsworth Center has conducted tests on samples from more than 2,300 patients, and 55 have been found to be positive for Zika virus. New York has the second highest total of any state in the continental United States after Florida. With the exception of one possible case of sexual transmission, all of these infections have occurred in returning travelers from countries with active mosquito-borne transmission of Zika virus.

In the Western Hemisphere, the Zika virus has been primarily transmitted by a mosquito bite from the species *Aedes aegypti*. That species is not currently established in New York State; however, a related species of mosquito, *Aedes albopictus*, is established in New York City, as well as Orange, Nassau, Putnam, Rockland, Suffolk, and Westchester Counties. Additionally, Dutchess, Sullivan, and Ulster Counties are located on the northern border of these affected areas.

Because *Aedes albopictus* is a tropical mosquito, it has difficulty surviving cold winters, limiting its northward spread, but it has adapted to survive in a broader temperature

range. Although researchers are currently uncertain if *Aedes albopictus* can effectively transmit the Zika virus, New York State must prepare for this contingency.

A primary public health objective is to reduce the risk to developing fetuses of pregnant women in New York State. As such, during the spring, summer and fall, it is important that the Department and LHDs take action to protect the health and safety of all New Yorkers from the Zika virus.

LHDs are integral State partners and play important roles in human disease monitoring, response and control; health education and prevention; and mosquito trapping, testing, habitat inspection, and control. As a result, it is essential that LHDs are prepared to respond to the threat of Zika virus in their communities. Many LHDs may need to respond to travel-associated cases only, because they do not have mosquitoes capable of transmitting Zika virus within their borders. However, those counties that do have mosquitoes capable of transmitting Zika virus generally have large human populations and a high number of travelers to affected areas.

Accordingly, these regulations require that, as a condition of State Aid for public health work, each LHD must adopt and implement a Zika Action Plan (ZAP) that includes specified elements, but that can also be tailored to the situation within its borders. Those counties that do not have *Aedes albopictus*, or other mosquitoes capable of transmitting the Zika virus, must perform human disease monitoring of travel-associated cases and provide education about Zika virus. For those counties that have, or that are at risk for acquiring, *Aedes albopictus*, or other mosquitoes capable of transmitting the Zika virus, additional required activities include: enhanced human disease monitoring and disease

control; enhanced education about Zika virus and its prevention; mosquito trapping, testing and habitat inspection specific to *Aedes albopictus*, or other mosquitoes capable of transmitting the Zika virus; mosquito control; and identification and commitment of appropriate staff available to join State-coordinated rapid response teams, which may be deployed to those areas where the Department determines that there is a potential transmission of Zika virus by mosquitoes.

**Costs:**

Although exact costs cannot be predicted at this time, the Department does not expect compliance to result in significant costs with respect to plan development, which can be achieved using existing staff. Preparation time will vary according to the demographics of the jurisdiction served by the LHD. However, the cost of these personnel hours is expected to be greatly outweighed by the benefit to public health. LHDs may incur costs including salaries and related expenditures associated with ongoing human disease monitoring, response and control, as well as public education activities and programs.

Those LHDs identified by the Department as jurisdictions where mosquitoes capable of transmitting the Zika virus are currently located or may be located in the future may incur additional costs, including salaries and related expenditures associated with mosquito trapping, testing, and habitat inspections as well as expenditures related to mosquito control, to the extent such counties are not already performing these activities.

**Local Government Mandates:**

Although compliance is not strictly mandatory, the adoption, implementation, and updating of a ZAP is a condition of State Aid for general public health work. As set forth in the regulation, the activities that must be performed to be eligible for State Aid vary by county, and are described in detail below.

By April 15, 2016 all LHDs must electronically transmit a ZAP to the Department that describes how they will conduct timely education, as well as human disease monitoring and reporting of Zika virus.

For those LHDs identified by the Department as jurisdictions where mosquitoes capable of transmitting the Zika virus are currently located or may be located in the future, their ZAP must include processes and procedures for:

- (1) enhanced human disease monitoring, response and control;
- (2) enhanced education to the public and health care providers regarding the possibility of local Zika virus transmission and the risk to pregnant women;
- (3) mosquito trapping, testing, and habitat inspections;
- (4) mosquito control plans tailored to local needs; and
- (5) names, roles and contact information of LHD and/or county staff that will join the state-coordinated rapid response teams.

**Paperwork:**

This regulation requires preparation of a ZAP to respond to an emergency threat to public health.

**Duplication:**

No relevant rules or legal requirements of the Federal and State governments duplicate, overlap or conflict with this rule.

**Alternatives:**

The alternative would be to continue a situation in which there is inconsistent approaches across the State with respect to monitoring and control of the spread of the Zika virus.

**Federal Standards:**

The rule does not exceed any minimum standards of the Federal government for the same or similar subject area.

**Compliance Schedule:**

These permanent regulations will be effective upon publication of a Notice of Adoption in the State Register. LHDs must adopt and implement their ZAPs by April 15, 2016, consistent with the emergency regulations issued on March 17, 2016.

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## **Regulatory Flexibility Analysis for Small Businesses and Local Governments**

### **Effect on Small Business and Local Governments:**

Local health departments (LHDs) will be required to develop Zika Action Plans (ZAPs).

### **Compliance Requirements:**

These regulations apply exclusively to local governments. Accordingly, please refer to the Regulatory Impact Statement.

### **Professional Services:**

In response to the mosquito control plan requirement, those LHDs identified by the Department as jurisdictions where mosquitoes capable of transmitting the Zika virus are currently located, or may be located in the future, may need to obtain the services of a commercial pesticide applicator.

### **Capital Costs and Annual Costs of Compliance:**

The Department does not expect compliance to result in significant costs. Compliance can be achieved using existing staff. Preparation time will vary according to the demographics of the jurisdiction served by the LHD. However, the cost of these personnel hours is expected to be greatly outweighed by the benefit to public health.

**Economic and Technology Feasibility:**

The proposed regulatory changes will not impose any new technology requirements or costs, or otherwise pose feasibility concerns.

**Minimizing Adverse Impact:**

No adverse impacts have been identified.

**Small Business and Local Government Input:**

The Department has been in contact with LHDs regarding the emergency regulations, upon which these permanent regulations are based.

**Cure Period:**

Chapter 524 of the Laws of 2011 requires agencies to include a “cure period” or other opportunity for ameliorative action to prevent the imposition of penalties on the party or parties subject to enforcement under the proposed regulation. Zika virus represents a significant threat to public health. Further, the emergency regulations, effective March 17, 2016, provided time for LHDs to adopt and implement their ZAPs. Hence, no cure period is necessary.

### **Statement in Lieu of Rural Area Flexibility Analysis**

A Rural Area Flexibility Analysis for these amendments is not being submitted because 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**

A Job Impact Statement for these amendments is not being submitted because it is apparent from the nature and purposes of the amendments that they will not have a substantial adverse impact on jobs and/or employment opportunities.