Pursuant to the authority vested in the Public Health Council by Sections 225(4) and 225(5)(a), (g), (h) and (i) of the Public Health Law and in the Commissioner by Public Health Law Section 206(1)(d) and (e), Part 2 of the State Sanitary Code as contained in Chapter I of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York, is amended to be effective upon filing a Notice of Adoption with the Secretary of State, as follows:

Subdivision (a) of Section 2.1 is amended to read as follows:

2.1 Communicable diseases designated: cases, suspected cases and certain carriers to be reported to the State Department of Health.

(a) When used in the Public Health Law and in this Chapter, the term infectious, contagious or communicable disease, shall be held to include the following diseases and any other disease which the commissioner, in the reasonable exercise of his or her medical judgment, determines to be communicable, rapidly emergent or a significant threat to public health, provided that the disease which is added to this list solely by the commissioner's authority shall remain on the list only if confirmed by the Public Health Council at its next scheduled meeting:

Amebiasis

Anthrax

Babesiosis

Botulism

Brucellosis

Campylobacteriosis

Chancroid

Chlamydia trachomatis infection

Cholera

Cryptosporidiosis

Cyclosporiasis

Diphtheria

E. coli 0157:H7 infections

Ehrlichiosis

Encephalitis

Giardiasis

Glanders

Gonococcal infection

Group A Streptococcal invasive disease

Group B Streptococcal invasive disease

Hantavirus disease

Hemolytic uremic syndrome

Hemophilus influenzae (invasive disease)

Hepatitis (A; B; C)

Hospital-associated infections (as defined in section 2.2 of this Part)

Legionellosis

Listeriosis

Lyme disease

Lymphogranuloma venereum

Malaria

Measles

Melioidosis

Meningitis

Aseptic

Hemophilus

Meningococcal

Other (specify type)

Meningococcemia

Monkeypox

Mumps

Pertussis (whooping cough)

Plague

Poliomyelitis

Psittacosis

Q Fever

Rabies

Rocky Mountain spotted fever

Rubella

Congenital rubella syndrome

Salmonellosis

Severe Acute Respiratory Syndrome (SARS)

Shigellosis

Smallpox

Staphylococcal enterotoxin B poisoning

Streptococcus pneumoniae invasive disease

Syphilis, specify stage

Tetanus

Toxic Shock Syndrome

Trichinosis

Tuberculosis, current disease (specify site)

Tularemia

Typhoid

Vaccinia disease (as defined in section 2.2 of this Part)

Viral hemorrhagic fever

Yellow Fever

Yersiniosis

* * *

Section 2.5 of Part 2 is amended as follows:

2.5 Physician to submit specimens for laboratory examination in cases or suspected cases of certain communicable diseases. A physician in attendance on a person affected with or suspected of being affected with any of the diseases mentioned in this section shall submit to an approved laboratory, or to the laboratory of the State Department of Health, for examination of such specimens as may be designated by the State Commissioner of Health, together with data concerning the history and clinical manifestations pertinent to the examination:

Anthrax

Babesiosis

Botulism

Brucellosis

Campylobacteriosis

Chlamydia trachomatis infection

Cholera

Congenital rubella syndrome

Conjunctivitis, purulent, of the newborn (28 days of age or less)

Cryptosporidiosis

Cyclosporiasis

Diphtheria

E. coli 0157:H7 infections

Ehrlichiosis

Giardiasis

Glanders

Gonococcal infection

Group A Streptococcal invasive disease

Group B Streptococcal invasive disease

Hantavirus disease

Hemophilus influenzae (invasive disease)

Hemolytic uremic syndrome

Legionellosis

Listeriosis

Malaria

Melioidosis

Meningitis

Hemophilus

Meningococcal

Meningococcemia

Monkeypox

Plague

Poliomyelitis

Q Fever

Rabies

Rocky Mountain spotted fever

Salmonellosis

Severe Acute Respiratory Syndrome (SARS)

Shigellosis

Smallpox

Staphylococcal enterotoxin B poisoning

Streptococcus pneumoniae invasive

Syphilis

Tuberculosis

Tularemia

Typhoid

Viral hemorrhagic fever

Yellow Fever

Yersiniosis

REGULATORY IMPACT STATEMENT

Statutory Authority:

