

RULE MAKING ACTIVITIES

Each rule making is identified by an I.D. No., which consists of 13 characters. For example, the I.D. No. AAM-01-96-00001-E indicates the following:

- AAM -the abbreviation to identify the adopting agency
01 -the *State Register* issue number
96 -the year
00001 -the Department of State number, assigned upon receipt of notice
E -Emergency Rule Making—permanent action not intended (This character could also be: A for Adoption; P for Proposed Rule Making; RP for Revised Rule Making; EP for a combined Emergency and Proposed Rule Making; EA for an Emergency Rule Making that is permanent and does not expire 90 days after filing; or C for first Continuation.)

Italics contained in text denote new material. Brackets indicate material to be deleted.

Department of Agriculture and Markets

REGULATORY IMPACT STATEMENT, REGULATORY FLEXIBILITY ANALYSIS, RURAL AREA FLEXIBILITY ANALYSIS AND/OR JOB IMPACT STATEMENT

Pine Shoot Beetle Quarantine

I.D. No. AAM-20-04-00009-E

This regulatory impact statement, regulatory flexibility analysis, rural area flexibility analysis and/or job impact statement pertain(s) to a notice of emergency rule making, I.D. No. AAM-20-00009-E, printed in the *State Register* on May 19, 2004.

Regulatory Impact Statement

1. Statutory authority:

Section 18 of the Agriculture and Markets Law provides, in part, that the Commissioner may enact, amend and repeal necessary rules which shall provide generally for the exercise of the powers and performance of the duties of the Department as prescribed in the Agriculture and Markets Law and the laws of the State and for the enforcement of their provisions and the provisions of the rules that have been enacted.

Section 164 of the Agriculture and Markets Law provides, in part, that the Commissioner shall take such action as he may deem necessary to

control or eradicate any injurious insects, noxious weeds, or plant diseases existing within the State.

Section 167 of the Agriculture and Markets Law provides, in part, that the Commissioner is authorized to make, issue, promulgate and enforce such order, by way of quarantines or otherwise, as he may deem necessary or fitting to carry out the purposes of Article 14 of said Law. Said Section also provides that the Commissioner may adopt and promulgate such rules and regulations to supplement and give full effect to the provisions of Article 14 of the Agriculture and Markets Law as he may deem necessary.

2. Legislative objectives:

The proposed modification of the quarantine accords with the public policy objectives the Legislature sought to advance by enacting the statutory authority in that it will help to prevent the spread within the State of an injurious insect, the pine shoot beetle.

3. Needs and benefits:

The pine shoot beetle, *Tomicus piniperda*, an insect non-indigenous to the United States, is a destructive wood-boring insect native to Europe. The beetle attacks pine trees by nesting under the bark and feeding on new shoots. The resulting damage by the beetle causes shoot and branch mortality which affects the growth and appearance of the tree and may eventually lead to the death of the tree. Although it is a slow-moving pest, the pine shoot beetle is easily spread through the movement of Christmas trees, nursery stock and pine logs and lumber.

The pine shoot beetle was first detected in a Christmas tree farm near Cleveland, Ohio in July of 1992 and subsequently spread to other parts of Ohio as well as to sections of Michigan, Indiana, Illinois, Pennsylvania and New York. On November 19, 1992, the United States Department of Agriculture (USDA) adopted regulations (7 CFR sections 301.50 through 301.50-10), establishing a pine shoot beetle quarantine as well as requirements and restrictions governing the movement of regulated materials from counties where this pest has been detected. On November 25, 1992, the Department, as an emergency measure, adopted section 131.1 of 1 NYCRR, which required that pine Christmas trees, pine nursery stock and pine, spruce, larch and fir logs and lumber, with bark attached, shall not be shipped, transported or otherwise moved from any point within Allegany, Cattaraugus, Erie, Genesee, Livingston, Monroe, Niagara, Oswego, Ontario and Wyoming Counties to any point outside said counties, except in accordance with federal regulations at 7 CFR sections 301.50 through 301.50-10. This emergency measure was ultimately adopted as a permanent rule on March 17, 1993. However, subsequent observations of the pine shoot beetle in the Counties of Albany, Broome, Cayuga, Chemung, Chenango, Cortland, Delaware, Franklin, Fulton, Greene, Hamilton, Herkimer, Jefferson, Lewis, Madison, Montgomery, Oneida, Onondaga, Otsego, Rensselaer Saratoga, Schenectady, Schoharie, St. Lawrence, Schuyler, Seneca, Steuben, Sullivan, Tioga, Tompkins, Wayne and Yates, have resulted in the need to add these counties to the list of quarantined areas in section 131.1. This rule contains the needed additions. Although the beetle has not as yet been detected in the Counties of Clinton, Essex, Warren,* Washington and Columbia, extension of the quarantine into these counties would establish a buffer between infested and uninfested counties, thereby helping to control the further spread of this pest. These counties are not the only counties adjacent to counties in which the beetle has been detected, since the Counties of Ulster and Orange are also adjacent to the quarantined area. However, since the Counties of Clinton, Essex, Warren, Washington and Columbia contain 173 saw mills which process pine logs shipped from counties where the beetle has been detected, there is a greater likelihood that infested materials will be transported to these five counties. The need to establish such a buffer has

resulted in the need to add these five counties to the list of quarantined areas in section 131.1. This rule contains the needed additions. This rule also incorporates by reference, the most recent revision of the federal regulations at 7 CFR sections 301.50 through 301.50-10, revised as of January 1, 2004, which set forth requirements and restrictions governing the movement of regulated materials from counties where the pine shoot beetle has been detected. Finally, this rule deletes spruce, larch and fir from the list of regulated host materials subject to regulation under the quarantine, since the USDA has tested and determined that these materials are not a host to the pine shoot beetle.

The effective control of the pine shoot beetle within the areas of the State where the insect has been found is important to protect New York's Christmas tree, nursery and forest products industries. It is estimated that there are 3,970 nursery dealers, 2,205 nursery growers, 673 forest products companies, 119 arborists and 116 Christmas tree farms in the State which engage in these industries. They employ an estimated 42,000 people and generate 1.51 billion dollars in revenue per year. The failure of states to control insect pests within their borders can lead to federal quarantines as well as quarantines by other states which would affect all areas of those states, rather than just the infested portions. Such widespread quarantines would adversely affect the Christmas tree, nursery and forest products industries throughout New York State.

4. Costs:

- (a) Costs to the State government: None.
- (b) Costs to local government: None.
- (c) Costs to private regulated parties:

Regulated parties exporting host material from the quarantined area, other than pursuant to compliance agreement, will require an inspection and the issuance of a federal or state phytosanitary certificate. This service is available at a rate of \$25 per hour. Most inspections will take one hour or less. It is anticipated that there will be 25 or fewer such inspections each year with a total annual cost of less than \$1000.

Most shipments will be made pursuant to compliance agreements for which there is no charge.

(d) Costs to the regulatory agency:

(i) The initial expenses the agency will incur in order to implement and administer the regulation:

None.

(ii) It is anticipated that the Department will be able to administer the quarantine with existing staff.

5. Local government mandate:

None.

6. Paperwork:

Regulated articles inspected and certified to be free of the pine shoot beetle moving from quarantined areas must be accompanied by a state or federal phytosanitary certificate of a limited permit or be undertaken pursuant to a compliance agreement.

7. Duplication:

None.

8. Alternatives:

None. The failure of the State to modify the quarantine to reflect the areas in which the pine shoot beetle has been observed could result in exterior quarantines by foreign and domestic trading partners as well as a federal quarantine of the entire State. In addition, the failure to regulate the movement of host material from the buffer area may be viewed by these partners as facilitating the spread of this pest. It could also place the State's own natural resources (forest, urban and agricultural) at risk from the spread of pine shoot beetle that could result from the unrestricted movement of regulated articles from the areas covered by the modified quarantine. In light of these factors there does not appear to be any viable alternative to the modification of quarantine proposed in this rulemaking.

9. Federal standards:

The rule does not exceed any minimum standards for the same or similar subject areas.

10. Compliance schedule:

It is anticipated that regulated persons will be able to comply with the rule immediately.

This rule amends the pine shoot beetle quarantine in section 131.1 of 1 NYCRR by extending that quarantine to the Counties of Albany, Broome, Cayuga, Chemung, Chenango, Clinton, Columbia, Cortland, Delaware, Essex, Franklin, Fulton, Greene, Hamilton, Herkimer, Jefferson, Lewis, Madison, Montgomery, Oneida, Onondaga, Otsego, Rensselaer, Saratoga, Schenectady, Schoharie, St. Lawrence, Schuyler, Seneca, Steuben, Sullivan, Tioga, Tompkins, Warren, Washington, Wayne and Yates. This rule also incorporates by reference, the most recent revisions to federal regulations at 7 CFR sections 301.50 through 301.50-10, revised as of January 1, 2004, which set forth requirements and restrictions for the movement of host materials. Finally, this rule deletes spruce, larch and fir from the list of regulated host materials subject to regulation under the quarantine, since the United States Department of Agriculture (USDA) has tested and determined that these materials are not a host to the pine shoot beetle.

It is estimated that there are 1,899 nursery dealers, 1,408 nursery growers, 673 forest products companies, 119 arborists and 67 Christmas tree farms in the 37 counties which have been added to the pine shoot beetle quarantine. Most of these entities are small businesses.

Although it is not anticipated that local governments will be involved in the shipment of regulated articles from the quarantined areas, in the event that they do, they would be subject to the same requirements and restrictions governing such movement set forth in 7 CFR sections 301.50 through 301.50-10 as are other regulated parties.

2. Compliance requirements:

All regulated parties in the modified quarantined areas will be required to obtain state or federal phytosanitary certificates and limited permits in order to ship regulated articles from quarantined areas. In order to facilitate such shipments, regulated parties may enter into compliance agreements.

3. Professional services:

In order to comply with the amendments, businesses and local governments shipping regulated articles from the modified quarantined areas will require professional inspection services, which will be provided by the Department and the USDA.

4. Compliance costs:

(a) Initial capital costs that will be incurred by a regulated business or industry or local government in order to comply with the proposed rule: None.

(b) Annual cost for continuing compliance with the proposed rule:

Regulated parties exporting host material from the modified quarantined area, other than pursuant to a compliance agreement, will require an inspection and the issuance of a federal or state phytosanitary certificate. This service is available at a rate of \$25 per hour. Most such inspections will take one hour or less. It is anticipated that there will be 25 or fewer such inspections each year, with a total cost of less than \$1,000. Most shipments will be made pursuant to compliance agreements for which there is no charge.

Local governments shipping regulated articles from the modified quarantined areas would incur similar costs.

5. Minimizing adverse impact:

The Department has designed the rule to minimize adverse economic impact on small businesses and local governments. The rule limits the modified quarantined areas to only those areas where the pine shoot beetle has been detected and those areas that will serve as a buffer to prevent the spread of the pest through transportation of infested materials to uninfested areas. The rule also limits the regulated articles to only those susceptible to infestation by the pine shoot beetle. Finally, the rule limits the inspection and permit requirements to only those necessary to detect the presence of the pine shoot beetle and prevent its movement in host materials from the quarantined areas. As set forth in the regulatory impact statement, the rule provides for agreements between the Department and regulated parties that permit the shipment of regulated articles without state or federal inspection. These agreements, for which there is no charge, are another way in which the rule was designed to minimize adverse impact. The approaches for minimizing adverse economic impact required by section 202-a(1) of the State Administrative Procedure Act and suggested by section 202-b(1) of the State Administrative Procedure Act were considered. Given all of the facts and circumstances, it is submitted that the rule minimizes adverse economic impact as much as is currently possible.

6. Small business and local government participation:

The Department has contacted representatives of the Empire State Forest Products Association, New York State Nursery/Landscape Association and the Christmas Tree Farmers Association of New York to discuss the expansion of the pine shoot beetle quarantine. The representatives of these three trade organizations representing regulated parties, expressed support for the expansion of the quarantine.

* Since the filing of this amendment as an emergency rule on May 3, 2004, the Department learned that the pine shoot beetle has been detected in Warren County. Accordingly, although the text of the rule remains unchanged, Warren County no longer constitutes a buffer.

Regulatory Flexibility Analysis

1. Effect on small business:

7. Assessment of the economic and technological feasibility of compliance with the rule by small businesses and local governments:

The economic and technological feasibility of compliance with the rule by small businesses and local governments has been addressed and such compliance has been determined to be feasible. Regulated parties shipping host materials from the quarantined areas, other than pursuant to a compliance agreement, will require an inspection and the issuance of a phytosanitary certificate. Most shipments, however, will be made pursuant to compliance agreements for which there is no charge.

Rural Area Flexibility Analysis

1. Type and estimated numbers of rural areas:

This rule amends the pine shoot beetle quarantine in section 131.1 of 1 NYCRR by extending that quarantine to the Counties of Albany, Broome, Cayuga, Chemung, Chenango, Clinton, Columbia, Cortland, Delaware, Essex, Franklin, Fulton, Greene, Hamilton, Herkimer, Jefferson, Lewis, Madison, Montgomery, Oneida, Onondaga, Otsego, Rensselaer, Saratoga, Schenectady, Schoharie, St. Lawrence, Schuylar, Seneca, Steuben, Sullivan, Tioga, Tompkins, Warren, Washington, Wayne and Yates. This rule also incorporates by reference, the most recent revisions to federal regulations at 7 CFR sections 301.50 through 301.50-10, revised as of January 1, 2004, which set forth requirements and restrictions for the movement of host materials. Finally, this rule deletes spruce, larch and fir from the list of regulated host materials subject to regulation under the quarantine, since the United States Department of Agriculture (USDA) has tested and determined that these materials are not a host to the pine shoot beetle.

It is estimated that there are 1,899 nursery dealers, 1,408 nursery growers, 673 forest products companies, 119 arborists and 67 Christmas tree farms in the 37 counties which have been added to the pine shoot beetle quarantine. Many of these entities are located in rural areas of the State.

2. Reporting, recordkeeping and other compliance requirements; and professional services:

All regulated parties in the modified quarantined areas will be required to obtain state or federal phytosanitary certificates and limited permits in order to ship regulated articles from quarantined areas. In order to facilitate such shipments, regulated parties may enter into compliance agreements.

In order to comply with the amendments, entities that ship regulated articles from the modified quarantined areas will require professional inspection services, which will be provided by the Department and the USDA.

3. Costs:

Regulated parties exporting host material from the modified quarantined area, other than pursuant to a compliance agreement, will require an inspection and the issuance of a federal or state phytosanitary certificate. This service is available at a rate of \$25 per hour. Most such inspections will take one hour or less. It is anticipated that there will be 25 or fewer such inspections each year, with a total cost of less than \$1,000. Most shipments will be made pursuant to compliance agreements for which there is no charge.

4. Minimizing adverse impact:

In conformance with State Administrative Procedure Act Section 202-bb(2), the amendments were drafted to minimize reporting and testing requirements for all regulated parties, including those in rural areas. The rule limits the modified quarantined areas to only those areas where the pine shoot beetle has been detected and those areas that will serve as a buffer to prevent the spread of the pest through transportation of infested materials to uninfested areas. The rule also limits the regulated articles to only those susceptible to infestation by the pine shoot beetle. Finally, the rule limits the inspection and permit requirements to only those necessary to detect the presence of the pine shoot beetle and prevent its movement in host materials from the quarantined areas. As set forth in the regulatory impact statement, the rule provides for agreements between the Department and regulated parties that permit the shipment of regulated articles without state or federal inspection. These agreements, for which there is no charge, are another way in which the rule was designed to minimize adverse impact. Given all of the facts and circumstances, it is submitted that the rule minimizes adverse economic impact as much as is currently possible.

5. Rural area participation:

The Department has contacted representatives of the Empire State Forest Products Association, New York State Nursery/Landscape Association and the Christmas Tree Farmers Association of New York to discuss the expansion of the pine shoot beetle quarantine. The representatives of these three trade organizations representing regulated parties, expressed support for the expansion of the quarantine.

Job Impact Statement

The rule will not have a substantial adverse impact on jobs and employment opportunities. The modification of the quarantine area is designed to prevent the spread of the pine shoot beetle to other parts of the State. It is estimated that there are 3,970 nursery dealers, 2,205 nursery growers, 673 forest products companies, 119 arborists and 116 Christmas tree farms in the State which engage in these industries. They employ an estimated 42,000 people and generate 1.51-billion dollars in revenue per year. A spread of the infestation would have very adverse economic consequences to these industries in New York State, both from the destruction of the regulated articles upon which these industries depend, and from the more restrictive quarantines that could be imposed by the federal government and by other states. By helping to prevent the spread of the pine shoot beetle, the rule will help to prevent such adverse economic consequences and in so doing, protect the jobs and employment opportunities associated with the State's Christmas tree, nursery and forest products industries.

Banking Department

NOTICE OF ADOPTION

Budget Planners

I.D. No. BNK-06-04-00005-A

Filing No. 544

Filing date: May 6, 2004

Effective date: May 26, 2004

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following action:

Action taken: Repeal of Part 402 and addition of new Part 402 to Title 3 NYCRR.

Statutory authority: Banking Law, art. 12-C, section 587

Subject: Regulation of budget planning activities conducted by entities licensed under art. 12-C of the New York Banking Law.

Purpose: To set forth the regulatory requirements and standards of operation for entities licensed under art. 12-C of the New York Banking Law to conduct the business of budget planning.

Text or summary was published in the notice of proposed rule making, I.D. No. BNK-06-04-00005-P, Issue of February 11, 2004.

Final rule as compared with last published rule: No changes.

Text of rule and any required statements and analyses may be obtained from: Christine M. Tomczak, Secretary to the Banking Board, Banking Department, One State St., 6th Fl., New York, NY 10004-1417, (212) 709-1642, e-mail: christine.tomczak@banking.state.ny.us

Assessment of Public Comment

The agency received no public comment.

REGULATORY IMPACT STATEMENT, REGULATORY FLEXIBILITY ANALYSIS, RURAL AREA FLEXIBILITY ANALYSIS AND/OR JOB IMPACT STATEMENT

Changes in the Regulations Governing Credit Unions

I.D. No. BNK-19-04-00005-E

This regulatory impact statement, regulatory flexibility analysis, rural area flexibility analysis and/or job impact statement pertain(s) to a notice of emergency rule making, I.D. No. BNK-19-04-00005-E, printed in the *State Register* on May 12, 2004.

Regulatory Impact Statement

1. Statutory authority:

Banking Law Section 14(1) gives the Banking Board the power "to make, alter and amend rules and regulations not inconsistent with law." Section 454 of the Banking Law states that the powers of a credit union specified therein shall be subject to any regulations promulgated by the Superintendent or, in certain specified cases, to regulations promulgated by the Banking Board. Section 454(6) of the Banking Law authorizes a

credit union to lend money to its members, subject to such regulations and restrictions as the banking board finds necessary and proper. Section 454(9) of the Banking Law authorizes a credit union, subject to such regulations and restrictions as the Banking Board finds necessary and proper, to borrow money from any source in an aggregate amount not exceeding fifty percent of assets without the written approval of the Superintendent. Section 454(14) of the Banking Law permits a credit union to hold shares in and make loans to other credit unions, whether state or federally chartered, subject to the limitations contained in Section 456(7) of the Banking Law. Section 454(19) of the Banking Law provides that investments in and loans to a credit union organization by a credit union shall be subject to regulations and restrictions of the Banking Board. Section 458(9) of the Banking Law gives the Superintendent the power to promulgate regulations or take other measures necessary to provide for and implement the repeal of Section 458. Section 458-a of the Banking law gives the Superintendent the power to prescribe by regulation the net worth reserve categories which a credit union shall contribute to and maintain.