Sections 225(4) and 225(5)(a), (g), (h), and (i) of the Public Health Law ("PHL") authorize the Public Health Council to establish and amend State Sanitary Code provisions relating to designation of communicable diseases dangerous to public health, designation of diseases for which specimens shall be submitted for laboratory examination, and the nature of information required to be furnished by physicians in each case of communicable disease. PHL Section 206(1)(d) authorizes the commissioner to "investigate the causes of disease, epidemics, the sources of mortality, and the effect of localities, employments and other conditions, upon the public health." PHL Section 206(1)(e) permits the commissioner to "obtain, collect and preserve such information relating to marriage, birth, mortality, disease and health as may be useful in the discharge of his duties or may contribute to the promotion of health or the security of life in the state." PHL Article 21 requires local boards of health and health officers to guard against the introduction of such communicable diseases as are designated in the sanitary code by the exercise of proper and vigilant medical inspection and control of persons and things infected with or exposed to such diseases.

Legislative Objectives:

This regulation meets the legislative objective of protecting the public health by adding Monkeypox to reportable disease and laboratory specimen submission requirements, thereby permitting enhanced disease monitoring and authorizing isolation and quarantine measures if necessary to prevent further transmission.

Needs and Benefits:

Monkeypox is a rare viral disease that manifests itself in animals with a rash, or blisters, fever, eye discharge and swollen lymph nodes. In humans, it resembles smallpox and is associated with fever, headache, backache, swollen lymph nodes, and a blister-like rash. It is transmitted from animal to person and from person to person through direct contact or respiratory droplets.

Monkeypox is found mostly in central and western Africa and was first noted in monkeys in 1958. The human fatality rate has ranged from 1 to 10 percent in Africa. The first cases in humans were seen in 1970.

In May 2003, the first outbreak of human monkeypox in the United States was reported with 19 confirmed or suspected cases in Wisconsin, Illinois and Indiana. Clinical onset was as early as May 15th, as late as June 3rd. Since then, there have been other suspect cases in other states. To date, no cases have been identified in New York State. These human cases of monkeypox were a result of contact with ill prairie dogs. The sick prairie dogs became infected through contact with infected African rodents that had been imported to the United States. There is concern that monkeypox could spread to other animals housed with affected prairie dogs or African rodents from the infected shipment. The New York State Department of Health (NYSDOH) has identified 20 prairie dogs that have been shipped to dealers or individuals in New York State. Twelve of these prairie dogs have been identified, collected and euthanized per guidance issued by CDC and lab results were negative. The NYSDOH continues to work with the local health department to track down the remaining 8 prairie dogs. The Centers for Disease Control has issued guidelines for pet owners so that they can be on the lookout for monkeypox symptoms. The NYSDOH is developing documents for pet owners and veterinarians providing

monkeypox information and guidance for handling of sick animals and reporting and testing procedures.

If monkeypox spreads in the general population, there could be severe public health consequences. On July 11, 2003, the New York State Commissioner of Health determined that monkeypox is communicable and a significant threat to the public health, and designated monkeypox as a communicable disease under 10 NYCRR Section 2.1. Per this authority, this designation will expire unless confirmed at the next scheduled meeting of the Public Health Council on July 25, 2003. Adding monkeypox to the reportable disease list will confirm the Commissioner's designation and permit the NYSDOH to systematically monitor for the disease, make its progress known to both State and federal officials, and permit decisions about isolation or quarantine of suspect or confirmed cases to be made on a timely basis.

COSTS:

Costs to Regulated Parties:

Since monkeypox is a newly emerging disease, it is not possible to accurately predict the extent of an outbreak or potential costs. In the event of the occurrence of monkeypox cases, however, it is imperative to the public health that suspect cases be reported immediately and investigated thoroughly to curtail additional exposure and potential morbidity and mortality and to protect the public health.

The costs associated with implementing the reporting of this disease are lessened as reporting processes and forms already exist. Hospitals, practitioners and clinical laboratories are accustomed to reporting communicable disease to public health authorities.