2. Legislative objectives:

As more fully described in response to Item 3, "Needs and benefits" below, the proposed repeal of Section 95.2 of the General Regulations of the Banking Board ("General Regulations"), the proposed amendment to Section 96.1 of the General Regulations, the proposed amendment to Section 96.3 of the General Regulations, the proposed amendment to Section 97.5 of the General Regulations, the proposed adoption of new Superintendent's Regulation Part 326 and the proposed repeal of Part 113 of the General Regulations all implement, or conform the regulations of the Banking Department to, specific changes made by the Legislature in the Banking Law, and thereby presumably accord with the public policy objectives of the Legislature in making such changes. As also more fully described in response to Item 3 below, the proposed adoption of new Superintendent's Regulation 327 addresses safety and soundness concerns which may arise from the repeal of Part 113 of the General Regulations, and thereby accords with the public policy objectives set forth in Section 10 of the Banking Law that the business of all banking organizations be regulated in such a manner as to ensure, among other things, the safe and sound conduct of such business.

3. Needs and benefits:

The repeal of Section 95.2 of the General Regulations of the Banking Board will conform the regulation to a change in the law by removing an obsolete limitation contained in the regulation requiring a credit union to obtain the approval of the Superintendent to borrow more than 15 but less than 50 percent of its assets. New Section 454(9) of the Banking Law permits a credit union to borrow up to 50 percent of its assets without the approval of the Superintendent.

The amendment to Section 96.1 of the General Regulations of the Banking Board will implement a change in the law by eliminating references in the regulation to the surplus of a credit union and conforming the definition of "net worth" to the regulations of the National Credit Union Administration. Section 458 of the Banking Law, requiring credit unions to maintain surplus accounts, will be repealed effective October, 2004.

The amendment to Section 96.3 of the General Regulations of the Banking Board modifies the statutory references in the regulation to reflect changes made in Article XI of the Banking Law.

The amendment to Section 97.5 of the General Regulations of the Banking Board conforms the regulation to amended Section 454(19) of the Banking Law, which increases the limit on investments by a credit union in a credit union organization from one percent to three percent of the total sum due to members on shares and deposits.

New Superintendent's Regulation Part 326 implements new Section 458-a of the Banking Law. Section 458-a requires a credit union to maintain such net worth reserves as the Superintendent by regulation shall prescribe and mandates that the regulations prescribe a system of maintaining net worth reserves comparable to that promulgated by the National Credit Union Administration, except as otherwise deemed necessary by the Superintendent.

The repeal of Part 113 of the General Regulations of the Banking Board conforms the regulations to the investment powers of credit unions under Section 454(14) of the Banking Law. Part 113 limits a credit union to investing no more than 50 percent of its capital in shares of a central (*i.e.*, corporate) credit union located in this state. However, Banking Law Section 454(4) authorizes credit unions to hold shares of other credit unions, subject to the limitations in Banking Law Section 456(7). The latter section specifically excludes from its investment limitations investments in state or federal corporate credit unions.

New Superintendent's Regulation Part 327 addresses any possible safety and soundness concerns arising from the repeal of Part 113 by requiring that a credit union which intends to invest in the shares of a state or federal corporate credit union located in this state in an amount that exceeds 50 percent of its total capital or its insured limit, whichever is greater, give the Superintendent prior written notice of its intent. The regulation gives the Superintendent an opportunity to determine whether the proposed investment is consistent with the policy set forth in Section 10 of the Banking Law, which includes safety and soundness considerations.

4. Costs:

The repeal of Section 95.2 of the General Regulations of the Banking Board is not projected to impose any costs on regulated persons or the state government.

The amendment to Section 96.1 of the General Regulations of the Banking Board will conform the definition of net worth in state's credit union regulations to that of the federal regulator of credit unions, and is not therefore projected to impose any additional costs on regulated persons or the state government.

The amendment to Section 96.3 of the General Regulations of the Banking Board will conform statutory cross-references in the regulation to changes in the Banking Law and is not projected to impose any costs on regulated persons or the state government.

The amendment to Section 97.5 of the General Regulations of the Banking Board raises a limit on certain investments, in accordance with recent legislation, and therefore is not projected to impose any additional costs on regulated persons or the state government.

New Superintendent's Regulation Part 326 implements a statutory mandate that the Superintendent prescribe a system of maintaining net worth reserves comparable to that promulgated by the National Credit Union Administration. The amendment will conform the state's regulation to that of the federal government and therefore is not projected to impose any costs on regulated persons or the state government.

The repeal of Part 113 of the General Regulations of the Banking Board is not projected to impose any costs on regulated persons or the state government.

New Superintendent's Regulation Part 327 requires a credit union provide prior notice to the Superintendent if it seeks to invest more than 50% of its capital or its insured limit, whichever is greater, in a state or federal corporate credit union located in New York, and requires the Superintendent to ascertain whether such notice is consistent with the declared policies of the Banking Law. Prior to the repeal of Part 113 and the adoption of Part 327, credit unions were prohibited from making investments in excess of the 50% notice threshold. An institution need only give the notice if it chooses to exercise the excess investment authority. The cost to institutions of giving the required notice, for which no particular form is prescribed, and the cost to the Department of reviewing such notices is expected to be minimal and is deemed necessary to ensure that the new investment powers are exercised in a safe and sound manner.

5. Local government mandates:

The proposed rule making will not impose any program, service, duty or responsibility upon any county, city, town, village, school district, fire district or other special district.

6. Paperwork:

The repeal of Section 95.2 of the General Regulations of the Banking Board will not require any new reporting or other paperwork.

The amendment to Section 96.1 of the General Regulations of the Banking Board will reduce reporting burdens on institutions by eliminating the reference to surplus and conforming the definition of net worth to that of the National Credit Union Administration.

The amendment to Section 96.3 of the General Regulations of the Banking Board updating statutory cross-references will not require any new reporting or other paperwork.

The amendment to Section 97.5 of the General Regulations of the Banking Board raising certain investment limits will not require any new reporting or other paperwork.

New Superintendent's Regulation Part 326 will reduce the reporting burden on institutions by requiring credit unions to maintain the same reserve accounts as are required by the federal regulator of credit unions.

The repeal of Part 113 of the General Regulations of the Banking Board will not require any new reporting or other paperwork.

New Superintendent's Regulation Part 327 will require institutions seeking to make certain investments to provide the Department with prior notice. Prior to the repeal of Part 113 and the adoption of Part 327, credit unions were prohibited from making investments in the shares of corporate

credit unions in excess of the 50% notice threshold. An institution need only give the notice if it chooses to exercise the new investment powers. The paperwork burden of giving the notice is expected to be modest, especially as no particular form of notice is prescribed. The Department believes that the notice requirement is necessary to ensure that the new investment powers are exercised in a safe and sound manner.

7. Duplication:

The repeal of Section 95.2 of the General Regulations of the Banking Board will not result in duplication, overlap or conflict with any rules or other legal requirements of the state and federal governments.

The amendment to Section 96.1 of the General Regulations of the Banking Board will reduce duplication, overlap and conflict with the rules of the federal government by conforming the definition of net worth in the Banking Department's regulations to that in the regulations of the National Credit Union Administration.

The amendment to Section 96.3 of the General Regulations of the Banking Board updating certain statutory cross-references will not result in duplication, overlap or conflict with any rules or other legal requirements of the state and federal governments.

The amendment to Section 97.5 of the General Regulations of the Banking Board raising certain investment limits will not result in duplication, overlap or conflict with any rules or other legal requirements of the state or federal governments.

New Superintendent's Regulation Part 326 will reduce duplication, overlap and conflict with the rules of the federal government by requiring credit unions to maintain the same reserve accounts as are required by the National Credit Union Administration.

The repeal of Part 113 of the General Regulations of the Banking Board will not result in duplication, overlap or conflict with any rules or other legal requirements of the state and federal governments.

New Superintendent's Regulation Part 327, requiring institutions seeking to make certain investments to provide the Department with prior notice, will not result in duplication, overlap or conflict with any rules or other legal requirements of the state and federal governments.

8. Alternative approaches:

The repeal of Section 95.2 of the General Regulations of the Banking Board will conform the regulation to new Section 454(9) of the Banking Law. No significant alternatives to the rule were considered.

The amendment to Section 96.1 of the General Regulations of the Banking Board implements the repeal of Section 458 of the Banking Law. No significant alternatives to the rule were considered.

The amendment to Section 96.3 of the General Regulations of the Banking Board updates certain statutory cross-references. No significant alternatives to the rule were considered.

The amendment to Section 97.5 of the General Regulations of the Banking Board will conform the regulation to amended Section 454(19) of the Banking Law. No significant alternatives to the rule were considered.

New Superintendent's Regulation Part 326 implements new Section 458-a of the Banking Law. No significant alternatives to the rule were considered.

The repeal of Part 113 of the General Regulations of the Banking Board conforms the regulations to Section 454(4) and 456(7) of the Banking Law. No significant alternatives to the rule were considered.

New Superintendent's Regulation Part 327 essentially replaces repealed Part 113. Consideration was given to simply repealing Part 113, thus permitting credit unions to invest in the shares of federal or state corporate credit unions without limitation. However, in light of concerns expressed about potential safety and soundness issues if such a course were followed, it was determined to adopt Part 327.

9. Federal standards:

No minimum standards of the federal government for the same or similar subject areas will be exceeded by the repeal of Section 95.2 of the General Regulations of the Banking Board.

The amendment to Section 96.1 of the General Regulations of the Banking Board will conform the definition of "net worth" to the regulations of the National Credit Union Administration.

No minimum standards of the federal government for the same or similar subject areas will be exceeded by the amendment of Section 96.3 of the General Regulations of the Banking Board updating certain statutory cross-references.

No minimum standards of the federal government for the same or similar subject areas will be exceeded by the amendment to Section 97.5 of the General Regulations of the Banking Board. The National Credit Union Administration regulations applicable to federal credit union investments

in credit union service organizations impose more restrictive investment limits.

New Superintendent's Regulation Part 326 requires credit unions to maintain the same reserve accounts as are required by the National Credit Union Administration.

No minimum standards of the federal government for the same or similar subject areas will be exceeded by the repeal of Part 113 of the General Regulations of the Banking Board.

New Superintendent's Regulation Part 327 exceeds minimum standards of the federal government for the same subject area insofar as it imposes a prior notice requirement for certain investments by credit unions whereas no notice or approval requirement for such investments is imposed by federal law or regulations. The Department believes that the prior notice requirement is an appropriate prudential measure.

10. Compliance schedule:

No time will be necessary to enable regulated persons to achieve compliance with the repeal of Section 95.2 of the General Regulations of the Banking Board, which removes a limitation on borrowing by credit unions.

The amendment to Section 96.1 of the General Regulations of the Banking Board adopts the definition of "net worth" used in the regulations of the National Credit Union Administration (NCUA). Since credit unions are federally insured they are already subject to this NCUA regulation and will not require any time to achieve compliance with this amendment.

No time will be necessary to enable regulated persons to achieve compliance with the amendment to Section 96.3 of the General Regulations of the Banking Board, which updates certain statutory cross-references.

No time will be necessary to enable regulated persons to achieve compliance with the amendment to Section 97.5 of the General Regulations of the Banking Board, which increases the existing limits on credit union investments.

New Superintendent's Regulation Part 326 requires credit unions to maintain the reserve accounts required by the regulations of the National Credit Union Administration (NCUA). Since credit unions are federally insured they are already subject to this NCUA regulation and will not require any time to achieve compliance with this amendment.

No time will be necessary to enable regulated persons to achieve compliance with the repeal of Part 113 of the General Regulations of the Banking Board, which removes a limitation on investments by credit unions.

No time will be necessary to enable regulated persons to achieve compliance with new Superintendent's Regulation Part 327, since it requires that credit unions give prior notice of investments which were previously prohibited.

Regulatory Flexibility Analysis

The amendments to Part 95, Part 96 and Part 97, and the repeal of Part 113, will not impose any adverse economic or technological impact upon small business beyond any such effects that may be caused by changes in the Banking Law, to which the amendments conform the regulations. These amendments will not impose any adverse economic or technological impact upon local governments. These amendments will impose no adverse reporting, recordkeeping or compliance requirements on small businesses or local governments.

New Superintendent's Regulation Part 326 implements a new statutory requirement that the Superintendent promulgate regulations prescribing a system of maintaining credit union net worth reserves comparable to that promulgated by the National Credit Union Administration. Credit unions are federally insured and thus already subject to the relevant NCUA regulations. Thus, Part 326 will impose no adverse economic or technological impact upon small business or local governments and will impose no new reporting, recordkeeping or compliance requirements on small businesses or local governments.

New Superintendent's Regulation Part 327 requires a credit union which intends to invest in the shares of a state or federal corporate credit union in an amount that exceeds specified limits to provide prior written notice to the Superintendent. Such investments were previously prohibited. Thus, the new regulation will not impose any adverse economic or technological impact upon small business or local governments. While Part 327 will impose new reporting and compliance requirements upon all credit unions, large or small, seeking to make certain investments, the Department believes that the requirements are modest and constitute appropriate prudential measures. Part 327 does not impose any reporting, recordkeeping or compliance requirements on local governments.

Rural Area Flexibility Analysis

The amendments to Part 95, Part 96 and Part 97, and repeal of Part 113, do not impose any reporting, recordkeeping or other compliance requirements on public or private entities in rural areas.

New Superintendent's Regulation Part 326 implements a new statutory requirement that the Superintendent promulgate regulations prescribing a system of maintaining credit union net worth reserves comparable to that promulgated by the National Credit Union Administration. Credit unions are federally insured and thus already subject to the relevant NCUA regulations. Thus, Part 326 will not have any adverse impact on credit unions located in rural areas.

New Superintendent's Regulation Part 327 requires a credit union which intends to invest in the shares of a state or federal corporate credit union in an amount that exceeds specified limits to provide prior written notice to the Superintendent. Such investments were previously prohibited. While Part 327 will impose new reporting and compliance requirements upon all credit unions, including credit unions located in rural areas, seeking to make certain investments, the Department believes that the requirements are modest and constitute appropriate prudential measures.

Parts 326 and 327 do not impose any reporting, recordkeeping or compliance requirements on public entities in rural areas.

Department of Civil Service

PROPOSED RULE MAKING NO HEARING(S) SCHEDULED

Jurisdictional Classification

I.D. No. CVS-21-04-00001-P

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following proposed rule:

Proposed action: Amendment of Appendix(es) 1 of Title 4 NYCRR.

Statutory authority: Civil Service Law, section 6(1)

Subject: Jurisdictional classification.

Purpose: To classify a position in the exempt class in the Council on the Arts.

Text of proposed rule: Amend Appendix(es) 1 of the Rules for the Classified Service, listing positions in the exempt class, in the Council on the Arts, by adding thereto the position of Confidential Aide.

Text of proposed rule and any required statements and analyses may be obtained from: Shirley LaPlante, Department of Civil Service, State Campus, Albany, NY 12239, (518) 457-6210, e-mail: sjl@cs.state.ny.us

Data, views or arguments may be submitted to: Same as above.

Public comment will be received until: 45 days after publication of this notice.

Regulatory Impact Statement, Regulatory Flexibility Analysis, Rural Area Flexibility Analysis and Job Impact Statement

The proposed rule is subject to consolidated statements and analyses printed in the issue of February 18, 2004 under the notice of proposed rule making I.D. No. CVS-07-04-00005-P.

PROPOSED RULE MAKING NO HEARING(S) SCHEDULED

Jurisdictional Classification

I.D. No. CVS-21-04-00002-P

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following proposed rule:

Proposed action: Amendment of Appendix(es) 1 of Title 4 NYCRR.

Statutory authority: Civil Service Law, section 6(1)

Subject: Jurisdictional classification.

Purpose: To classify a position in the exempt class in the Executive Department.

Text of proposed rule: Amend Appendix(es) 1 of the Rules for the Classified Service, listing positions in the exempt class, in the Executive Department under the subheading "Division of Parole," by increasing the number of positions of Special Assistant from 1 to 2.

Text of proposed rule and any required statements and analyses may be obtained from: Shirley LaPlante, Department of Civil Service, State Campus, Albany, NY 12239, (518) 457-6210, e-mail: sjl@cs.state.ny.us

Data, views or arguments may be submitted to: Same as above.

Public comment will be received until: 45 days after publication of this notice.

Regulatory Impact Statement, Regulatory Flexibility Analysis, Rural Area Flexibility Analysis and Job Impact Statement

The proposed rule is subject to consolidated statements and analyses printed in the issue of February 18, 2004 under the notice of proposed rule making I.D. No. CVS-07-04-00005-P.

PROPOSED RULE MAKING NO HEARING(S) SCHEDULED

Jurisdictional Classification

I.D. No. CVS-21-04-00003-P

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following proposed rule:

Proposed action: Amendment of Appendix(es) 1 of Title 4 NYCRR.

Statutory authority: Civil Service Law, section 6(1)

Subject: Jurisdictional classification.

Purpose: To classify a position in the exempt class in the Banking Department.

Text of proposed rule: Amend Appendix(es) 1 of the Rules for the Classified Service, listing positions in the exempt class, in the Banking Department, by increasing the number of positions of Special Assistant from 3 to 4.

Text of proposed rule and any required statements and analyses may be obtained from: Shirley LaPlante, Department of Civil Service, State Campus, Albany, NY 12239, (518) 457-6210, e-mail: sjl@cs.state.ny.us

Data, views or arguments may be submitted to: Same as above.

Public comment will be received until: 45 days after publication of this notice.

Regulatory Impact Statement, Regulatory Flexibility Analysis, Rural Area Flexibility Analysis and Job Impact Statement

The proposed rule is subject to consolidated statements and analyses printed in the issue of February 18, 2004 under the notice of proposed rule making I.D. No. CVS-07-04-00005-P.

PROPOSED RULE MAKING NO HEARING(S) SCHEDULED

Jurisdictional Classification

I.D. No. CVS-21-04-00004-P

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following proposed rule:

Proposed action: Amendment of Appendix(es) 1 of Title 4 NYCRR.

Statutory authority: Civil Service Law, section 6(1)

Subject: Jurisdictional classification.

Purpose: To classify a position in the exempt class in the Department of Family Assistance.

Text of proposed rule: Amend Appendix(es) 1 of the Rules for the Classified Service, listing positions in the exempt class, in the Department of Family Assistance under the subheading "Office of Children and Family Services," by increasing the number of positions of Special Assistant from 3 to 4.

Text of proposed rule and any required statements and analyses may be obtained from: Shirley LaPlante, Department of Civil Service, State Campus, Albany, NY 12239, (518) 457-6210, e-mail: sjl@cs.state.ny.us

Data, views or arguments may be submitted to: Same as above.

Public comment will be received until: 45 days after publication of this notice.

Regulatory Impact Statement, Regulatory Flexibility Analysis, Rural Area Flexibility Analysis and Job Impact Statement

The proposed rule is subject to consolidated statements and analyses printed in the issue of February 18, 2004 under the notice of proposed rule making I.D. No. CVS-07-04-00005-P.

**PROPOSED RULE MAKING
NO HEARING(S) SCHEDULED**

Jurisdictional Classification

I.D. No. CVS-21-04-00005-P

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following proposed rule:

Proposed action: Amendment of Appendix(es) 1 of Title 4 NYCRR.

Statutory authority: Civil Service Law, section 6(1)

Subject: Jurisdictional classification.

Purpose: To classify a position in the exempt class in the Executive Department.

Text of proposed rule: Amend Appendix(es) 1 of the Rules for the Classified Service, listing positions in the exempt class, in the Executive Department under the subheading "State Consumer Protection Board," by increasing the number of positions of Secretary from 2 to 3.

Text of proposed rule and any required statements and analyses may be obtained from: Shirley LaPlante, Department of Civil Service, State Campus, Albany, NY 12239, (518) 457-6210, e-mail: sjl@cs.state.ny.us

Data, views or arguments may be submitted to: Same as above.