Human monkeypox testing is currently conducted only at the NYSDOH Wadsworth Laboratory and the federal Centers for Disease Control and Prevention (CDC). These tests are under development and are continually being optimized. At this time, it is not possible to accurately predict the extent of an outbreak or potential costs. However, thus far, costs appear to be minimal. Costs to hospitals, practitioners and clinical laboratories relate to the cost of shipping specimens to the Wadsworth Laboratory. One sample must be shipped per patient to the Wadsworth Laboratory using a collection kit and shipping containers provided by Wadsworth. Shipping costs are estimated to be $25.00 per sample.

Animal monkeypox testing is currently conducted only at the NYSDOH Wadsworth Laboratory. The Wadsworth Rabies Laboratory is conducting necropsies on the submitted animals and the Clinical Bacteriology Laboratory is conducting tissue testing. Wadsworth is providing shipping containers for animal specimens to local health departments. Shipping costs are estimated to be $25.00 per sample. Local health departments are also hand-delivering specimens to the NYSDOH.

Costs to Local and State Governments:

The additional cost of reporting monkeypox is expected to be mitigated because the staff who are involved in reporting this disease at the local and State health departments are the same as those currently involved with reporting of other communicable diseases listed in 10 NYCRR Section 2.1.

The cost of laboratory testing is expensive (discussed in the section below), and is paid for by the NYSDOH Wadsworth Laboratory and CDC. There is no charge to local governments for this testing.

The additional cost to local or state governments associated with investigating and implementing control strategies to curtail the spread of monkeypox could become significant depending upon the extent of an outbreak. Because the possibility of human-to-human transmission cannot be excluded, a combination of standard, contact and airborne precautions should be applied in health care settings to minimize spread. Suspect cases are to be reported to the local health department, who should immediately notify the Regional Epidemiologist or the NYSDOH after-hours duty officer.

By preventing the spread of monkeypox, savings may include reducing costs associated with public health control activities, morbidity, treatment and premature death.

Costs to the Department of Health:

The NYSDOH already collects communicable disease reports from local health departments, checks the reports for accuracy and transmits them to the federal Centers for Disease Control and Prevention. The addition of monkeypox to the list of communicable diseases should not lead to substantial additional costs for data entry, particularly as the Department adopts systems for electronic submission of case reports.

As mentioned above, monkeypox testing is expensive. In New York State, human monkeypox testing is currently only performed by the NYSDOH Wadsworth Laboratory. Positive samples are sent to CDC for additional testing. The cost per patient tested by the Wadsworth Laboratory is approximately $390.00. The cost for laboratory testing is about $350.00 per patient, which includes supplies and reagents only, not technician time. One sample must be shipped per patient at a cost of $40.00 (shipping container, estimated to cost $15.00; shipping estimated to cost $25.00). These samples include diagnostic samples for testing for the presence of the monkeypox agent and also convalescent sera from the same patient.

Animal monkeypox testing is currently performed by the NYSDOH Wadsworth Laboratory. The cost per animal specimen is approximately $50 per specimen, which includes supplies and reagents only, not staff time. Wadsworth Laboratory is providing shipping containers to local health departments. The estimated cost of these containers is $15 each.

Paperwork:

The existing general communicable disease reporting form (DOH-389) will be revised. This form is familiar to and is already used by regulated parties.

Local Government Mandates:

Under Part 2 of the State Sanitary Code (10 NYCRR Part 2), the city, county or district health officer receiving reports from physicians in attendance on persons with or suspected of being affected with monkeypox, will be required to immediately forward such reports to the State Health Commissioner and to investigate and monitor the cases reported.

Duplication:

There is no duplication of this initiative in existing State or federal law.

Alternatives:

No other alternatives are available.

Reporting of cases of monkeypox is of critical importance to public health. There is an urgent need to conduct surveillance, identify human cases in a timely manner, and reduce the potential for further exposure to contacts.