Public comment will be received until: 45 days after publication of this notice.

Regulatory Impact Statement, Regulatory Flexibility Analysis, Rural Area Flexibility Analysis and Job Impact Statement

The proposed rule is subject to consolidated statements and analyses printed in the issue of February 18, 2004 under the notice of proposed rule making I.D. No. CVS-07-04-00005-P.

**PROPOSED RULE MAKING
NO HEARING(S) SCHEDULED**

Jurisdictional Classification

I.D. No. CVS-21-04-00006-P

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following proposed rule:

Proposed action: Amendment of Appendix(es) 1 of Title 4 NYCRR.

Statutory authority: Civil Service Law, section 6(1)

Subject: Jurisdictional classification.

Purpose: To classify a position in the exempt class in the Education Department.

Text of proposed rule: Amend Appendix(es) 1 of the Rules for the Classified Service, listing positions in the exempt class, in the Education Department under the subheading "New York State Higher Education Services Corporation," by increasing the number of positions of Special Assistant from 2 to 3.

Text of proposed rule and any required statements and analyses may be obtained from: Shirley LaPlante, Department of Civil Service, State Campus, Albany, NY 12239, (518) 457-6210, e-mail: sjl@cs.state.ny.us

Data, views or arguments may be submitted to: Same as above.

Public comment will be received until: 45 days after publication of this notice.

Regulatory Impact Statement, Regulatory Flexibility Analysis, Rural Area Flexibility Analysis and Job Impact Statement

The proposed rule is subject to consolidated statements and analyses printed in the issue of February 18, 2004 under the notice of proposed rule making I.D. No. CVS-07-04-00005-P.

**PROPOSED RULE MAKING
NO HEARING(S) SCHEDULED**

Jurisdictional Classification

I.D. No. CVS-21-04-00007-P

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following proposed rule:

Proposed action: Amendment of Appendix(es) 1 of Title 4 NYCRR.

Statutory authority: Civil Service Law, section 6(1)

Subject: Jurisdictional classification.

Purpose: To delete a position from and classify a position in the exempt class in the Department of Mental Hygiene.

Text of proposed rule: Amend Appendix(es) 1 of the Rules for the Classified Service, listing positions in the exempt class, in the Department of Mental Hygiene under the subheading "Office of Alcoholism and Substance Abuse Services," by decreasing the number of positions of Associate Commissioner from 4 to 3 and by adding thereto the position of Deputy Commissioner.

Text of proposed rule and any required statements and analyses may be obtained from: Shirley LaPlante, Department of Civil Service, State Campus, Albany, NY 12239, (518) 457-6210, e-mail: sjl@cs.state.ny.us

Data, views or arguments may be submitted to: Same as above.

Public comment will be received until: 45 days after publication of this notice.

Regulatory Impact Statement, Regulatory Flexibility Analysis, Rural Area Flexibility Analysis and Job Impact Statement

The proposed rule is subject to consolidated statements and analyses printed in the issue of February 18, 2004 under the notice of proposed rule making I.D. No. CVS-07-04-00005-P.

**PROPOSED RULE MAKING
NO HEARING(S) SCHEDULED**

Jurisdictional Classification

I.D. No. CVS-21-04-00008-P

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following proposed rule:

Proposed action: Amendment of Appendix(es) 1 of Title 4 NYCRR.

Statutory authority: Civil Service Law, section 6(1)

Subject: Jurisdictional classification.

Purpose: To delete a position from and classify a position in the exempt class in the Executive Department.

Text of proposed rule: Amend Appendix(es) 1 of the Rules for the Classified Service, listing positions in the exempt class, in the Executive Department under the subheading "Office of General Services," by decreasing the number of positions of Promotion and Public Affairs Agent from 21 to 20 and by increasing the number of positions of Building Superintendent from 11 to 12.

Text of proposed rule and any required statements and analyses may be obtained from: Shirley LaPlante, Department of Civil Service, State Campus, Albany, NY 12239, (518) 457-6210, e-mail: sjl@cs.state.ny.us

Data, views or arguments may be submitted to: Same as above.

Public comment will be received until: 45 days after publication of this notice.

Regulatory Impact Statement, Regulatory Flexibility Analysis, Rural Area Flexibility Analysis and Job Impact Statement

The proposed rule is subject to consolidated statements and analyses printed in the issue of February 18, 2004 under the notice of proposed rule making I.D. No. CVS-07-04-00005-P.

**PROPOSED RULE MAKING
NO HEARING(S) SCHEDULED**

Jurisdictional Classification

I.D. No. CVS-21-04-00009-P

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following proposed rule:

Proposed action: Amendment of Appendix(es) 2 of Title 4 NYCRR.

Statutory authority: Civil Service Law, section 6(1)

Subject: Jurisdictional classification.

Purpose: To classify a position in the non-competitive class in the Banking Department.

Text of proposed rule: Amend Appendix(es) 2 of the Rules for the Classified Service, listing positions in the non-competitive class, in the Banking Department, by adding thereto the position of Administrative Assistant (1).

Text of proposed rule and any required statements and analyses may be obtained from: Shirley LaPlante, Department of Civil Service, State Campus, Albany, NY 12239, (518) 457-6210, e-mail: sjl@cs.state.ny.us

Data, views or arguments may be submitted to: Same as above.

Public comment will be received until: 45 days after publication of this notice.

Regulatory Impact Statement, Regulatory Flexibility Analysis, Rural Area Flexibility Analysis and Job Impact Statement

The proposed rule is subject to consolidated statements and analyses printed in the issue of February 18, 2004 under the notice of proposed rule making I.D. No. CVS-07-04-00005-P.

**PROPOSED RULE MAKING
NO HEARING(S) SCHEDULED**

Jurisdictional Classification

I.D. No. CVS-21-04-00010-P

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following proposed rule:

Proposed action: Amendment of Appendix(es) 2 of Title 4 NYCRR.

Statutory authority: Civil Service Law, section 6(1)

Subject: Jurisdictional classification.

Purpose: To classify a position in the non-competitive class in the Department of Civil Service.

Text of proposed rule: Amend Appendix(es) 2 of the Rules for the Classified Service, listing positions in the noncompetitive class, in the Department of Civil Service, by adding thereto the position of Community Outreach Specialist 2 (1).

Text of proposed rule and any required statements and analyses may be obtained from: Shirley LaPlante, Department of Civil Service, State Campus, Albany, NY 12239, (518) 457-6210, e-mail: sjl@cs.state.ny.us

Data, views or arguments may be submitted to: Same as above.

Public comment will be received until: 45 days after publication of this notice.

Regulatory Impact Statement, Regulatory Flexibility Analysis, Rural Area Flexibility Analysis and Job Impact Statement

The proposed rule is subject to consolidated statements and analyses printed in the issue of February 18, 2004 under the notice of proposed rule making I.D. No. CVS-07-04-00005-P.

Department of Health

**EMERGENCY
RULE MAKING**

Treatment of Opiate Addiction

I.D. No. HLT-37-03-00001-E

Filing No. 542

Filing date: May 5, 2004

Effective date: May 5, 2004

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following action:

Action taken: Addition of section 80.84 and amendment of section 80.86 of Title 10 NYCRR.

Statutory authority: Public Health Law, sections 3308(2), 3351 and 3352

Finding of necessity for emergency rule: Preservation of public health.

Specific reasons underlying the finding of necessity: We are proposing that these regulations be adopted on an emergency basis because immediate adoption of the regulations is necessary to protect the public health and safety. The regulations are based on the federal Drug Addiction Treatment Act of 2000 (DATA), which dramatically expands opioid dependent patients' access to treatment of addiction. The provisions in the DATA become effective immediately upon the FDA approval of a Schedule III-V controlled substance for the treatment of opiate addiction. A product containing buprenorphine has received FDA approval for such use and is the first such product to receive FDA approval for this indication.

Pre-existing Public Health Law requires the Commissioner to specifically designate in regulation any controlled substance approved for the treatment of opiate addiction.

The proposed amendments to Part 80 specifically state that buprenorphine may be utilized for the treatment of opiate addiction. Due to its

significant potential for abuse and diversion, it is important that the department monitor the prescribing, administering and dispensing of buprenorphine by pharmacies and physicians. Such monitoring can be accomplished by the registration of physicians and pharmacies and by requiring dispensers to transmit such prescription data to the department.

These regulations are necessary to protect the public from the significant abuse potential of buprenorphine, while still allowing access to legitimate treatment. Greater access to addiction treatment will promote health for the opiate dependent patient, and protect society at large by reducing the violence associated with drug crimes. Public health will be protected by allowing opiate dependent patients a legal means of maintaining their disease, as an alternative to seeking drugs from illegal sources.

Subject: Treatment of opiate addiction.

Purpose: To allow the treatment of opiate addiction in an office-based setting while curtailing controlled substance diversion.

Text of emergency rule: Section 80.84 is added to read as follows:

80.84 Physicians and pharmacies; prescribing, administering and dispensing for the treatment of narcotic addiction.

Pursuant to the provisions of the federal Drug Addiction Treatment Act of 2000 (106 P.L. 310, Div. B, Title XXXV, Section 3502(a)), an authorized physician may prescribe, administer or dispense an approved controlled substance, and a licensed registered pharmacist may dispense an approved controlled substance, to a patient participating in an authorized controlled substance maintenance program approved pursuant to Article 32 of the Mental Hygiene Law for the treatment of narcotic addiction.

(a) An approved controlled substance shall mean the following controlled substance which has been approved by the Food and Drug Administration (FDA) and the New York State Department of Health for the treatment of narcotic addiction:

(1) buprenorphine

(b) An authorized physician is a physician registered with the department to prescribe, administer or dispense an approved controlled substance for the treatment of narcotic addiction pursuant to this section and specifically registered with the Drug Enforcement Administration to prescribe, administer or dispense an approved controlled substance for the treatment of narcotic addiction, and approved for such purpose pursuant to the provisions of Article 32 of the Mental Hygiene Law.

(1) The total number of such patients of an authorized physician or group practice at any one time shall not exceed 30.

(2) A physician must register with the department every two years to provide such treatment. Such registration will be provided at no cost.

(3) An authorized physician prescribing an approved controlled substance for the treatment of narcotic addiction, in addition to preparing and signing a prescription in accordance with Section 3335 of the Public Health Law, shall also write his/her unique DEA identification number on the prescription.

(c) An authorized pharmacy is a pharmacy registered with the department to dispense an approved controlled substance for the treatment of narcotic addiction.

(1) A pharmacy must register with the department every two years to provide such treatment. Such registration will be provided at no cost.

(2) A pharmacist may dispense an approved controlled substance for the treatment of narcotic addiction pursuant to a prescription issued by an authorized physician. Such dispensing shall be in accordance with Section 3336 of the Public Health Law.

(3) A pharmacist dispensing such a prescription shall file the prescription information with the department either electronically in accordance with Section 80.73 (c)(2) of this Part, or manually on an approved departmental form. The pharmacist shall report the practitioner's narcotic addiction treatment registration number in lieu of the practitioner's Drug Enforcement Administration registration number.

(d) Each incident or alleged incident involving the theft, loss or possible diversion of controlled substances shall also be reported to the department immediately.

Section 80.86 is amended to read as follows:

80.86 Records and reports of treatment programs. (a) All persons approved pursuant to article [23] 32 of the Mental Hygiene Law to operate a [substance abuse] chemical dependence program, other than authorized physicians and pharmacists as defined in Section 80.84 of this Part who are registered with the department to prescribe, administer or dispense approved controlled substances for the treatment of narcotic addiction, and who possess a Federal registration by the Drug Enforcement Administration, United States Department of Justice to purchase, possess and use controlled substances shall keep the following records:

(1) records of controlled substances received by approved persons including date of receipt, name and address of distributor, type and quantity of such drugs received and the signature of the individual receiving the controlled substance. A duplicate invoice or separate itemized list furnished by the distributor will be sufficient to satisfy this record requirement provided it includes all required information and is maintained in a separate file. In addition, duplicate copies of Federal order forms for schedule II controlled substances must be retained; and

(2) records of controlled substances administered or dispensed including date of administration or dispensing, name of patient, signature of person administering or dispensing, type and quantity of drug and such other information as may be required by this Part.

(b) By the 10th day of each month, a person *other than an authorized physician as defined in Section 80.84(b) of this Part*, approved to conduct a maintenance program pursuant to article [23] 32 of the Mental Hygiene Law, shall file with the department a report summarizing its controlled substances activity in the preceding month. Such a report shall be on forms provided by the department and shall include:

(1) an inventory of the quantity of controlled substances on hand at the commencement and at the conclusion of such month's activity;

(2) the date of the inventory;

(3) the signature of the persons performing the inventory;

(4) the total quantity of controlled substances received, the distributor from whom each order was received, and the form and dosage unit in which such substance was received;

(5) a separate listing of the total quantity of controlled substances prescribed, dispensed and administered during such month;

(6) total quantity of methadone surrendered to the department for destruction;

(7) total number of patients treated during the month; and

(8) each incident or alleged incident involving the theft, loss or possible diversion of controlled substances.

(c) Each incident or alleged incident involving the theft, loss or possible diversion of controlled substances shall also be reported to the department immediately.

This notice is intended to serve only as a notice of emergency adoption. This agency intends to adopt the provisions of this emergency rule as a permanent rule, having previously published a notice of proposed rule making, I.D. No. HLT-37-03-00001-P, Issue of September 17, 2003. The emergency rule will expire July 3, 2004.

Text of emergency rule and any required statements and analyses may be obtained from: William Johnson, Department of Health, Division of Legal Affairs, Office of Regulatory Reform, Corning Tower, Rm. 2415, Empire State Plaza, Albany, NY 12237, (518) 473-7488, fax: (518) 486-4834, e-mail: regsqa@health.state.ny.us

Regulatory Impact Statement

Statutory Authority:

United States Public Law 106-310, the Children's Health Act of 2000 was enacted on October 17, 2000. Title XXXV of this law, Waiver Authority for Physicians Who Dispense or Prescribe Certain Narcotic Drugs for Maintenance Treatment or Detoxification Treatment, is better known by the short title Drug Addiction Treatment Act of 2000 (DATA).

DATA allows physicians to prescribe and dispense narcotics in Schedules III, IV, and V of the Controlled Substances Act (CSA) that have been specifically approved by the Food and Drug Administration (FDA) for the purpose of maintenance or detoxification of opiate addiction.

The drug buprenorphine was just approved by FDA for this purpose. The federal law supercedes any existing state law that prohibits such treatment.

New York State Public Health Law, Article 33, Section 3308 states that the Commissioner is authorized and empowered to make any regulations necessary to supplement the purpose of Article 33. Section 3351 states that the Commissioner shall designate in regulation the name of all controlled substances appropriate for use in the treatment of opiate addiction. Section 3352 states that persons certified to operate treatment programs should follow certain recordkeeping requirements, as the Commissioner shall require by regulation.

Legislative Objectives:

Article 33 of the Public Health Law, officially known as the New York State Controlled Substances Act, was enacted to govern and control the possession, prescribing, manufacturing, dispensing, administering, and distribution of licit controlled substances within New York State. In the year 2000 a legislative purpose was added to the law to clarify that its purpose is to allow for the legitimate use of controlled substances, while curtailing their illicit use.

Needs and Benefits:

Prior to the adoption of DATA, the treatment of opiate addiction was limited to authorized methadone clinics and licensed substance abuse programs. According to the National Institute of Drug Abuse (NIDA), the regulatory burden involved in delivering methadone to opioid-dependent individuals has been so heavy that it has prevented expansion of the system.

The result has been a "treatment gap," which NIDA defines as the difference between the total number of opioid-dependent persons and those in treatment. In an effort to close the treatment gap, NIDA explored other strategies and studied the use of other drugs to treat opioid addiction. Restrictions were intended to decrease abuse and diversion while permitting legitimate treatment. However a treatment gap continues to exist.

There are approximately 125 MMTPs in New York State with a license capacity to treat 46,000, or 23%, of the estimated 200,000 opiate dependent patients in New York State. Also, over three-quarters of the MMTPs are located in the New York City area, therefore addicts living in rural areas may not have access to an MMTP. It is also believed that many middle and upper class addicts do not seek enrollment in MMTPs due to the stigma associated with MMTPs.

The DATA expands availability of treatment of opiate dependent patients allowing physicians to prescribe narcotic drugs for opiate addiction, requiring only self-certification, and moves the treatment of addiction from the clinic to the private physician's office and the patient's own pharmacy. The law allows qualified physicians to prescribe and dispense Schedule III, IV, and V narcotics that have been approved by FDA for use in maintenance or detoxification treatment. Currently the only such drug approved for such use is buprenorphine.

Buprenorphine is a partial opioid agonist with a significant potential for abuse. To meet the legislative purpose of Article 33 and the intent of the DATA, additional regulations are necessary to ensure buprenorphine is not diverted into illegal channels, while ensuring access to care.

These regulations require that the physician register with the Department of Health, as well as the Office of Alcohol and Substance Abuse Services (OASAS), to provide such treatment. This will ensure that the physician possesses the addiction treatment qualifications required by DATA and is in good standing with respect to adherence to controlled substance laws. Pharmacies that wish to dispense buprenorphine will also be required to register with the department. Registered pharmacies will be required to file buprenorphine prescription data with the department in the same manner they currently follow for Schedule II controlled substances and benzodiazepines. The department will have the capability of monitoring the utilization of buprenorphine by the analysis of this data in the same manner currently utilized for controlled substances with significant abuse potential.

DOH/OASAS Task Force:

In the fall of 2000, the Department of Health (DOH) partnered with the Office of Alcoholism and Substance Abuse Services (OASAS) to begin planning for the implementation of DATA. The agencies established a joint task force charged with establishing complementary regulations, as well as a joint application process by which New York State physicians could register to provide this new treatment modality.

The task force met routinely for over two years. The result was a streamlined application process by which physicians could register with New York State to provide such treatment, as well as streamlined regulations.

The agencies sent a joint mailing to physicians detailing the regulatory requirements and registration process. The agencies established a joint registration application by which qualified physicians simply complete the joint application and send it to OASAS. Once OASAS reviews and approves the application, the approved application is sent to DOH for their approval. Due to the joint application process, the agencies work closely together through the registration process.

Both agencies also adopted emergency regulations in the fall of 2002. The task force ensured the adoption of emergency regulations that meet the needs and responsibilities of both agencies, while ensuring accessibility of this new treatment to the citizens of New York State.

Outreach:

DOH met with the pharmaceutical Society of the State of New York (PSSNY), as well as the Medical Society of the State of New York (MSSNY), during the drafting of this regulation. PSSNY did not have present any concerns with the regulations. MSSNY was opposed to the concept of a patient registry. The original regulations contained a requirement for physicians to maintain a registry of the patients whom they were treating, and to share such registry with the DOH. MSSNY stated that the

registry requirement might deter patients from seeking such treatment. Due to such concerns, DOH decided to remove the patient registry requirement from the regulations.

Costs:

This proposal does not pose any cost to the physician, pharmacy, or the department. The registration of physicians and pharmacies will be provided free of charge. 93% of all pharmacies in the state are already set up to transmit data to the department electronically in the required format, therefore only minimal software modification will be necessary. The remaining 7% submit the data manually on a departmental form.

Local Government Mandates:

The proposed rule does not impose any new programs, services, duties or responsibilities upon any county, city, town, village, school district, fire district or other specific district.

Paperwork:

The Department of Health anticipates a simple registration form for physicians and pharmacies that wish to register for this program. Participation in this program is entirely voluntary. The Department of Health has partnered with OASAS to streamline the registration process for physicians.

Ninety-three percent of all New York State pharmacies currently have the capacity to send the department prescription data electronically. The department can't predict how many pharmacies will participate in this program. Approximately 60% of the pharmacies in the State have registered thus far to participate in the Expanded Syringe Access Program (ESAP), and it is anticipated that participation in this new incentive will be similar. Those choosing manual submission may simply complete a manual submission form in the same manner they currently utilize for Schedule II controlled substances and benzodiazepines.

Physicians who prescribe buprenorphine will be required to keep the same records they currently maintain for all controlled substances. Physicians choosing to dispense buprenorphine will be required to submit a manual submission form or submit the data electronically, in the same manner as required for pharmacies.

Methadone clinics are currently required to submit dispensing reports to the department; therefore the collection of dispensing data for drugs that treat addiction is not a new concept.

Duplication:

The requirements of this proposed regulation do not duplicate any other state or federal requirement.

Alternatives:

The proposed regulation is designed to curtail the potential diversion and abuse of buprenorphine in this new treatment modality. Buprenorphine is a narcotic with significant abuse potential and will be utilized in a population of patients who have a prior history of controlled substance abuse. The federal law sets basic parameters for such treatment but leaves specific oversight up to the individual states. The department believes it is in the best interest of public health to monitor the prescribing and dispensing of this drug for this new treatment modality.

There are no alternatives that would ensure accessibility to treatment while curtailing the potential for abuse and diversion.

Federal Standards:

The regulatory amendment does not exceed any minimum standards of the federal government. This amendment does not prohibit the provisions of the federal DATA, it simply achieves consistency with existing New York State standards aimed at curtailing the diversion of medication with a high potential for diversion.

Compliance Schedule:

Physicians and pharmacies may begin to register with the department immediately. Once a physician has registered with the department for this program, and has received his/her unique identification registration number from the Drug Enforcement Administration (DEA), he/she may begin to prescribe and/or dispense buprenorphine for the treatment of opiate addiction. Once a pharmacy has registered with the department for this program, they may begin to dispense buprenorphine for this treatment.

Regulatory Flexibility Analysis

Effect of Rule:

Physician and pharmacy participation in this program is voluntary. There are currently 72,920 physicians licensed to practice medicine in New York State. According to the New York State Board of Pharmacy, as of September 2002, there were a total of 4,434 pharmacies in New York State. Of these, 62 were sole proprietorship, 274 were partnerships, 72 are small chains (fewer than 3 pharmacies per chain) and the rest were large chains or other corporations (some of which may be small businesses) or located in public institutions.

Compliance Requirements:

Pharmacies that choose to register for this program will be required to submit the buprenorphine prescription information in the same manner that they currently utilize for CII and benzodiazepine prescriptions; either electronically or manually. Physicians who choose to dispense will also be required to submit buprenorphine prescription information either electronically or manually, in the same format they currently utilize when dispensing CII and benzodiazepines. The recordkeeping requirements for physicians and pharmacies will be consistent with existing requirements.

Professional Services:

Registered pharmacies that choose to submit the required prescription data electronically may need to make a minor change to their current software. Because almost all New York State pharmacies already have a program in place to submit this data, the department does not anticipate that they will be charged for adding buprenorphine data to the current data they submit to the department. The department does not expect a large number of physicians to dispense buprenorphine. Of those that do, the department does not expect them to submit the required data electronically; therefore there no professional services will be required.

Compliance Costs:

The department anticipates that there will be no compliance costs associated with this regulation.

Economic and Technological Feasibility:

The proposed rule is both economically and technologically feasible. Small businesses may choose not to submit electronically, in which case no new, or additional, equipment would be required. Those businesses that do opt to submit data electronically will require only a standard personal computer and software already utilized by the pharmacy community.

Minimizing Adverse Impact:

The proposed rule was designed to minimize the impact on small businesses by allowing the dispenser to have the choice of submitting specified data electronically or manually. The rule does not require non-computerized pharmacies or physicians to become computerized. The department has worked with the pharmacy societies and software vendors to adopt transmission standards already utilized by the pharmacy community. Also, at the request of the pharmacy societies, the department is allowing dispensers to submit electronic information in batch format, as opposed to a more costly point-of-sale transmission.

Small Business and Local Government Participation:

To ensure that small businesses were given the opportunity to participate in this rule making, the department met with the pharmacy societies representing independent pharmacies. Local governments are not affected.

Rural Area Flexibility Analysis

Finding:

Pursuant to 202-bb of the State Administrative Procedure Act, a Rural Area Flexibility Analysis is not required.

The proposed amendment does not impose any adverse impact on rural areas. The proposed amendment makes the treatment of addiction in rural settings more feasible, as addicts will no longer have to travel to a methadone clinic to obtain their medication. Many rural areas do not have a methadone clinic in close proximity.

Measures Taken to A Certain Finding:

Approximately 93% of the pharmacies in the State currently transmit controlled substance prescription data to the department in the format allowed by this proposal. The remaining 7%, many of which may be in rural areas, do not use computers and will not be forced to computerize. They, as well as physicians, will be allowed to transmit their data manually on a departmental form.

Job Impact Statement

Nature of Impact:

This proposal will not have a negative impact on jobs and employment opportunities. This proposal expands the treatment options for physicians and pharmacies and is not expected to have impact on increasing or decreasing jobs overall.

Categories and Numbers Affected:

This rule affects the 4,423 pharmacies in New York State. Approximately 93% of the pharmacies are currently submitting controlled substance prescription data to the department electronically.

It is anticipated that a small percentage of the 72,920 physicians in the State will register to participate in this program. Of that number, it is expected that most of the physicians will only perform the prescribing of buprenorphine. It is expected that a very small percentage of physicians will actually dispense buprenorphine. Most patients will be receiving their buprenorphine from a registered pharmacy.

Regions of Adverse Impact:

There are no regions of the State where this rule would have a disproportionate adverse impact on jobs or employment opportunities.

Minimizing Adverse Impact:

There are no unnecessary adverse impacts on existing jobs pursuant to this rule; therefore no measures to minimize such impacts were necessary. Promotions of the development of new employment opportunities are not affected by this rule.

Self-Employment Opportunities:

This proposal does not have any measurable impact on opportunities for self-employment.

Assessment of Public Comment

The agency received no public comment since publication of the last assessment of public comment.

EMERGENCY RULE MAKING

Expedited HIV Testing of Women and Newborns

I.D. No. HLT-12-04-00012-E

Filing No. 549

Filing date: May 11, 2004

Effective date: May 11, 2004

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following action:

Action taken: Amendment of section 69-1.3(1)(2) of Title 10 NYCRR.

Statutory authority: Public Health Law, sections 576, 2500-a and 2500-f

Finding of necessity for emergency rule: Preservation of public health and general welfare.

Specific reasons underlying the finding of necessity: Immediate adoption of this amendment is necessary to protect the public health and welfare and to prevent harm to infants born in New York State. The New York State Department of Health is actively engaged in the prevention of mother-to-child HIV transmission. Recent advances in medical knowledge concerning the prevention of perinatal HIV transmission have demonstrated that antiretroviral therapy, given to prevent HIV transmission, is most efficacious when given prenatally, during labor, or within the first 12 hours of an infants birth. Although approximately 94 percent of women are tested for HIV during prenatal care, the HIV status of six percent is unknown at presentation for delivery. Women at high risk for HIV who have received no prenatal care are over-represented within this group. In 1999, the Department implemented expedited HIV testing in the labor and delivery setting so that providers can initiate partial antiretroviral regimens either to the mother in labor or to the infant immediately after birth. The turn-around-time for reporting the result was 48 hours from the drawing of blood from the mother (with her consent) or from the newborn (no consent required).

Heretofore, the program has been limited by the lack of a point-of-care rapid HIV test. In cases of HIV-exposure in a newborn where prenatal and/or intrapartum antiretroviral therapy (ART) were not given, studies have shown that therapy must be started for the newborn within 12 hours of birth to be effective in reducing the risk of transmission. The expedited HIV testing protocols in most New York State birth facilities did not meet this 12-hour timeline for initiating prophylactic newborn ART. In 2001 to 2002, over 1400 HIV-infected women gave birth in New York State. Of these, one hundred mother/infant pairs were first identified as HIV-infected/exposed through expedited HIV testing in the labor, delivery or in the immediate newborn period. In the vast majority of cases (98 of 100), the median time from the mothers admission to the collection of the specimen for expedited HIV testing was 2.5 hours. However, even when testing was performed on-site, results were not returned for at least 20 hours, and treatment was not initiated in the newborn until 22.5 hours after birth. Clearly, achieving timelier reporting of expedited HIV test results is hampered by the lack of a point-of-care rapid test.

In November 2002, the U.S. Food and Drug Administration approved the first of a new generation of point-of-care rapid HIV tests. The test is waived under the Clinical Laboratories Improvement Act (CLIA) and may be performed under the supervision of a licensed physician, nurse practitioner or physician assistant, provided the facility performing the test has obtained a CLIA number and is registered with the Clinical Laboratories Evaluation Program (CLEP).

The availability of point-of-care HIV testing offers providers the opportunity to intervene during this most critical time frame for perinatal HIV transmission: labor and delivery. The purpose of this emergency and proposed rule making, which amends 10 NYCRR, Subpart 69-1.3(1)(2), is

to ensure that the HIV exposure status is available as soon as possible for all newborns whose mothers have not been tested for HIV during the current pregnancy or for whom HIV test results are not available at delivery. By requiring a maximum turn-around-time of twelve hours from the time the mother consents to testing or from the time of the infants birth to the receipt of the result of the expedited HIV test, medical providers and patients will have information that is critical for the administration of antiretroviral medication during labor and delivery and to the newborn immediately after birth.

As a result of the Expedited HIV Testing regulations (effective August 1999) and the consequent increase of prenatal and expedited HIV testing, along with the prompt initiation of treatment to HIV-infected mothers, the rates of perinatal HIV transmission in New York State have decreased: from 10.9% in 1997 to 3.9% in 2001. New, rapid, point-of-care HIV testing technology can provide test results within 20 to 40 minutes. In most cases, this technology will allow obstetricians to have preliminary HIV test results before the mother delivers, when the initiation of antiretroviral therapy can be of significant benefit. In light of the advances in testing technology, the Department is proposing a regulatory change to 10NYCRR 69-1.3(1)(2) that would apply in cases where a woman presents for delivery with no documentation of her HIV status. In these cases, the amended regulation would require the birth facility to arrange an immediate HIV screening test of the mother with her consent or of her newborn without consent with results available as soon as possible, but in no event longer than 12 hours after the mother provides consent for testing or, if she does not consent, 12 hours after the time of the infants birth. Reducing the turn-around-time for expedited HIV testing allows health care providers to provide antiretroviral therapy in time to reduce the risk of mother-to-child transmission of HIV.

The emergency rule will take effect upon filing with the Secretary of State.

Subject: Expedited HIV testing for women and newborns.

Purpose: To amend the current comprehensive program in response to recent advances in medical knowledge and the rapid HIV testing technology to enhance protection of newborns.

Text of emergency rule: Paragraph (2) of Subdivision (1) of Section 69-1.3 of NYCRR is amended to read as follows:

(2) if no HIV test result obtained during the current pregnancy is available for the mother not known to be HIV-infected, arrange an immediate screening test of the mother with her consent or of her newborn for HIV antibody with results available as soon as practicable, but in no event longer than [48 hours] 12 hours after the mother provides consent for testing or, if she does not consent, 12 hours after the time of the infants birth.

This notice is intended to serve only as a notice of emergency adoption. This agency intends to adopt the provisions of this emergency rule as a permanent rule, having previously published a notice of proposed rule making, I.D. No. HLT-12-04-00012-P, Issue of March 24, 2004. The emergency rule will expire July 9, 2004.

Text of emergency rule and any required statements and analyses may be obtained from: William Johnson, Department of Health, Division of Legal Affairs, Office of Regulatory Reform, Corning Tower, Rm. 2415, Empire State Plaza, Albany, NY 12237, (518) 473-7488, fax: (518) 486-4834, e-mail: regsqna@health.state.ny.us

Regulatory Impact Statement

Statutory Authority:

Public Health Law (PHL) section 2500-f requires the commissioner to promulgate regulations to implement a comprehensive program for the testing of newborns for HIV and/or the presence of HIV antibodies. The proposed revision to the regulation amends the current comprehensive program in response to recent advances in medical knowledge concerning the prevention of perinatal HIV transmission and the availability of rapid HIV testing technology, with at least one device suitable for "point-of-care" use.

Legislative Objectives:

In the memorandum accompanying the comprehensive newborn testing bill (Chapter 220 of the Laws of 1996), the legislature indicated its purpose was "to ensure that newborns who are born exposed to HIV receive prompt and immediate care and treatment and counseling that can enhance, prolong and possibly save their lives". Transmission of HIV from mother to newborn can be prevented in many cases by the administration of antiretroviral medications, which are recommended to be given to the mother starting during the second trimester of pregnancy, continued during labor, and given to the newborn after birth. The proposed amendment to 10 NYCRR, Subpart 69-1.3(2) will ensure that the HIV exposure status is

available for all newborns whose mothers have not been tested for HIV during the current pregnancy or for whom HIV test results are not available at delivery. By requiring that HIV test results be available as soon as is practicable but in no case later than twelve hours from the time of the mothers consent to testing or the time of the infants birth, the Department intends to ensure that medical providers and patients have the information they need to make decisions about preventive treatment in a timely manner.

Needs and Benefits:

Improvements in medical knowledge and major advances in medical technology have occurred since the current program for the Expedited HIV Testing of Women and Newborns was implemented in August 1999. To date, the success of New York States efforts to reduce perinatal HIV transmission to the lowest possible level has resulted in a decrease in the rate of perinatal HIV transmission for all HIV-exposed infants born in New York from 10.9% in 1997 to 3.9% in 2001. However, transmission is still occurring in instances where the HIV exposure status of an infant was identified too late to provide effective intervention. In such infants therapy must begin within 12 hours of birth to be effective in reducing the risk of transmission. In an addendum to the NYSDOH PCR study, published in the New England Journal of Medicine on 4/1/99, it was demonstrated that when ARV was given to the newborn within 12 hours of birth there was a 5.9% rate of HIV transmission. There was no significant benefit if ARV was begun after 12 hours birth as the transmission rate increased to 25%. The ability to have results from expedited HIV testing as soon as possible in cases where there was no history of prenatal HIV testing, coupled with the administration of prophylactic antiretroviral therapy, ideally during labor but no later than 12 hours of birth, is of vital importance in further reducing perinatal HIV transmission. To reduce perinatal HIV transmission to the greatest extent possible, facilities are urged not to view the 12-hour turn-around-time as the goal of testing, but as the outside limit for offering effective therapeutic interventions to prevent transmission of HIV from the mother to her newborn.

Costs:

Costs to State and Local Governments:

The cost to State Government is minimal and can be covered by existing programs and staff. There is no cost to local government except to the extent they own and operate maternity hospitals. Any cost to the State and local governments will be reduced by the savings to the Medicaid program by reducing the costs of care as fewer incidences of HIV transmission to newborns occur. Local governments that operate medical facilities will incur costs as described in the section on Costs to Regulated Parties noted below.

Costs to Regulated Parties:

The approved rapid test is CLIA- waived due to low complexity and may be performed either in the centralized laboratory or at the point-of-care, subject to appropriate NYSDOH approvals. The Department will work closely with facilities to assist them in meeting the turn-around-time requirements of this proposal.

The vast majority (141) of the 159 birthing facilities currently hold a clinical laboratory permit in HIV testing or are eligible for fast-track approval for a permit in HIV testing. These facilities already have or could readily develop the capability of generating HIV test results on-site within twelve hours without additional costs. This is especially true for facilities with around-the-clock centralized laboratory services. Reagent, equipment, personnel and overhead costs for testing a single specimen using an instrument-based method (i.e., EIA) are approximately \$15 for routine testing, but up to ten times that amount for 'on demand' (STAT) testing. Birth facilities would incur costs directly related to this proposal whenever expedited testing needed to be performed in the laboratory outside normal testing hours, and qualified staff needed to be called in specifically to run one test. Facilities using such an on-call staffing approach to expedited newborn HIV testing would incur up to 1.5 times the usual hourly wage for a medical technologist, which is estimated to be \$40 per hour (including benefits) or \$50 per hour (including benefits) if the technologist is a supervisor.

The Department will work closely with facilities that do not have current capacity to consistently generate results in 12 hours or less, and assist them in meeting regulatory requirements. Costs of introducing in-house HIV testing include costs of reagents, devices and human resources necessary to validate the test method and write protocols, at an estimated maximum one-time cost of \$1000. Facilities that conduct testing at point of care, i.e., in the labor and delivery department, would also incur minimal costs associated with initial training and ongoing competency assessment of non-laboratory testing personnel, i.e., labor and delivery nursing staff,

although technologists may also travel to patient floors to lend their expertise in the performance of tests and interpretation of results. The cost of conducting initial training for a group of 8 or fewer nurses can be estimated by multiplying the hourly wage of a supervisor-qualified technologist by 8 hours of training in device use, troubleshooting, recordkeeping and quality assurance activities, and adding the cost of 25 test devices. The device designated for point-of-care testing has a list price of \$10.00 - \$15.00 for each test kit.

Overall, the Department estimates that the costs of performing tests at the point-of-care are likely to be less than, or equal to, the costs of expedited HIV tests currently performed in a centralized laboratory. This estimate is based on the fact that rapid HIV tests do not require the purchase or maintenance of expensive laboratory equipment and that the cost of testing devices (OraQuick®, SUDS®) and the salaries of personnel conducting the tests are comparable. The cost of expedited HIV testing done in a reference laboratory (cost at one commercial laboratory is \$75.00/ expedited test) may not change, but birth facilities using these laboratories will have to ensure that they will be able to report results within the 12-hour turn-around-time. The cost to the birth facility in time spent to provide pre-test HIV counseling is not expected to differ from the current cost of expedited HIV testing, which includes reimbursement rates of \$52 for testing and \$44 for counseling (\$96.00/expedited test).

In light of the advances in testing technology, and the benefits of early initiation of antiretroviral therapy to prevent mother-to-child transmission of HIV, many birth facilities will opt to use a rapid HIV test device that generates results in a half-hour or less. Facilities may perform rapid HIV testing either in the laboratory itself or at the point-of-care subject to appropriate NYSDOH approval. Laboratories with an HIV testing permit may choose to conduct "stat" testing 24 hours a day, 7 days a week using a standard instrument-based (e.g., EIA) testing technology within the 12 hour time limit. However, testing using rapid testing devices is encouraged to obtain HIV tests results as soon as possible. While procedures such as immediate transport of specimens by courier to a near-by laboratory, may, in theory, be effective for meeting a 12-hour turn-around-time, the Departments experience with such complex arrangements shows them to usually be an unacceptable alternative for on-site expedited testing.

Of the 159 regulated hospitals and birthing centers affected by this amendment, 141 hold laboratory permits that include HIV and/or diagnostic immunology testing, the latter of which would be allowed, in response to the adoption of this amendment, to add HIV testing through a fast-track mechanism. For any of these 141 facilities that choose to add a new test to an existing HIV or fast-tracked diagnostic immunology permit, costs for protocol development, staff training, test validation and implementation of quality assurance measures are expected to be approximately \$1000. There are no additional costs associated with modifying an existing permit to add a category or test. The remaining 18 birth facilities would incur an additional cost if they seek to provide HIV testing on-site, including an initial cost of \$1000 plus annual fees based on gross annual receipts.