Federal Standards:

Currently there are no federal standards requiring the reporting of monkeypox. The Department of Health and Human Services Centers for Disease Control (CDC) and the Food and Drug Administration have issued a joint order of embargo and prohibition on the sale, transport and importation of prairie dogs and certain rodents from Africa to mitigate the harm of further introductions of monkeypox virus into the United States. This further includes a ban on the intrastate sale or offering for any other type of commercial or public distribution of these species. The CDC has issued infection-control/exposure management guidelines for suspected human cases that include: general precautions, patient placement, vaccination of healthcare workers and household contacts of suspected cases of monkeypox, monitoring of exposes healthcare personnel of patients, and isolation precautions. CDC has also issued guidelines for animal cases that include: case definition and classification, guidance for veterinarians, pet owners.

Compliance Schedule:

Reporting of monkeypox is currently mandated, pursuant to the authority vested in the Commissioner of Health by 10 NYCRR Section 2.1(a). This mandate will be extended upon filing of a Notice of Emergency Adoption of this regulation with the Secretary of State and made permanent by publication of a Notice of Adoption of this regulation in the New York State Register.

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REGULATORY FLEXIBILITY ANALYSIS

Effect on Small Business and Local Government:

It is unclear what impact the proposed reporting change will have on small business (hospitals, clinics, nursing homes, physicians, and clinical laboratories). The ultimate impact is dependent on the extent of any monkeypox outbreak. There are approximately 6 hospitals, 15 nursing homes and 1,000 clinical laboratories that employ fewer than 100 people in New York State. There are 397 licensed clinics; information about how many operate as small businesses is not available. There are approximately 70,000 physicians in New York State but it is not known how many can be categorized as small businesses. This regulation will apply to all local health departments.

Compliance Requirements:

Hospitals, clinics, physicians, nursing homes, and clinical laboratories that are small businesses and local governments will utilize revised NYSDOH reporting forms and specimen shipping procedures.

Professional Services:

No additional professional services will be required since providers are expected to be able to utilize existing staff to report occurrences of monkeypox and to ship samples to the Wadsworth Laboratory for testing. Local health departments have also hand-delivered animal specimens to NYSDOH utilizing existing local and regional staff.

Compliance Costs:

No initial capital costs of compliance are anticipated. Annual compliance costs will depend upon the number of monkeypox cases. The reporting of monkeypox should have a negligible to modest effect on the estimated cost of disease reporting by hospitals, but the exact cost cannot be estimated. The cost would be less for physicians and other small businesses. Isolation authority, and the related costs, may also need to be invoked by local governments. The magnitude of these costs is dependent on the number of monkeypox cases in New York State.

Human and animal monkeypox testing is currently conducted only at the NYSDOH Wadsworth Laboratory and the CDC. Costs to hospitals, practitioners and clinical laboratories relate to the cost of shipping one specimen per patient to the Wadsworth Laboratory. Costs to local governments relate to the cost of shipping animal specimens to the Wadsworth Laboratory. Shipping costs for both human and animal specimens are estimated at $25.00 per specimen. Shipping containers are provided by the Wadsworth Laboratory. Once monkeypox testing is refined and validated, other laboratories may begin testing.

Minimizing Adverse Impact:

There are no alternatives to the reporting or laboratory testing requirements. Adverse impacts have been minimized since revised forms and reporting staff will be utilized by regulated parties. Electronic reporting will save time and expense. The approaches suggested in the State Administrative Procedure Act Section 202-b(1) were rejected as inconsistent with the purpose of the regulation.

Feasibility Assessment:

Small businesses and local governments will likely find it easy to report conditions due to the availability to them of electronic reporting and tabulation.

There is an additional burden and cost to hospitals, practitioners and local health departments of shipping monkeypox samples to the Wadsworth Laboratory.

Small Business and Local Government Participation:

Local governments have been consulted in the process through ongoing communication on this issue with local health departments and the New York State Association of County Health Officers (NYSACHO).

RURAL AREA FLEXIBILITY ANALYSIS

Effect on Rural Areas:

The proposed rule will apply statewide. Given that the number of cases that will be reported from rural areas is unknown, it is not possible to calculate the actual impact on local health units, physicians, hospitals and laboratories that are located in rural areas.

Compliance Requirements:

Local health units, hospitals, clinics, physicians and clinical laboratories in rural areas will continue to utilize NYSDOH reporting forms that will be revised to include monkeypox. Existing procedures will be used to ship specimens to the Wadsworth Laboratory for testing.