Facilities offering on-site testing at the point-of-care, i.e., in the labor and delivery suite under the auspices of an existing permitted laboratory, would incur minimal costs for initial training and ongoing competency assessment of non-laboratory testing personnel, i.e., labor and delivery nurses. The cost of conducting initial training for a group of 8 or fewer nurses can be estimated by multiplying the hourly wage of a supervisor-qualified technologist by 8 hours of training (on average approximately \$50.00/hour by 8 hours equating to \$400.00) in device use, troubleshooting, recordkeeping and quality assurance activities, and adding the cost of 25 test devices (\$15 per test by 25=\$375). Therefore, the total training costs would be approximately \$775. Cost attributable to periodic competency assessments of one to two hours could be calculated using the same formula. A materials cost of approximately \$10.00 - \$15.00 a test would be attributable to one single-use device and control materials.

Costs would be offset by revenue generated from third party billing, including Medicaid. Costs of expedited HIV testing in labor, delivery and newborn nursery settings will continue to diminish as efforts to increase prenatal HIV counseling and testing succeed. Any other provider costs associated with rapid HIV testing in the labor and delivery settings are medically appropriate and must continue to be considered part of labor and delivery costs.

Costs to the Department of Health:

The Department will use existing staff to review and approve HIV testing applications, and to conduct on-site surveys of applicant facilities.

Local Government Mandates:

This amendment to the current regulation will not impose any new program services, duties or responsibilities upon any county, city, town,

village, school district, fire district or any other special district, except for those local governments operating hospitals with maternity services.

Paperwork:

Paperwork related to point-of-care rapid HIV tests does not significantly differ from that currently required by expedited testing regulations. This paperwork includes the clinicians written order for testing, notation of the completion of pre- and post-test counseling, documentation of the acquisition of the test specimen and recording the test result in the medical record. Some paperwork will be required of birth facilities that seek an addition to an existing permit, and for those that choose to seek a new HIV testing permit.

Duplication:

None.

Alternatives:

There are no alternatives to the 12-hour time limit proposed by this amendment because a longer time period would result in some HIV-exposed infants not being detected in time to administer therapy to prevent HIV transmission. Because advances in scientific knowledge and medical technology allow for rapid HIV testing, the Department determined that the proposed revision to the regulation is the best approach to protect the public health.

Federal Standards:

There are currently no Federal regulations related to prenatal or newborn testing. The Federal government has provided only recommendations and guidelines for these activities. The proposed regulatory change is consistent with current federal recommendations.

Compliance Schedule:

The Department has already advised regulated parties that this emergency amendment is in place. The Department understands that many facilities previously initiated activities to implement rapid HIV testing. The Department understands that facilities have been in compliance since the first emergency regulations November 2003 effective date.

Regulatory Flexibility Analysis

Effect on Small Businesses:

The proposed rule will impact an estimated three birth hospitals and four birthing centers that meet the definition of a small business (independently owned and employs 100 or fewer individuals). No real impact on small businesses is expected, since regulations requiring expedited HIV testing are already in place. No new costs to local governments are anticipated, except for those operating hospitals with maternity services.

Compliance Requirements:

The reporting, recordkeeping and other affirmative acts that impact small businesses or local governments would not change with this proposed amendment. Current regulations require hospitals and birthing centers to assess whether mothers who present for delivery have a negative HIV test result from the current pregnancy or a positive HIV test result during or prior to the pregnancy. If no test result is documented, the mother is offered consented expedited HIV testing. If she declines, an expedited HIV test is performed on her infant, without consent. Current regulations require a turn-around-time for preliminary HIV test results of no more than 48 hours from the time the specimen is collected. The proposed rule change would decrease the turn-around-time to within 12 hours after the mothers consent for testing, or if she does not consent, within 12 hours of the infant's birth.

Professional Services:

Impacted small businesses and local governments would need the same staff of health care providers (doctors, nurses, nurse practitioners, physicians assistants), counseling and support staff as they currently employ. No additional staff would be needed.

Compliance Costs:

The percentage of women receiving prenatal counseling and testing is steadily increasing, and the need for expedited HIV testing in the intrapartum period is decreasing. As of December 2002, hospital data indicate that approximately 94% of all women giving birth have documentation of their HIV status before delivery. This rate was 62% in July 1999, one month before expedited testing in delivery settings was implemented. Using these data, the need for expedited HIV testing has clearly decreased through the years, from an estimated 120,000 mothers/infants in 1999 to less than 15,000 in 2002. At \$52 per test, the total statewide testing cost in 1999, estimated to be \$6.24 million per year, has decreased to \$780,000 per year. This number is expected to continue to decline as more women accept prenatal HIV testing. The cost for expedited HIV testing using rapid, point-of-care testing kits is not expected to exceed the cost of expedited testing as currently performed and would be considerably less if facilities choose to take advantage of point-of-care rapid testing.

Economic and Technological Feasibility:

The proposed amendment to the regulatory program is economically and technologically feasible since it is not anticipated that additional staff would be required and rapid, point-of-care testing technology is readily available.

Minimizing Adverse Impact:

Provider costs associated with rapid, point-of-care expedited HIV testing are medically appropriate and must be considered part of labor and delivery costs. Current reimbursement rates for expedited HIV testing subsidize the costs incurred by the delivery facility (\$44 for counseling and \$52 for testing), and will continue. Since preventing HIV transmission saves the high treatment costs for HIV-infected persons, expedited HIV testing in the labor and delivery setting is actually cost effective. Hospitals and birthing centers also realize savings as a result of this program by not having to employ outreach staff to find mothers after discharge since post-test counseling can be done while the mother is still in the hospital.

Small Businesses and Local Government Participation:

In advance of publication, the proposed amendment to the regulation was discussed at a two hour meeting held on March 23, 2003 by the Greater New York Hospital Association with representatives from 31 birthing facilities and the Health and Hospitals Corporation attending, and on April 30, 2003 at a videoconference hosted by the Hospital Association of New York State and broadcast to birthing facilities statewide.

Rural Area Flexibility Analysis

Types and Estimated Numbers of Rural Areas:

Forty-four counties meet the definition of a rural area (population less than 200,000) and an additional 11 counties have towns that are classified as rural (towns with population densities of 200 persons or less per square mile). The proposed amendment to the current regulation applies to hospitals and birthing facilities in 55 counties. These facilities already follow the Expedited HIV Testing regulation; significant program expansion is not expected. There are no birth facilities in the remaining seven counties.

Reporting, Record Keeping and Other Compliance Requirements:

The reporting, recordkeeping and other affirmative acts that will impact hospitals in rural areas have already been undertaken to comply with the Expedited HIV Testing regulation. Current regulations require maternity hospitals and freestanding birthing centers to ensure that all women who present for delivery with no documentation of HIV status are counseled about expedited HIV testing, and, arrange that an immediate HIV screening test of the mother with her consent or of her newborn without consent is performed. Technological advances mean that rapid HIV screening tests can now be performed at the point-of-care. Birth facilities can choose to use the new technology for rapid HIV testing, or to continue with the expedited HIV testing program already in place at their facilities. If the new technology is not chosen, the decreased turn-around-time for the return of preliminary test results will have to be negotiated with either the hospital-based or the commercial laboratories that perform expedited HIV testing.

Professional Services:

Hospitals in rural areas would not need additional professional staff to provide this service for women without known HIV test results.

Costs:

According to current annualized data, fewer than 50 maternity patients or newborns in any hospital or birthing center operated in rural areas require expedited HIV testing. This number will continue to diminish as efforts to promote prenatal HIV testing succeed. If an average of \$52 (the total per test average cost of ELISA or SUDS testing, exclusive of counseling) for each expedited HIV test is used to estimate the total cost of expedited testing (test device, equipment and personnel), the total annual cost for rapid expedited HIV testing in each rural birth facility will be approximately \$2,600, or less, depending on the number of maternity patients or newborns needing rapid testing.

Minimizing Adverse Impact:

Additional provider costs associated with testing are medically appropriate and must be considered part of labor and delivery costs. However, preventing HIV transmission is cost effective because of the high cost of treatment for HIV-infected persons. Hospitals and birthing centers will realize savings as a result of this program by not having to employ outreach staff to find mothers after discharge since post-test counseling can be done while the mother is still in the hospital.

Rural Area Participation:

In advance of publication, the proposed amendment to the regulation was discussed at a two hour meeting held on March 23, 2003 by the Greater New York Hospital Association with representatives from 31 birthing facilities and the Health and Hospitals Corporation attending, and

on April 30, 2003 at a videoconference hosted by the Hospital Association of New York State and broadcast to birthing facilities statewide.

Job Impact Statement

A Job Impact Statement is not attached because this amended rule will not have a substantial adverse impact on jobs and employment opportunities as apparent from its nature and purpose.

NOTICE OF ADOPTION

Public Notification, Disinfectants/Disinfection Byproducts and Interim Enhanced SWTR

I.D. No. HLT-46-03-00007-A

Filing No. 545

Filing date: May 10, 2004

Effective date: May 26, 2004

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following action:

Action taken: Amendment of Part 5 of Title 10 NYCRR.

Statutory authority: Public Health Law, sections 201, 225, 1150 and 1151

Subject: Public notification, disinfectants/disinfection byproducts and interim enhanced SWTR.

Purpose: To retain primacy over the New York State Drinking Water Program.

Substance of final rule: The proposed code amendments incorporate the requirements of the Interim Enhanced Surface Water Treatment Rule (IESWTR) and the Stage 1 Disinfectants and Disinfection Byproducts Rule (DBP Rule), which were both promulgated by the United States Environmental Protection Agency on December 16, 1998; the Public Notification Rule, which was promulgated on May 4, 2000; the Filter Backwash Recycling Rule, which was promulgated on June 8, 2001; and the Long Term 1 Enhanced Surface Water Treatment Rule, which was promulgated on January 14, 2002. All of these rules are requirements of 40 CFR Part 141. As a condition of primacy, New York State must have rules or other authority that are at least as stringent as 40 CFR Part 141 to assure that public water systems comply with the requirements of the IESWTR, DBP Rule, Public Notification Rule, Filter Backwash Recycling Rule, and Long Term 1 Enhanced Surface Water Treatment Rule. In order to satisfy that federal condition, the proposed code amendments for the IESWTR/DBP Rule must be adopted as soon as possible since the Federal regulations became effective for systems serving a population greater than 10,000 persons on January 1, 2002. Federal regulations will become effective for the smaller systems on January 1, 2004. The Public Notification Rule must be adopted by May 6, 2004.

The following is a summary of the proposed amendments to Subpart 5-1 of 10 NYCRR Part 5, which address the requirements of the IESWTR, DBP Rule and Public Notification Rule:

Section 5-1.1 Definitions

Definitions of the following terms have been added: Comprehensive Performance Evaluation (CPE); enhanced coagulation; filter profile; GAC10; haloacetic acids (five) (HAA5); maximum residual disinfectant level (MRDL); SUVA; Tier 1 notification; Tier 2 Notification; Tier 3 Notification; total organic carbon (TOC); and transient noncommunity water system. Definitions of the following terms have been revised: public health hazard; public notification; and state notification.

Section 5-1.30 Providing treatment for public water systems

The goal of the IESWTR is to improve public health by reducing exposure to Cryptosporidium and other pathogens through improvements in filtration at water systems. All public water systems that use surface water or groundwater under the direct influence of surface water, and filter their water will be required to achieve 99% Cryptosporidium removal. These amendments require that public water systems operating with filtration avoidance determinations provide protection from Cryptosporidium contamination as part of their watershed control programs.

Section 5-1.30(d) amends the public notification requirements for a system operating under avoidance criteria. When the raw water turbidity exceeds five nephelometric turbidity units, systems are required to comply with the State within 24 hours after learning of a turbidity exceedance. Based on this consultation, the State may decide to elevate the violation from Tier 2 to Tier 1.

Section 5-1.30(c) includes a requirement that systems using conventional or direct filtration and recycling spent filter backwash or other return flows do so through the treatment processes.

Section 5-1.51 Maximum contaminant levels

The DBP Rule introduces maximum allowable levels of disinfectants in drinking water under normal operating conditions. Since disinfectants are not considered "contaminants", a new group of standards, maximum residual disinfectant levels (MRDLs), will be added. Changes to Sections 5-1.51, 5-1.51(a), and 5-1.51(b) would add references to MRDLs where MCLs and treatment technique requirements are currently mentioned.

The proposed amendments require public water systems to implement a monitoring plan. A provision allowing time to comply with the proposed disinfection byproduct standards is provided for public water systems that are intending to install granular activated carbon or membrane technology.

Section 5-1.52 Tables

The following tables are amended to incorporate the requirements of the IESWTR, the DBP Rule, and the Public Notification Rule into Subpart 5-1:

Table 1. Inorganic Chemicals and Physical Characteristics — Maximum Contaminant Level Determination: MCLs for bromate of 0.010 mg/L, and for chlorite of 1.0 mg/L, have been added.

Table 2. Nitrate, Nitrite, Total Nitrate/Nitrite Maximum Contaminant Level Determination:

Table 2 is modified so that noncommunity water systems that are permitted an MCL of 20 mg/L for Nitrate must continuously post a notice in accordance with a Tier 1 notification when the nitrate levels exceed the 10 mg/L MCL. Systems unable to collect an additional sample within 24 hours must issue a Tier 1 notification instead of a public notice to consumers.

Table 3. Organic Chemicals — Maximum Contaminant Level Determination: MCL for total trihalomethanes has been changed from 0.10 mg/L to 0.08 mg/L. An MCL of 0.060 mg/L for haloacetic acids has been added.

Table 3A. Maximum Residual Disinfectant Level (MRDL) Determination: A new table listing MRDLs for chlorine, chloramines, and chlorine dioxide of 4.0 mg/L, 4.0 mg/L, and 0.8 mg/L, respectively, has been added.

Table 4A. Surface Water Turbidity Performance Standards — Maximum Contaminant Level Determination: Revised table to reduce the turbidity performance standard for conventional filtration from 0.5 NTU to 0.3 NTU for surface water systems or systems using groundwater under the direct influence of surface water.

Table 8B. Inorganic Chemicals and Physical Characteristics — Minimum Monitoring Requirements: Monitoring requirements for bromate and chlorite have been added.

Table 9A. Organic Chemicals — Disinfection Byproducts — Minimum Monitoring Requirements: This table has been expanded substantially to address the different monitoring requirements for disinfection byproducts that vary based on system size and whether the system uses surface water or groundwater.

Table 10A. Turbidity — Monitoring Requirements. Additional turbidity monitoring requirements have been included.

Table 13 Required Notifications.

Table 13 Required Notifications is reformatted and revised. The table accounts for every violation and situation that requires a public notice.

Table 15 Disinfection Monitoring for Systems using Chlorine or Chloramines.

The table title has been changed to specifically address chlorine and chloramines.

Table 15A Disinfectant Residual Minimum Monitoring Requirements.

Table 15A has been added to address monitoring requirements for determining MRDL compliance for chlorine, chloramines and chlorine dioxide.

Section 5-1.60 — 1.63 Monitoring and Control of Disinfection Byproduct Precursors

Sections 5-1.60 through 5-1.63 have been added to incorporate new requirements for the monitoring and removal of disinfection byproduct precursors. New regulations for community and nontransient noncommunity public water systems using conventional filtration require that total organic carbon (TOC) be measured in the source water of systems and again after filtration (but before disinfection) to calculate how effectively the TOC is being removed.

Section 5-1.72 Operation of a public water system

Paragraphs 5-1.72(c)(2) and 5-1.72(c)(3) have been added to address the reporting requirements for individual filter turbidity monitoring. Public water systems with filtration will have to report based on individual filter turbidity values and the number of consecutive high measurements. Systems using conventional or direct filtration that recycle filter backwash or other return flows must keep operational records and report to the state the flow rates and locations of return flows.

Section 5-1.77 State notification

Section 5-1.77: Public health hazard notification is renamed and amended to address the detailed requirements of state notification. Existing public health hazard notification requirements are addressed under the requirements for a Tier 1 notification in Section 5-1.78(c).

Section 5-1.78 Public notifications

Section 5-1.78: Content of Consumer and Public notifications is repealed in its entirety and will be replaced with the new Section 5-1.78 (Public notifications). The new section adds general requirements and amends the content, form, manner, and frequency requirements for public notifications.

Section 5-1.91 Variance from required use of any specified treatment technique

The Best Available Technologies (BATs) table included in Section 5-1.91(d) has been amended to include additional information about BATs for achieving compliance with the total trihalomethane and haloacetic acid MCLs. GAC10, as defined in section 5-1.1, has been added. Enhanced coagulation for precursor removal has also been added.

Appendix 5-C

Appendix 5-C has been updated to include all laboratory analytical methods referenced in the code, including those required by this amendment as well as methods which are referenced in other pending code amendments.

Final rule as compared with last published rule: Nonsubstantive changes were made in sections 5-1.1(f), (ax), (bp), (bq), (br), 5-1.51(c)(3), Table 4A, Table 13 and 5-1.63(b)(1)(ii).

Text of rule and any required statements and analyses may be obtained from: William Johnson, Department of Health, Division of Legal Affairs, Office of Regulatory Reform, Corning Tower, Rm. 2415, Empire State Plaza, Albany, NY 12237, (518) 473-7488, fax: (518) 486-4834, e-mail: regsqna@health.state.ny.us

Regulatory Impact Statement, Regulatory Flexibility Analysis, Rural Area Flexibility Analysis and Job Impact Statement

Although the regulation has been changed since it was published in the *State Register* on November 19, 2003, the changes do not necessitate any changes to the Regulatory Impact Statement, Regulatory Flexibility Analysis, Rural Area Flexibility Analysis or Job Impact Statement.

Assessment of Public Comment

The public comment period for the proposed rule making ended on January 3, 2004. On January 13, 2004, the New York Section of the American Water Works Association (NYSAWWA) commented on two issues in the rulemaking.

NYSAWWA commented that the compliance date for the provision to lower the turbidity standard for filtered systems serving fewer than 10,000 should be consistent with the Federal Rule (LT1 ESWTR).

In response, the New York State Department of Health (NYSDOH) has changed the compliance date for this provision to January 14, 2005 (see section 5-1.52 table 4A, note 5). The compliance date was originally proposed for January 1, 2004, as projected in the proposed Federal Rule. In the final Federal Rule, the compliance date was delayed until January 14, 2005.

NYSAWWA commented on an element required in disinfection byproduct monitoring plans. This element, which is proposed in paragraph 5-1.51(c)(3), reads as follows: "if approved for monitoring as a consecutive system, or if providing water to a consecutive water system, the sampling plan must reflect the entire distribution system." NYAWWA commented that EPA does not define a consecutive system, nor provide requirements for monitoring by consecutive systems in the rule. NYSAWWA commented that it appears the state is adding stage 2 rule requirements for consecutive systems under stage 1 of the disinfection byproduct rule. NYSAWWA commented that the proposed element is unclear and will place a burden on producing systems to monitor purchasing systems that was not intended by the Federal Rule.

In response, the NYSDOH has clarified paragraph 5-1.51(c)(3) by referencing existing section 5-1.76 Monitoring of consecutive public water systems. The proposed paragraph 5-1.51(b)(3) now reads as follows: "if approved for monitoring as a consecutive system, or if providing water to a consecutive water system, under the provisions of section 5-1.76 of this Subpart, the sampling plan must reflect the entire distribution system." EPA made a similar reference in the Disinfectants/Disinfection Byproducts Rule. A large number of systems in New York State already monitor for disinfection byproducts according to section 5-1.76. According to section 5-1.76, when a public water system supplies water to one or more other public water systems, the State may modify the monitoring requirements when the circumstances justify treating them as a single system for

monitoring purposes. Overall, this reduces the total number of disinfection byproduct monitoring samples required by purchase systems, without increasing the total number of samples required by producing systems.

**PROPOSED RULE MAKING
NO HEARING(S) SCHEDULED****Perinatal Regionalization**

I.D. No. HLT-21-04-00011-P

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following proposed rule:

Proposed action: Amendment of sections 405.21, 407.14, 708.2, 708.5 and 711.4; and addition of Part 721 to Title 10 NYCRR.

Statutory authority: Public Health Law, sections 2500, 2800, 2803 and 2803-j

Subject: Perinatal regionalization.

Purpose: To update standards for perinatal designation of obstetrical hospitals and consolidate standards for perinatal regionalization.

Substance of proposed rule (Full text is posted at the following State website: www.health.state.ny.us): The proposed regulatory changes update existing requirements for maternal and newborn care, aggregate perinatal regionalization and designation requirements and new Part 721 is being added to collect in one section all the regulations governing the perinatal regionalization system, which are currently divided among several sections of the New York State Hospital Code ("Hospital Code"). The proposed regulatory changes also describe what kinds of resources should be available for different levels of hospitals, and delete outdated appropriateness review standards used in the 1985 designation of hospitals at different levels of high risk neonatal care.

Section 405.21 for hospital-based perinatal services is being amended to support perinatal regionalization efforts and to clarify and simplify some other existing regulatory requirements.

Sections 407.14, 711.4(d)(21) and (e)(10) are being amended merely to reflect the change in terminology in section 405.21 in which hospital-based "maternity and newborn" services are now being referred to as "perinatal" services.

Section 708.2(b)(6) and Section 708.5(f) are repealed since new Part 721 will integrate the requirements for perinatal re-designation and regionalization in one section.

Part 721 defines the perinatal regionalization system including requirements for affiliation agreements between Levels I, II and III hospitals and regional perinatal centers (RPCs), staffing requirements and quality improvement activities. The regulations will formalize the designation process, update the Department of Health expectations for resources to be available at each level of care, and clarify the relationship between Levels I, II, and III programs and RPCs.

Text of proposed rule and any required statements and analyses may be obtained from: William Johnson, Department of Health, Division of Legal Affairs, Office of Regulatory Reform, Corning Tower, Rm. 2415, Empire State Plaza, Albany, NY 12237, (518) 473-7488, fax: (518) 486-4834, e-mail: regsqna@health.state.ny.us

Data, views or arguments may be submitted to: Same as above.

Public comment will be received until: 45 days after publication of this notice.

Regulatory Impact Statement

Statutory Authority:

These regulations are authorized pursuant to Public Health Law (PHL) Sections 2500, 2800, 2803 and 2803-j.

Legislative Objectives:

Section 2500(1) of the PHL authorizes the Commissioner to oversee care in hospitals "...in matters pertaining to the safeguarding of motherhood and the prevention of maternal, perinatal, infant and child mortality, the prevention of diseases, low birth weight, and defects of childhood and the promotion of maternal, prenatal and child health, including care in hospitals." Section 2803(2) of Article 28 of PHL authorizes the State Hospital Review and Planning Council to adopt and amend rules and regulations subject to the approval of the Commissioner to effectuate the provisions and purposes of Article 28.

A primary legislative objective of Article 28 of PHL is "the protection and promotion of the health of the inhabitants of this State." PHL § 2800, provides inter alia, that, "the Department shall have the central, comprehensive responsibility for the development and administration of the state's policy with respect to hospital and related services." Those statutes

authorize the Commissioner to establish regulatory standards to promote quality maternal, child and infant health care and to prevent maternal, perinatal, infant, and child mortality and low birth weight, including the care these populations receive in hospital settings.

Public Health Law Section 2803-j requires each hospital to prepare and distribute to each prospective maternity patient an informational leaflet describing physical and mental health of the maternity patient, insurance coverage provisions, a description of the dangers of shaking infants and young children and hospital specific maternity related statistics.

Needs and Benefits:

The Department has established regulatory standards to promote quality care for women and infants in hospitals throughout the state set forth at:

- Section 405.21 — Maternity and newborn services;
- Part 407- Primary care hospitals — minimum standards; and,
- Section 711.4 — General structural, equipment and safety standards for existing hospitals.

To enhance the quality of appropriate levels of care provided to newborns, the Department implemented a system for regionalization of hospitals providing obstetrical services. In the previous regionalization system, which, up until the recent perinatal designations of all obstetrical hospitals, had been in place since 1985, hospitals had a designation of one of four levels (Level I — Basic care; Level II — Specialty care; Level III — Subspecialty care; and, Regional Perinatal Center (“RPC”). The designations were intended to reflect each hospital’s capacity to manage high-risk pregnancies and/or treat mothers and babies who need extraordinary care. The designations were based on a neonatal designation, which reflected the ability of the facility to provide services to neonates (i.e., newborns up to twenty-eight days of age). All Level I through Level III hospitals are affiliated with an RPC to ensure timely access to the continuum of specialized care needed. Additionally, RPCs provide a quality improvement function for all affiliates.

Since 1985, significant changes in perinatal health have directly impacted hospital designations. Changes include an increase in the availability of neonatologists statewide, advances in technology which increase hospitals’ capabilities for caring for at-risk neonates, and changes in hospital affiliations and corporate relationships.

Research strongly supports a shift from the concept of neonatal designation to perinatal regionalization to ensure the highest quality care for mothers and infants.¹ Perinatal regionalization takes into account factors which enhance quality of care for mothers, as well as newborns. Studies of appropriate patient volume and level of Neonatal Intensive Care Unit (“NICU”) care at the hospital of birth shows that regionalization has significant effects on neonatal mortality.² Women transported to appropriate levels of care prior to delivery also experience a lower rate of morbidity and mortality. A study of maternal mortality in New York found that a frequent contributing factor was lack of high-level care for women with serious underlying illnesses and/or pregnancy complications.³ Recent studies suggest that transfer of infants in utero to appropriate levels of care results in significant reductions of infant morbidity and mortality and a decrease in costs for neonatal care.⁴

Previously, the designation levels were based solely on newborn criteria extracted from information collected in 1985. The coordination of perinatal care in each region of the state must be optimized to ensure that pregnant women, new mothers, and their newborns receive care at settings appropriate to their needs. The Department of Health has completed the process of updating and refining responsibilities of the perinatal regionalization system for hospitals providing perinatal services statewide. This effort will result in greater access to more appropriate levels of care for pregnant women and newborns, and strengthen the relationships of the RPCs and affiliative hospitals for purposes of quality improvement.

In order to support this effort, several sections of the current regulations require revision or consolidation as follows:

- Section 405.21, which governs hospital-based perinatal services, is amended to update terminology and requirements for affiliation agreements between Levels I, II and III hospitals and RPCs and to clarify and simplify other existing regulatory requirements.
- Subdivision (b), paragraph 6 of section 708.2 and subdivision (f) of section 708.5 are repealed since the new Part 721 integrates the requirements for perinatal re-designation and regionalization in one section.

- New Part 721 is added to consolidate all regulations governing the perinatal regionalization system, which are currently divided among several sections of the Hospital Code. The regulations will formalize the designation process, update expectations for resources to be available at each level of care, and clarify the relationship between each level and RPCs. New Part 721, entitled “Perinatal Regionalization System,” articulates responsibilities of regional perinatal centers and their perinatal affiliates including responsibilities for regional quality improvement activities.
- Section 407.14 and paragraphs (d)(21) and (e)(10) of section 711.4 are amended to reflect the change in terminology in section 405.21 in which hospital-based maternity and newborn services are being referred to as “perinatal” services.

Failure to adopt these regulations will negatively impact the ability of the Department to improve maternal and infant mortality and morbidity.

Background:

Significant efforts have been made by the Bureau of Women’s Health to obtain meaningful input into this process by key stakeholders and other interested parties. An Ad Hoc Work Group on Perinatal Regionalization was convened to advise the Department about the impact of managed care on perinatal regionalization. Its thirty-three members included pediatricians, neonatologists, obstetricians, and hospitals, managed care plans, and other organizations concerned with perinatal health around the state. Organizations involved included the Greater New York Hospital Association, Healthcare Association of New York State, Medical Society of the State of New York, State Senate, NYS HMO Council, NYS Perinatal Association, District II of the American College of Obstetricians and Gynecologists, American Academy of Pediatrics, and American College of Nurse-Midwives. The Work Group advised the Department about revising the regionalized perinatal care system, particularly in light of the growth of managed care.

As a result of the advice of the Ad Hoc Work Group, the Department convened a second work group called the Work Group on Perinatal Re-designation in late 1997. Its charge was to implement the recommendations of the Ad Hoc Work Group, including the development of draft regulations, revising the current maternal and newborn section of the Hospital Code, and to add new regulations designed to implement re-designation and a statewide perinatal data system. Its members include neonatologists, obstetricians, hospital administrators, representatives of professional organizations, and representatives of the Greater New York Hospital Association, the Healthcare Association of New York State, and Nassau-Suffolk Hospital Council.

These proposed modifications to the regulations are also based on the current edition of the widely recognized professional standards of care, “Guidelines for Perinatal Care, 4th Edition,” published by the American Academy of Pediatrics and the American College of Obstetricians and Gynecologists and input from the aforementioned workgroups. DOH has also obtained expert advice from neonatologists, obstetricians, midwives, obstetric anesthesiologists, and hospital administrators. These key stakeholders have had the opportunity to provide input into the development and revisions of regulatory language and the process to implement regulatory requirements.

The concept of perinatal regionalization has widespread acceptance from both health care providers and patient advocates. Regionalization has contributed to the decrease in newborn mortality over the past two decades. The proposed standards reflect existing, generally accepted, standards of care. Specific provisions will continue to be subject to review and input from obstetricians, pediatricians, hospital representatives, midwives, nurses and a wide range of other interested parties.

Costs:

Costs for the Implementation of and Compliance with the Regulations to Regulated Entities:

There should not be a negative fiscal impact on hospitals since the primary intent of the regulations is to update and reorganize current regulations dealing with perinatal services in hospitals, rather than make them more stringent. Further, hospitals have the ability to apply for a designation that is consistent with the hospital’s existing capabilities and current practices, thus resulting in little or no impact on a hospital’s cost of providing these services. For some hospitals, this will have a positive impact because they will be able to apply for a higher level perinatal designation resulting in their eligibility for the higher reimbursement rates established for high risk mothers and newborns. Hospital reimbursement is centered around Diagnosis Related Groups (DRGs), a classification system used to categorize patient discharge information into meaningful groupings. The criteria used to select a DRG includes the principal diagnosis, secondary diagno-

sis, operating room procedures, the presence of absence of comorbidity and/or complication, age, and discharge status. The concept behind DRGs is that higher levels of reimbursement will be received for more seriously ill patients.

Regionalization will promote the process of lower level hospitals transferring high-risk mothers and newborns to facilities with the capability to treat them, rather than attempting to manage such cases in-house. These transfers will lead to improved outcomes and reduce the incidence of preventable complications that require expensive, extraordinary services. Regionalization should also contribute to more effective management of complex cases and reduced costs through quality improvement. Hospitals will receive enhanced reimbursement to provide care to high-risk mothers and newborns based on the DRGs. In addition, RPCs will receive a grant from the Department to cover certain costs of their added regionwide quality improvement responsibilities, depending upon the availability of funding.

Costs to State and Local Governments:

There will be no additional costs to State or local government. RPCs will receive a grant from the Department to cover certain costs of their added regionwide quality improvement responsibilities on an annual basis, depending upon the availability of funding. Currently, this funding is provided by the Commissioner's Priority Pool fund.

Costs to the Department of Health:

The cost of designating hospitals will be absorbed by the Department using existing resources. The statewide redesignation process was completed in March, 2003. Monitoring activities do not significantly increase the Department's current oversight responsibilities with regard to perinatal services in hospitals.

Paperwork:

Periodically, hospitals must complete questionnaires to enable the Department to determine appropriate perinatal designation. The information included in questionnaires will be similar to information currently required for neonatal special care designation under current section 708.5(f) of Title 10.

All Level I, II and III perinatal care hospitals must have perinatal affiliation agreements with a designated RPC that meet the criteria as contained in regulation. This agreement shall include criteria, policies and procedures for transfer of patients, criteria and process for consultation, provisions for cooperation in outreach, education, training and data collection activities, and provisions for participation in the statewide perinatal data system.

Finally, if two or more hospitals jointly sponsor an RPC, they must define in a written agreement between or among the hospitals comprising the RPC how the functions and responsibilities of the RPC will be implemented.

Neither of these presents an undue burden to any hospital. All Level I, II and IIIs have current affiliation agreements with an RPC. These agreements will need to be updated to ensure all requirements as stipulated in regulation are included in the agreement. The only hospitals currently comprising a joint RPC are Mt. Sinai Hospital and New York University Hospitals Center as well as Bellevue Hospital Center and Jacobi Medical Center.

Local Government Mandates:

These amendments do not impose any new program, services, duties or responsibilities upon any county, city, town, village, school district, fire district or other special district.

Duplication:

These regulations do not duplicate any other State or federal law or regulation.

Alternatives:

Regulatory changes are necessary to implement and support perinatal regionalization, which is critical to the effective organization and delivery of perinatal services statewide. Existing regulations are not consistent with current standards of care and do not reflect the current structure of the health care system. In updating the regulations, DOH considered placing standards for the program in section 405.21, currently entitled "Maternity and Newborn Services." The Department subsequently decided to move the standards into a new Part 721 so that the standards describing development and implementation of perinatal regionalization and perinatal services could be viewed as discrete and distinct from the minimum day-to-day operating standards contained in Part 405.

Federal Requirement:

These regulatory amendments do not exceed any minimum standards of the federal government for the same or similar subject areas. Since federal Medicare Conditions of Participation do not address perinatal

services, there are no comparable federal requirements in this area. Perinatal regionalization will, however, help New York to meet Healthy People 2010 maternal and infant health goals established by the US Department of Health and Human Services.

Compliance Schedule:

The proposed regulation will become effective upon publication of a Notice of Adoption in the State Register. The voluntary statewide redesignation effort was completed in March 2003. It is anticipated that all hospitals will be in significant compliance by January 1, 2004.

¹ Yeast JD, Poskin M, Stockbauer JW, Shaffer S. Changing patterns in regionalization in perinatal care and the impact on neonatal mortality. *American Journal of Obstetrics and Gynecology* (1998) 178 (Pt 1): 131-5.

Richardson DK, Reed K, Cutler JC, Boardman RC, Moynihan T, Driscoll J, Raye JR. Perinatal regionalization versus hospital competition: the Hartford example. *Pediatrics* (1995) 96 (Pt 1): 417 —23.

² Powell SL, Holt VL, Hickok DE, Easterling T, Connell FA. Recent changes in delivery site of low-birth-weight infants in Washington: impact on birth weight-specific mortality. *American Journal of Obstetrics and Gynecology* (1995) 173(5): 1585-92.

Cifuentes J, Bronstein J, Phibbs CS, Phibbs RH, Schmitt SK, Carlo WA. Mortality in low birth weight infants according to level of neonatal care at hospital of birth. *Pediatrics* (2002) 109: 745-751.

Menard MK, Liu Q, Holgren EA, Sappenfield WM. Neonatal mortality for very low birth weight deliveries in South Carolina by level of hospital perinatal service. *American Journal of Obstetrics and Gynecology* (1998) 179(2): 374-81

Bode MM, O'Shea TM, Metzguer KR, Stiles AD. Perinatal regionalization and neonatal mortality in North Carolina, 1986-1994. *American Journal of Obstetrics and Gynecology* (2001) 184(6):1302-7.

³ *Maternal Mortality in New York State: A Final Report on the New York State Maternal Mortality Review* — Executive Summary.

⁴ Schlossman PA, Manley JS, Sciscione AC, Colmorgen GHC. An analysis of neonatal morbidity and mortality in maternal (in utero) and neonatal transport at 24-34 weeks gestation. *American Journal of Perinatology* (1997) 14:449-56.

Regulatory Flexibility Analysis

Pursuant to section 202-b of the State Administrative Procedure Act, a Regulatory Flexibility Analysis is not required. These amendments will assist DOH and hospital-based perinatal care programs in the establishment and maintenance of a perinatal regionalization program. They will promote high quality perinatal care statewide by recognizing the appropriate level of care that can be provided by each hospital and will facilitate the movement of patients into facilities that can meet their needs. They will also promote inter-hospital cooperative efforts designed to optimize the quality of care provided at each facility.

The proposed rules will not impose adverse economic impact on small businesses or local governments in New York State and will not impose any additional recordkeeping, reporting or other compliance requirements. Out of the eight hospitals in the state employing less than 100 people, none of them provide obstetrical services. A total of 14 hospitals are either state, county or New York City sponsored hospitals. Out of these, four are RPCs, eight are Level IIIs, one is a Level II and one is a Level I. The RPCs will receive a grant from the Department to cover certain costs of their added regionwide quality improvement responsibilities, depending upon the availability of funding. Hospitals will need to update their current perinatal affiliation agreements and complete perinatal designation questionnaires as requested. Both documents are similar to paperwork currently required of facilities and do not present an undue burden. Participation in the Statewide Perinatal Data Systems (SPDS) will also not be an undue burden for hospitals. Currently, all hospitals submit electronic birth certificate data to either the Department or the New York City Department of Health. The SPDS incorporates the electronic birth certificate and will make close to real-time data available for quality improvement purposes.

Rural Area Flexibility Analysis

Pursuant to section 202-bb of the State Administrative Procedure Act, a Rural Area Flexibility Analysis is not required. These amendments will assist DOH and hospital-based programs in the implementation and maintenance of a perinatal regionalization system. This system will be particularly beneficial to rural areas. Rural maternity patients and newborns who have or who develop special care needs will have these needs addressed systematically in the most appropriate setting, and small rural hospitals will have improved access to assistance from a regional perinatal center in

meeting their training and quality assurance/improvement needs. Perinatal regionalization also includes formalized transfer criteria and protocols to assure the optimal use of such transfers. The proposed regulations also include flexibility to ensure rural areas with potentially limited resources will not be adversely impacted by the re-designation process. Section 721.3(a)(6) states that the department shall consider the geographic distribution of designated hospitals to ensure access to appropriate levels of care. This is especially relevant in rural areas of the state where services tend to be limited. The proposed regulations will have no negative impact on any affected parties. The proposed rules will not impose adverse economic impact on rural areas in New York State and will not impose any additional recordkeeping, reporting or other compliance requirements on rural areas. Hospital will need to update their current perinatal affiliation agreements and to complete perinatal designation questionnaires as requested. Both documents are similar to paperwork currently required of facilities and do not present an undue burden.

Participation in the Statewide Perinatal Data System (SPDS) will also not be an undue burden for hospitals. Currently, all hospitals submit electronic birth certificate data to either the Department or the New York City Department of Health. The SPDS incorporates the electronic birth certificate and will make close to real-time data available for quality improvement purposes.

Job Impact Statement

A Job Impact Statement is not included because the regulations will not have a substantial adverse impact on jobs and employment opportunities. In fact, enhanced employment opportunities at hospitals designated as regional perinatal centers may exist. These hospitals may increase staff in the areas of training, outreach, data analysis, and quality assurance/improvement since they provide support in these areas for their perinatal affiliates.

PROPOSED RULE MAKING NO HEARING(S) SCHEDULED

Environmental Laboratory Standards (Bioterrorism)

I.D. No. HLT-21-04-00012-P

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following proposed rule:

Proposed action: Addition of section 55-2.13 to Title 10 NYCRR.

Statutory authority: Public Health Law, section 502

Subject: Environmental laboratory standards (bioterrorism).

Purpose: To establish minimum requisites for laboratories testing critical agents.

Text of proposed rule: Pursuant to the authority vested in the Commissioner of Health by Section 502 of the Public Health Law, existing Subpart 55-2 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York (NYCRR) is amended, to be effective upon publication of a Notice of Adoption in the New York State Register, as follows:

Subpart 55-2 is amended by reserving new Section 55-2.12 for future use and adding new Section 55-2.13 as follows:

Section 55-2.12 (reserved)

Section 55-2.13 Requirements for laboratories engaged in testing for critical agents in environmental samples.