Professional Services:

No additional professional services will be required. Rural providers are expected to use existing staff to comply with the requirements of this regulation.

Compliance Costs:

No initial capital costs of compliance are anticipated. See cost statement in Regulatory Impact Statement for additional information.

Minimizing Adverse Impact:

There are no alternatives to the reporting requirements. Adverse impacts have been minimized since familiar forms and reporting staff will be utilized by regulated parties. The

approaches suggested in State Administrative Procedure Act Section 202-bb(2) were rejected inconsistent with the purpose of the regulation.

Rural Area Input:

The New York State Association of County Health Officers (NYSACHO), including representatives of small counties, has been informed about this change and support the need for it.

JOB IMPACT STATEMENT

This regulation adds monkeypox to the list of diseases that health care providers must report to public health authorities and submit laboratory specimens. The staff who are involved in reporting monkeypox at the local and State health departments are the same as those currently involved with reporting, monitoring and investigating other communicable diseases. Similarly, existing staff at the local and State health departments collect and submit monkeypox specimens, and current State laboratory staff test monkeypox specimens. Since monkeypox is a newly emerging disease, it is not possible to accurately predict the extent of any outbreak and the degree of additional demands it will place on existing staff. The NYSDOH has determined that this regulatory change will not have a substantial adverse impact on jobs and employment.

Emergency Justification

On July 11, 2003 The New York State Commissioner of Health designated monkeypox as a communicable disease pursuant to authority set forth in 10 NYCRR Section 2.1(a). In order for this designation to continue, regulations adding monkeypox to the list of communicable diseases need to be adopted by the Public Health Council at its next scheduled meeting. By adopting this rule, the Public Health Council will confirm the Commissioner's designation and continue monkeypox on the list of communicable diseases which providers are required to report to local and/or the State health departments and require physicians to submit specimens for laboratory examination when they suspect a person is infected with monkeypox. Continuing monkeypox on the list of communicable diseases will also permit isolation of patients if necessary for disease control. Immediate adoption of this rule is necessary for accurate identification and monitoring of monkeypox cases and to prevent community transmission through enforcement of isolation measures if needed.

Monkeypox is a rare viral disease that manifests itself in animals with a rash, or blisters, fever, eye discharge and swollen lymph nodes. In humans, it resembles smallpox and is associated with fever, headache, backache, swollen lymph nodes, and a blister-like rash. It is transmitted from animal to person and from person to person through direct contact or respiratory droplets. Monkeypox is found mostly in central and western Africa and was first noted in monkeys in 1958. The human fatality rate has ranged from 1 to 10 percent in Africa. The first cases in humans were seen in 1970.

In May 2003, the first outbreak of human monkeypox in the United States was reported with 19 confirmed or suspected cases in Wisconsin, Illinois and Indiana. Clinical onset was as

early as May 15th, as late as June 3rd. Since then, there have been other suspect cases in other states. To date, no cases have been identified in New York State. These human cases of monkeypox were a result of contact with ill prairie dogs. The sick prairie dogs became infected through contact with infected African rodents that had been imported to the United States. There is concern that monkeypox could spread to other animals housed with affected prairie dogs or African rodents from the infected shipment. The New York State Department of Health (NYSDOH) has identified 20 prairie dogs that have been shipped to dealers or individuals in New York State. Twelve of these prairie dogs have been identified, collected and euthanized per guidance issued by CDC and lab results were negative. The NYSDOH continues to work with the local health department to track down the remaining 8 prairie dogs.

If monkeypox spreads in the general population, there could be severe public health consequences; therefore, immediate adoption of this rule is necessary. Surveillance efforts for monkeypox cases in New York State rely on the immediate reporting of suspect or probable monkeypox in animals and humans. Adding monkeypox to the list of communicable diseases will trigger mandatory provider reporting of monkeypox cases and enable mandatory isolation of suspect or confirmed cases if necessary. Requiring physicians to submit specimens from suspected cases for laboratory examination will further efforts to identify and respond to cases. Complete and timely reporting by physicians to the city, county or district health officer of all cases of monkeypox will assist local health departments and the State Department of Health in the earliest possible recognition of an outbreak, and enable steps to contain it.