(a) For purposes of this Subpart, *critical agent* shall mean an organism, chemical element or chemical compound, which is recognized as posing a risk to national security and/or requiring special action to protect the public health because the agent: can be disseminated (e.g., in air, water or food) or transmitted person-to-person with ease; causes moderate to high mortality and/or morbidity; and can have a significant public health impact. The term *organism* includes, but is not limited to, a virus, bacterium, or product of an organism. *Critical agents* shall include critical biological and chemical agents specified by the federal Centers for Disease Control and Prevention (CDC) in published documents, and other such agents as the Commissioner of Health has determined meet the above criteria.

(b)(1) Prior to performing testing for any critical agent in an environmental sample, a laboratory shall submit a request to the department, and receive an initial or revised certificate of approval that includes the specialty of critical agent testing. The certificate of approval shall also list the specific critical agent(s) included in the approval, the approved method(s), and the types of samples (e.g., surface swipes, powder, fluid and bulk material) the laboratory may accept for testing. No laboratory shall examine an environmental sample for a biological or chemical criti-

cal agent without certification of approval specific to each critical agent for which testing is conducted.

(2) The department may withhold or limit its approval if the department is not satisfied that the laboratory has in place adequate policies, procedures, facilities, equipment, instrumentation and trained personnel to ensure that collection, labeling, accessioning, preparation, analysis, result reporting, storage, transportation, shipping, and disposition of all environmental samples, derivatives and related materials shall be performed in a manner that: ensures consistently correct performance of the approved methods; ensures the protection of the health, safety and welfare of the laboratory's employees and the public; and is consistent with the requirements of this Subpart, and all other applicable laws, rules and regulations. The department shall also consider a laboratory's (bio)safety level facilities and practices in its determination to approve the laboratory for critical agent testing in environmental samples.

(c) In addition to application and attestation requirements found elsewhere in this Subpart, a laboratory seeking approval to perform critical agent testing in environmental samples shall submit:

(1) a standard operating procedure manual documenting laboratory policies, procedures, facilities, equipment, supplies, instrumentation and personnel for critical agent testing, which are designed to ensure that collection, labeling, accessioning, preparation, analysis, result reporting, storage, transportation, shipping, and disposition of all environmental samples, derivatives and related materials shall be performed in a manner that ensures consistently correct performance of the approved methods; ensures the protection of the health, safety and welfare of the laboratory's employees and the public; and is consistent with the requirements of this Subpart, and all other applicable laws, rules and regulations; and

(2) an attestation signed by the owner(s) and director(s) that the laboratory will accept only the type(s) of samples (e.g., surface swipes, powder, fluid and bulk material) specified on the laboratory's certificate of approval, and that the owner(s) and director(s) will take whatever action is necessary to ensure that such samples are collected, labeled, accessioned, prepared, analyzed, stored, transported, shipped and disposed of, and all results are reported in a manner consistent with the approved method and with all other documentation submitted to the department.

(d) In addition to the preceding requirements of this Subpart, a laboratory engaged in critical agent testing in environmental samples, through its owner(s) and director(s), shall:

(1) establish, maintain, review periodically, and implement written policies and procedures which are designed to ensure that collection, labeling, accessioning, preparation, analysis, result reporting, storage, transportation, shipping and disposition of samples shall be performed in a manner that ensures consistently correct performance of the approved methods, ensures the protection of the health, safety and welfare of laboratory personnel, sample collectors and the public to the extent possible, and is consistent with all applicable laws, rules and regulations, as well as recognized standards of practice designed to minimize the risks associated with potential exposure to similar hazardous substances or critical agents. Such policies and procedures shall include specific procedures for containment, secured storage, decontamination, and/or disposal or destruction of the sample(s), derivatives, and related collection materials, supplies and/or equipment, as necessary and/or appropriate for the relevant suspected critical agent;

(2) have written policies and procedures in place to implement a chain-of-custody protocol whenever required by a law enforcement agency. Such policies and procedures shall be developed in consultation with law enforcement officials or other persons with appropriate experience and training in chain-of-custody issues, and shall at a minimum require an intact continuous record of the physical possession, storage, and disposition of the sample and any derivatives, including the signatures of all persons who access the sample and derivatives, the date of such access and other pertinent information;

(3)(i) ensure that all laboratory employees engaged in collecting and/or transporting environmental samples receive sufficient training in hazardous material handling techniques to ensure they will perform their responsibilities in a safe and reliable manner. Such training shall include, but not be limited to, training in sample collection, packaging, decontamination, transportation, and chain-of-custody policies and procedures established by the laboratory. The laboratory shall maintain documentation of such training for a minimum of three (3) years and take such other action as is necessary to ensure ongoing compliance with such policies and procedures;

(ii) develop and implement sample acceptance criteria designed to protect the health, safety and welfare of laboratory personnel, sample

collectors, and the public to the extent feasible. Such criteria shall be consistent with approved methods for sample collection, handling, packaging and decontamination, and shall minimally define conditions under which a sample shall be rejected, and conditions under which a sample shall be tested and results reported with limitations. The laboratory shall make its sample acceptance criteria available to clients;

(4) issue reports of test results in a format and of a content required by the approved method, and necessary for interpretation of the test results, including, but not limited to, unambiguous identification of the tested environmental sample, including collection location, source and sample type, and limitations of the method. The department may restrict a laboratory's ability to report information concerning a test result whenever confirmatory or supplemental testing is required by the approved method;

(5) report laboratory findings to the department within twenty-four (24) hours via telephone, facsimile and/or electronic transmission, using a number or e-mail address designated by the department, whenever the findings indicate that an environmental sample contains an organism, its product or component, or a chemical, any of which exhibits characteristics or properties consistent with those of a critical agent. Whenever the department determines that supplemental testing is necessary to confirm the results of a test, and/or further identify the characteristics of a critical agent for public health protection, law enforcement or research purposes, the laboratory shall submit all or part of the sample or its derivative(s) to the department or its designee, as directed by the department; and

(6) establish and implement a critical agent inventory and tracking system that accounts for all environmental samples and their derivatives suspected or confirmed to contain critical agents. Unless required to document chain of custody pursuant to paragraph (2) above or required by this paragraph, a laboratory may discontinue inventory and tracking of samples and derivatives, provided laboratory findings have established the absence of a critical agent. Inventory and tracking documentation shall include the identity of all individuals who access such materials and the date of access, as well as specific information regarding transfer, disposal or other disposition of the materials. Samples and their derivatives, access records, chain of custody records and records of the analyses shall be maintained in a secure manner until the statute of limitations for bringing any related criminal or civil action has expired, and the sample and its derivatives are no longer needed for evidence in any pending legal matter or by law enforcement officials. Access records, chain of custody records and records of the analyses of confirmed positive samples, shall be maintained for ten (10) years, or as required above if longer.

(e) For critical biological agents, an environmental laboratory's proficiency testing performance shall be evaluated based on the known presence or absence of the critical agent, or, as applicable, its product or component. Satisfactory performance shall be a result correctly indicating the presence or absence of the critical agent, or, as applicable, its product or component. Unsatisfactory performance shall be a result incorrectly indicating the presence or absence of the critical agent, or, as applicable, its product or component.

(f) Personnel requirements for environmental sample testing for critical biological agents that are microbiologic organisms shall be as follows:

(1) notwithstanding the requirements of section 55-2.10 of this Subpart, the environmental laboratory shall employ, as director, one of the following:

(i) a person who holds or meets the qualifications for a New York State clinical laboratory director certificate of qualification in the applicable subspecialty of microbiology (such as bacteriology), pursuant to Part 19 of this Title;

(ii) a person with an earned doctoral degree or master's degree in the chemical, environmental, physical or biological sciences or engineering, with at least sixteen (16) college semester credit hours in the biological sciences including at least one (1) course having microbiology as a major component, and at least one year of experience in analysis of representative analytes for which the laboratory is approved or seeking approval; or

(iii) a person with a bachelor's degree in the chemical, environmental, physical or biological sciences or engineering, with at least sixteen (16) college semester credit hours in the biological sciences including at least one (1) course having microbiology as a major component, and at least two years of experience in analysis of representative analytes for which the laboratory is approved or seeking approval; and

(iv) with respect to environmental laboratories that limit their critical biological agent testing to toxin analysis, any of the following personnel qualifications may be substituted for qualifications set forth in

subparagraphs (i) through (iii) above, as follows: a New York State clinical laboratory director certificate of qualification in toxicology may be substituted for the certification in microbiology requirement specified in subparagraph (i) above; and coursework consisting of a minimum of sixteen (16) college semester credit hours in the biological and/or chemical sciences including at least (1) one course in biochemistry may be substituted for the coursework requirements, but not the educational degree requirements, specified in subparagraphs (ii) and (iii) above; and

(2) sample preparation, analysis and related responsibilities shall be performed by an analyst who shall have an associate's degree or equivalent, with at least twelve (12) college semester credit hours in the biological sciences, and at least one year of experience in analysis of representative analytes; provided, however, that a person with at least three (3) years experience in the analysis of representative analytes immediately preceding the effective date of this section shall be deemed to have met the requisite qualifications for performing critical agent analysis in the laboratory in which such experience has been obtained. Analysts with critical biological agent testing responsibilities that are limited to toxin sample preparation, analysis and related responsibilities may meet the semester credit hour qualifications set forth in this paragraph by completing a minimum of twelve (12) college semester credit hours in the biological and/or chemical sciences.

(g) This section shall not apply to bacteriologic testing for total and fecal coliform bacteria (i.e., the common form of *Escherichia coli*) in potable and non-potable water.

Text of proposed rule and any required statements and analyses may be obtained from: William Johnson, Department of Health, Division of Legal Affairs, Office of Regulatory Reform, Corning Tower, Rm. 2415, Empire State Plaza, Albany, NY 12237, (518) 473-7488, fax: (518) 486-4834, e-mail: regsqna@health.state.ny.us

Data, views or arguments may be submitted to: Same as above.

Public comment will be received until: 45 days after publication of this notice.

Regulatory Impact Statement

Statutory Authority:

Public Health Law Section 502 authorizes the Commissioner of Health to issue certificates of approval to environmental laboratories, and prescribe the requirements for granting such approvals. The Commissioner is also empowered to adopt and amend regulations for implementing the provisions and intent of Section 502, and to prescribe the educational and technical qualifications of environmental laboratory director(s).

Legislative Objectives:

Section 502 of the Public Health Law requires all laboratories performing environmental analysis on samples collected in New York State to hold certificates of approval on such analyses as issued by the Commissioner of Health. The Commissioner is authorized to establish standards for approved laboratories and technical and educational qualifications for laboratory directors to ensure that tests conducted for public health or personal health protection, or the protection of the environment or natural resources are performed in a reliable manner.

Needs and Benefits:

Accurate and reliable identification of critical agents in environmental samples is crucial to appropriate public health response to potential biological or chemical terrorism events, and/or other such incidents posing a significant public health threat. Therefore, the Department proposes the addition of a new Section 55-2.13 for the specialty of "critical agents testing" which sets forth minimum standards for: laboratory director and testing personnel qualifications; use of approved methods for environmental sample collection and decontamination; recordkeeping systems to track the location of confirmed positive samples and isolated agents; sample chain-of-custody protocols; test result reporting procedures, including appropriate notification of the Department; client result reports content; sample and/or derivative referral protocols; and proficiency testing.

The proposal's definition of "critical agents" is largely based on the federal Centers for Disease Control and Prevention (CDC)'s criteria for biological and chemical agents of significant public health or national security risk. However, the rule not only encompasses agents categorized by the CDC as critical agents, but also agents that the Commissioner of Health has determined may require special action to protect the public health because they are easily disseminated, could cause high to moderate morbidity and/or mortality and can have a significant public health impact. The proposal's consistency with the federal criteria will promote communication among responsible agencies and enhance coordinated response at all levels, while permitting the Commissioner to react swiftly to local conditions and preparedness needs.

Due to the increased complexity and special issues presented by critical agent testing, this regulation establishes new requirements in addition to expanding several minimum standards now in place for environmental laboratories. However, the decision to engage in critical agent testing is strictly voluntary, and a laboratory needs to comply with the new and expanded requisites only if it applies for the specialty.

The educational requirements for technical directors in microbiology have been expanded beyond those required for sewage and water treatment plant operation to include post-doctoral, master's and/or bachelor's degree credentials. Qualifications for technical directors involved in critical biological agent testing of toxins have been added, as existing Subpart 55-2.10 does not provide specific or appropriate alternative qualifications in this area. The proposed amendment recognizes the expertise resident in clinical laboratories, and would allow clinical laboratory directors certified in clinical microbiology to oversee environmental critical agent testing for microbiological organisms and toxins (e.g., ricin), and clinical laboratory directors certified in either microbiology or toxicology to oversee environmental critical agent testing for toxins, provided the facility is dually certified as an environmental laboratory with an approved specialty of "critical agent testing" pursuant to Subpart 55-2. Minimum qualifications for analysts performing critical agent testing for microbiological agents and/or toxins in environmental samples are also set forth at the level of an associate's degree. The Department believes this degree or its equivalent is a necessary requisite because of the higher level of knowledge, expertise and experience required to handle critical agents safely, and follow the attendant complex testing, reporting and security protocols. The setting of minimum educational and experience qualifications for critical agent analysts is consistent with the Department's approach to certifying environmental laboratories in the Contract Laboratory Protocol (CLP) tier. CLP laboratories must demonstrate capability to adhere to stringent testing protocols and to issue reports of a content and organization able to withstand a high level of scrutiny by scientific and legal authorities. The analyst qualifications set forth in this proposal are also consistent with those for clinical testing personnel performing high complexity testing specified in the federal Clinical Laboratory Improvement Amendment of 1988 (CLIA). To preclude displacement of any individuals currently employed due to the new minimum qualifications, the proposed rule contains a grandfather clause allowing analysts with three years' experience conducting similar analyses to qualify for critical agent testing within his or her current employment setting.

In addition to establishing personnel qualifications for environmental laboratory directors and testing personnel, the proposed amendment protects the public and ensures high quality environmental testing for biological and chemical critical agents by requiring laboratories to: use approved methods for sample collection, handling and decontamination; limit access to samples and sample derivatives, such as isolated organisms; and develop and maintain recordkeeping systems to track the location of samples and isolated agents. The proposed regulation also requires laboratory employees to be trained in hazardous materials handling, sample collection, packaging, decontamination, transport, disposal and chain-of-custody protocols. Furthermore, the regulation requires environmental laboratory director(s) to develop sample acceptability criteria to protect the health, safety and welfare of laboratory personnel, sample collectors and the public, and to make such criteria available to clients upon request. Such precautionary measures to be taken at the pre- and post-analytic stages are designed to reduce, to the extent feasible, submission of samples that may pose a danger to transporters and to recipient laboratory personnel.

The proposed regulation requires laboratories to employ facilities and practices for bio-safety and chemical safety as appropriate for the critical agent(s) tested, to protect the public health, safety and welfare and prevent the use of ineffective procedures that could fail to confine dangerous agents or even promote their further dissemination. Additionally, the rule effectively restricts the often complex and potentially dangerous procedures for confirmatory testing and further characterization of an agent to appropriately equipped sites.

The rule also provides for restricting the reporting of analytical results should the Department determine that limitation on report distribution, language or content is necessary to preclude dissemination of potentially misleading information, particularly for unconfirmed or preliminary results. Furthermore, the regulation requires laboratories to notify the Department of any analytical finding indicating the presence of a critical agent. This requirement will promote clear communication lines of test results for various agents, and permit the Department to make determinations regarding the need for supplemental or confirmatory testing, as well

as assess the public health threat and need for further governmental intervention.

The sensitive nature of critical agent testing requires environmental laboratories to establish procedures to keep track of environmental samples and their derivatives following testing and characterization, ensure continued proper handling of samples and any derived agents, and limit inappropriate access by laboratory personnel and the public. The proposed amendment establishes requirements for a tracking and inventory control system to record and identify the exact location and disposition of environmental samples and derivatives that test positive for a critical agent. The required retention period of at least ten years for access records and analysis records is consistent with the ten-year requirement for drinking water analysis records currently in place. Samples and their derivatives, access records and records of the analyses which are needed for potential civil or criminal actions must be retained in a secure manner until the statute of limitations for bringing a civil or criminal proceeding has expired and such items are no longer needed as evidence in any pending legal matter. However, it is anticipated that in most instances where such retention is required, the Department or a law enforcement agency will assume responsibility for the sample and any derivatives. The rule's enhanced recordkeeping requirements will also ensure the availability of records pertaining to positive samples until no longer needed for evidence in pending legal matters or by law enforcement officials, and provide grounds for admissibility of test results by establishing a chain-of-custody documentation requirement for testing initiated by law enforcement officials.

Laboratories applying for approval in the specialty of critical agent testing will be required to submit their policies and procedures to the Department for review and approval to ensure adherence to approved methods. The amendment also details criteria for scoring of proficiency testing results for environmental bacteriologic analytes, and excludes from the proposed requirements microbiological methods for detecting and monitoring for the common form of *E. coli* in potable and nonpotable waters, for which the Department already offers certification.

Costs:

Costs to Private Regulated Parties:

The costs of compliance will vary significantly, primarily by a laboratory's existing biosafety level (e.g. BSL-2 or BSL-3) and whether it meets U.S. Centers for Disease Control and Prevention (CDC) safety and security requisites for handling the particular critical agent(s) and specimen type(s) it proposes to test. A laboratory already meeting CDC's safety and security standards is expected to incur no new costs. On the other hand, a facility minimally equipped for handling infectious agents — because it limits testing to basic microbiology testing to monitor drinking water, for instance — may accrue extensive renovation and/or construction costs.

Since the regulation's initial filing, thirty facilities requested application information for certification in anthrax testing. Six laboratories have been granted certification in anthrax testing; two of the six applicants required minor modifications to existing facilities to comply with the proposed requisites for microbiologic testing. No additional modifications would be necessary by laboratories granted certification in anthrax testing in order to qualify them for certification in critical agent testing for toxins, as toxin testing requires less stringent biosafety facilities than those required for anthrax analyses.

Facilities which do not comply with these requirements currently may incur the following compliance costs: costs for purchase and installation of a state-of-the-art biological safety cabinet; costs for establishing negative air pressure conditions and adequate air filtration with space renovation or new construction; and costs for security systems, such as installation of card-key devices, and/or locks on entrances to storage and work areas. The Department expects that commercial laboratories voluntarily incurring costs by electing to establish critical agent testing capacity will be able to offset such costs with income from fee-for-service and contractual charges imposed on clients.

According to manufacturers' estimates, costs for purchase and installation of a biological safety cabinet to meet minimal BSL-2 standards range from \$6,275 to \$11,365. Upgrading existing standard microbiology work-space to BSL-3 would require extensive modifications to usable space and air handling and filtration systems, and would be expected to result in costs comparable to new construction. According to vendors of modular construction, who gave estimates to public health officials in NYS and other states, costs for a 600-square foot BSL-3 building range from \$240,000 to \$500,000. Given the Department's experience thus far, it is unlikely that any commercial entity will choose to develop new BSL-3 capacity. Since a BSL-2 facility is sufficient for testing of critical biological agents that are toxins, any costs associated with establishing a BSL-3 facility would not

be applicable to BSL-2 environmental laboratories applying for certification in toxins alone.

Relatively minor expenditures would be necessary for supplies related to sample collection, including personal protection gear, and secure storage of samples with presumptive or confirmed critical agent findings. Laboratory supply catalogues indicate that the two plastic zipper-lock bags per sample would cost less than \$1.00; a box of 100 disposable gloves costs approximately \$6.00; and a lockable refrigerator-freezer costs \$500. Costs to equip one individual sample collector or analyst with requisite personal protective equipment are estimated at a minimum of \$10 for one set of disposable outerwear comprised of gown, shoe covers and gloves, to a maximum of \$500 for a rechargeable self-contained breathing apparatus.

Costs related to security systems vary greatly, depending on the sophistication of the system (i.e., electronic or manual), and costs of maintenance and service contracts. According to estimates given by two manufacturers of card-key systems, one portal with card-key entry would cost \$5,000. One manufacturer of video surveillance equipment estimated that a laboratory installing a sixteen-camera system would incur costs of \$15,000. It is not possible to estimate operating and maintenance of security systems, since service contracts would vary according to the size of the system. Since no express requirements are in place for security equipment, a laboratory may control access to certain areas with stringent administrative controls, including sign-in logs and identification badges, at lower costs than a mechanical or electronic system.

Clinical laboratories seeking certification as environmental laboratories, as well as previously unregulated commercial concerns offering environmental testing (e.g., as part of remediation following confirmed incidents), will need to pay approval fees equivalent to first-year Department Environmental Laboratory Approval Program (ELAP) fees, estimated at \$550. Clinical laboratories and previously unregulated facilities may also incur compliance costs similar to those for existing environmental laboratories described above. Based on a written survey of clinical laboratories currently licensed in the category of microbiology pursuant to Public Health Law Article 5, Title V, the Department estimates that 73 percent of these laboratories have existing capability for critical agent testing and would not need to expend significant resources for biosafety facilities unless they need to purchase personal protective equipment and related items to comply with the more stringent safety practices for critical agents testing.

Most clinical laboratories interested in testing environmental samples for biological critical agents already employ laboratory directors and testing personnel who qualify under the proposed educational and experiential criteria. The majority of environmental laboratories certified to perform microbiology testing limit that testing to low biosafety level work (e.g., potable water testing), and generally do not employ personnel meeting the proposed requirements. While these sites would not incur additional personnel costs for analysts because of the proposal's grandfathering provision, requirements for a technical director would entail some added costs. According to a survey published in 2001 by the American Council of Independent Laboratories, the mean hiring rate for scientists with a bachelor's degree and one to three years' experience is \$38,900. A person with these credentials would meet the proposal's minimum requirements for a technical director of a laboratory performing anthrax testing on environmental samples. Since the regulation was first filed, the Department has found that none of the environmental laboratories currently limiting their services to monitoring of sewage and water treatment facilities are interested in performing critical agent testing. The majority of environmental laboratories certified to perform chemical testing (i.e., for environmental contaminants) already employ personnel meeting the proposed requirements for toxin testing.

Laboratories applying for approval under these regulations will incur costs of approximately \$3.00 to \$20.00 to copy to the Department all policies and procedures relevant to critical agent testing. On occasion, a laboratory may incur costs for shipping presumptively positive samples to the Wadsworth Center or another designated facility for further testing. The cost of shipping an isolate of a microbiologic critical agent (e.g., a culture tube) by common carrier is estimated at between \$25 and \$50, depending on the need for keeping the agent's temperature constant with ice packs, for example. As an alternative, law enforcement officials, laboratory employees or couriers may be used for transporting samples at an anticipated maximum cost of \$350, assuming an 800-mile round trip and a \$25 hourly personnel wage.

Costs for Implementation and Administration of the Rule:

Costs to State Government:

New York State, with the exception of the Department as stated below, would incur costs to the same extent as private regulated parties should any State-operated environmental laboratories, such as those operated by the Department of Environmental Conservation, take on critical agent testing.

Costs to the Department:

The Department will incur costs for development and implementation of a proficiency-testing program for one or more analytes in the critical agent specialty, and for travel to conduct onsite assessments of applicable laboratory facilities. Since existing staff will coordinate the initial development and implementation, as well as periodic mailings, of any proficiency testing designed to challenge laboratories engaged in critical agent testing, the Department anticipates no new costs for personnel salaries and overhead. Costs of one proficiency-testing event challenging 25 laboratories using surrogate material for the analyte are in the range of \$75-\$1200 for materials (depending on the organism, toxin and source); \$325 for mailing containers; \$250 for postage; and approximately \$100 for related paperwork. However, costs related to proficiency testing, as well as travel expenses for on-site assessments, would be recovered through approval fees charged to the laboratories.

Costs to Local Government:

Local government would incur no new costs, except that local government-operated facilities providing regulated services under this proposal would incur the costs described for private regulated parties.

Paperwork:

The only new paperwork requirements imposed by this regulation are: (1) development and submission of relevant policies and procedures; (2) submission of a request for approval to perform critical agent testing; (3) development of chain-of-custody policies and procedures; (4) development of a tracking system for specimens; and (5) reporting of presumptively positive results to the Department.

Local Government Mandates:

The proposed regulations impose no new mandates on any county, city, town or village government; or school, fire or other special district, unless a county, city, town or village government; or school, fire or other special district operates an environmental laboratory, and, therefore, is subject to these regulations to the same extent as a private regulated party.

Duplication:

These rules do not duplicate any other law, rule or regulation, except that some terminology found in federal critical agent rules promulgated by the CDC has been used in this regulation to facilitate response coordination for domestic preparedness. Federal standards and recommendations for (bio) safety, sample collection, testing algorithms and reporting serve as the underpinnings of this rule, but are not duplicated therein.

This proposal is not duplicative of, but will harmonize with, anticipated Department of Environmental Conservation rules to address the treatment, handling and disposal of waste resulting from critical agent incidents and response to such incidents.

Alternative Approaches:

The alternative to adopting the proposed amendments is to apply the Department's existing standards to critical agents testing. However, because of the special issues raised by critical agent testing the Department has determined that the alternative of applying existing minimal requirements to this area is totally unacceptable.

Federal Standards:

Since there is no federal certification program in place for environmental laboratories, these regulations do not duplicate any federal standards. To the extent that the CDC, the U.S. Environmental Protection Agency, or the federal Department of Transportation have promulgated standards affecting environmental laboratory testing for evaluation of adverse public health events, these regulations are consistent with, and complement, such standards.

Compliance Schedule:

Regulated parties which are adequately staffed and equipped to perform critical agent testing in a safe and reliable manner should be able to comply with all aspects these regulations as of their effective date, upon publication of a Notice of Emergency Adoption in the New York *State Register*, except for obtaining the approval of the Department. The Department is prepared to approve laboratories for critical agent testing for select analytes, such as anthrax and the toxin, ricin, on an expedited basis. Thus, it is expected that laboratories that are fully prepared to undertake such testing may be approved within days of publication of this regulation. Laboratories that are not ready and able to meet the requirements of this regulation should not be engaged in such testing.

Regulatory Flexibility Analysis

Effect of Rule:

The Department's Environmental Laboratory Approval Program (ELAP) currently certifies 779 laboratories. Of these, 227 are located out-of-State and do not qualify as small businesses. Of the remaining 552 laboratories, 275 are governmental laboratories, and 277 are commercial entities, of which 170 are estimated to be small businesses. For the most part, governmental laboratories, which are primarily drinking water and sewage treatment plant laboratories operated by counties, municipalities and townships, are not expected to apply for the environmental testing specialty of critical agents, for which this amendment sets standards.

Of the approximately 900 facilities holding a New York State clinical laboratory permit, 135 qualify as small businesses, and 50 are owned and operated by local governments.

Compliance Requirements:

This proposed rule establishes minimum standards necessary to protect the public and laboratory employees from the health and safety risks inherent in critical agent testing. Due to the increased complexity and special issues presented by critical agent testing, this regulation establishes new requirements in addition to expanding several minimum standards now in place for environmental laboratories. However, the decision to engage in critical agent testing is strictly voluntary, and small businesses and local governments need to comply with the new and expanded requisites only if they operate environmental laboratories that apply for the specialty.

Proposed Section 55-2.13 sets forth minimum standards for: laboratory director and testing personnel qualifications; use of approved methods for sample collection and decontamination; recordkeeping systems to track the location of confirmed positive samples and isolated agents; sample chain-of-custody protocols; test result reporting procedures, including appropriate notification of the Department; client result reports content; sample and/or derivative referral protocols; and proficiency testing.

This regulation's requirement that laboratories retain records of sample tracking and access for ten years is consistent with the ten-year retention requirement for drinking water analysis records already in place. The Department has contacted numerous laboratories representing various types of ELAP-approved facilities, including commercial, industrial and government laboratories, and has determined that many of these laboratories, particularly those with electronic recordkeeping systems, are already retaining records for periods well in excess of five years.

Laboratories applying for approval in the specialty of critical agent testing will be required to submit their policies and procedures to the Department for review and approval to ensure adherence to approved methods and the requirements of this new section. Since such information, often in the format of manuals, is a universal component of all laboratories' operation, this should not be a burdensome requirement to regulated parties.

Professional Services:

No need for additional professional services is anticipated.

Compliance Costs:

It is not expected that the cost of compliance for small businesses and local governments will be different than for other regulated parties. With the possible exception of environmental testing conducted for public health purposes by county- or city-operated laboratories, the Department expects that costs could be offset by income from per-test or per-site charges imposed by a laboratory on its clients. The costs of compliance will vary significantly, primarily by a laboratory's existing biosafety level (e.g., BSL-2 or BSL-3) and whether it meets U.S. Centers for Disease Control and Prevention (CDC) safety and security requisites for handling the particular critical agent(s) and specimen type(s) it proposes to test. A laboratory already meeting CDC's safety and security standards is expected to incur no new costs. On the other hand, a small business or government-operated facility minimally equipped for handling infectious agents — because it limits testing to basic chemistry and microbiology testing to monitor drinking water, for instance — may accrue extensive renovation and/or construction costs in the unlikely event it wished to take on critical agent testing.

Since the regulation's initial filing, thirty facilities requested application information for certification in anthrax testing. Six laboratories have been granted certification in anthrax testing; of those six, two are operated by local governments, and one is a small business. The two government-operated laboratories required only minor modifications to existing facilities to comply with the proposed requisites for microbiologic testing; two additional government-operated laboratories are currently undergoing modifications in order to qualify for certification for anthrax testing. The costs of on-going modifications at the two applicant facilities are being funded through a National Centers for Disease Control and Prevention

(CDC) public health preparedness grant to New York State. No additional modifications would be necessary by facilities already certified for anthrax testing in order that they qualify for certification in critical agent testing for toxins.

Facilities which do not comply with these requirements currently may incur the following compliance costs: costs for purchase and installation of a state-of-the-art biological safety cabinet; costs for establishing negative air pressure conditions and adequate air filtration with space renovation or new construction; and costs for security systems, such as installation of card-key devices, and/or locks on entrances to storage and work areas.

According to manufacturers' estimates, costs for purchase and installation of a biological safety cabinet to meet minimal BSL-2 standards range from \$6,275 to \$11,365. Upgrading existing standard microbiology work-space to BSL-3 would require extensive modifications to usable space and air handling and filtration systems, and would be expected to result in costs comparable to new construction. According to vendors of modular construction, who gave estimates to public health officials in NYS and other states, costs for a 600-square foot BSL-3 building range from \$240,000 to \$500,000. Given the Department's experience thus far, it is unlikely that any commercial entity will choose to develop new BSL-3 capacity.

Relatively minor expenditures would be necessary for supplies related to sample collection, including personal protection gear, and secure storage of samples with presumptive or confirmed critical agent findings. Laboratory supply catalogues indicate that the two plastic zipper-lock bags per sample would cost less than \$1.00; a box of 100 disposable gloves costs approximately \$6.00; and a lockable refrigerator-freezer costs \$500. Costs to equip one individual sample collector or analyst with requisite personal protective equipment are estimated at a minimum of \$10 for one set of disposable outerwear comprised of gown, shoe covers and gloves, to a maximum of \$500 for a rechargeable self-contained breathing apparatus.

Costs related to security systems vary greatly, depending on the sophistication of the system (i.e., electronic or manual), and costs of maintenance and service contracts. According to estimates given by two manufacturers of card-key systems, one portal with card-key entry would cost \$5,000. One manufacturer of video surveillance equipment estimated that a laboratory installing a sixteen-camera system would incur costs of \$15,000. It is not possible to estimate operating and maintenance of security systems, since service contracts would vary according to the size of the system. Since no express requirements are in place for security equipment, a laboratory may control access to certain areas with stringent administrative controls, including sign-in logs and identification badges, at lower costs than a mechanical or electronic system.

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Most clinical laboratories interested in testing environmental samples for biological critical agents already employ laboratory directors and testing personnel who qualify under the proposed educational and experiential criteria. The majority of environmental laboratories certified to perform microbiology testing limit that testing to low biosafety level work (e.g., potable water testing), and generally do not employ personnel meeting the proposed requirements. While these sites would not incur additional personnel costs for analysts because of the proposal's grandfathering provision, requirements for a technical director would entail some added costs. According to a survey published in 2001 by the American Council of Independent Laboratories, the mean hiring rate for scientists with a bachelor's degree and one to three years' experience is \$38,900. A person with these credentials would meet the proposal's minimum requirements for a technical director of a laboratory performing anthrax testing on environmental samples. Since the regulation was first filed, the Department has found that none of the environmental laboratories currently limiting their services to monitoring of sewage and water treatment facilities are interested in performing critical agent testing. The majority of environmental

laboratories certified to perform chemical testing (i.e., for environmental contaminants) already employ personnel meeting the proposed requirements for toxin testing.

Laboratories applying for approval under these regulations will incur costs of approximately \$3.00 to \$20.00 to copy to the Department all policies and procedures relevant to critical agent testing. On occasion, a laboratory may incur costs for shipping presumptively positive samples to the Wadsworth Center or another designated facility for further testing. The cost of shipping an isolate of a microbiologic agent (e.g., a culture tube) by common carrier is estimated at between \$25 and \$50, depending on the need for keeping the agent's temperature constant with ice packs, for example. As an alternative, law enforcement officials, laboratory employees or couriers may be used for transporting samples at an anticipated maximum cost of \$350, assuming an 800-mile round trip and a \$25 hourly personnel wage.

Economic and Technological Feasibility:

The proposed regulation would present no economic or technological difficulties to small businesses and local governments that are not already presented by undertaking these activities in a safe and reliable manner. Appropriate equipment and supplies to perform critical agent testing in a safe and reliable manner are currently available should a laboratory choose to begin testing in this specialty. The regulation does not require any laboratory, regardless of ownership type, to undertake testing for critical agents.

Minimizing Adverse Impact:

This regulation imposes requirements only on those laboratories which choose to undertake critical agent testing. Standards have been established at the absolute minimum necessary for safe and reliable testing. The department did not consider different compliance requirements or exceptions for small businesses or local governments because of the importance of this type of testing to public health, safety and welfare.

Small Business and Local Government Participation:

In the development of these regulations, the Department had informal discussions with environmental and clinical laboratories concerning their interest in and capacity to perform critical agent testing. Some of these discussions occurred with small businesses and local governments. The Department believes that the urgent need for public health and safety oversight in the area of critical agent testing obviates the need for extensive solicitation of regulated party input at this time.

Rural Area Flexibility Analysis

Effect of Rule:

The Department's Environmental Laboratory Approval Program (ELAP) currently certifies 779 environmental laboratories. Of these, 227 are located out-of-State and are not considered to be in rural areas. Of the remaining 552 laboratories, 374 are located in rural areas. Of these 374 rural facilities, 198 currently hold certifications in bacteriology, including 56 laboratories operated by counties, municipalities and townships, local governments that only conduct procedures to monitor water treatment. For the most part, environmental laboratories affiliated with drinking water or sewage treatment are not expected to apply for the environmental testing specialty of critical agents, for which this amendment sets standards.

Of the approximately 900 facilities holding a New York State clinical laboratory permit, only 118 are located in areas designated as rural. Of these, only 85 currently hold permits in bacteriology general or virology general and would be possible candidates for testing microbiological critical agents. Of the 118 clinical laboratories designated rural, fewer than 50 currently hold permits in toxicology. The vast majority of these restricts on-site toxicological analysis to screening for drugs of abuse in the emergency room setting, and would not likely be candidates for testing for critical biological agents that are toxins.

Compliance Requirements:

This proposed rule establishes minimum standards necessary to protect the public and laboratory employees from the health and safety risks inherent in critical agent testing. Due to the increased complexity and special issues presented by critical agent testing, this regulation establishes new requirements in addition to expanding several minimum standards now in place for environmental laboratories. However, the decision to engage in critical agent testing is strictly voluntary, and a laboratory needs to comply with the new and expanded requisites only if it applies for the specialty.

Proposed Section 55-2.13 sets forth minimum standards for: laboratory director and testing personnel qualifications; use of approved methods for sample collection and decontamination; recordkeeping systems to track the location of confirmed positive samples and isolated agents; sample chain-of-custody protocols; test result reporting procedures, including ap-

propriate notification of the Department; client result reports content; sample and/or derivative referral protocols; and proficiency testing.

This regulation's requirement that laboratories retain records of sample tracking and access for ten years is consistent with the ten-year retention requirement for drinking water analysis records already in place. The Department has contacted numerous laboratories representing various types of ELAP-approved facilities, including commercial, industrial and government laboratories, and has determined that many of these laboratories, particularly those with electronic recordkeeping systems, are already retaining records for periods well in excess of five years.

Laboratories applying for approval in the specialty of critical agent testing will be required to submit their policies and procedures to the Department for review and approval to ensure adherence to approved methods and the requirements of this new section. Since such information, often in the format of manuals, is a universal component of all laboratories' operation, this should not be a burdensome requirement to regulated parties.

Professional Services:

No need for additional professional services is anticipated.

Compliance Costs:

It is not expected that the cost of compliance for applicant laboratories located in rural areas will be different than for other regulated parties. With the possible exception of environmental testing for public health purposes by county- or city-operated laboratories, the Department expects that costs could be offset by income from per-test or per-site charges imposed by a rural laboratory on its clients. The costs of compliance will vary significantly, primarily by a laboratory's existing biosafety level (e.g. BSL-2 or BSL-3) and whether it meets U.S. Centers for Disease Control and Prevention (CDC) safety and security requisites for handling the particular critical agent(s) and specimen type(s) it proposes to test. A laboratory already meeting CDC's safety and security standards is expected to incur no new costs. On the other hand, any facility minimally equipped for handling infectious agents — because it limits testing to basic chemistry and microbiology testing to monitor drinking water, for instance - may accrue extensive renovation and/or construction costs in the unlikely event it wished to take on critical agent testing.

Since the regulation's initial filing, thirty facilities requested application information for certification in anthrax testing. None of the six laboratories that have been granted certification in anthrax testing are located in a county having townships with population densities of 150 persons or less per square mile. The Department expects few, if any, environmental laboratories located in rural areas to apply for certification in toxin testing, even though it requires less stringent (i.e., BSL-2) biosafety facilities than those required for microbiological critical agent testing.

Facilities which do not comply with these requirements currently may incur the following compliance costs: costs for purchase and installation of a state-of-the-art biological safety cabinet; costs for establishing negative air pressure conditions and adequate air filtration with space renovation or new construction; and costs for security systems, such as installation of card-key devices, and/or locks on entrances to storage and work areas. According to manufacturers' estimates, costs for purchase and installation of a biological safety cabinet to meet minimal BSL-2 standards range from \$6,275 to \$11,365. Upgrading existing standard microbiology workspace to BSL-3 would require extensive modifications to usable space and air handling and filtration systems, and would be expected to result in costs comparable to new construction. According to vendors of modular construction, who gave estimates to public health officials in NYS and other states, costs for a 600-square foot BSL-3 building range from \$240,000 to \$500,000. Given the Department's experience thus far, it is unlikely that any commercial entity will choose to develop new BSL-3 capacity.

Relatively minor expenditures would be necessary for supplies related to sample collection, including personal protection gear, and secure storage of samples with presumptive or confirmed critical agent findings. Laboratory supply catalogues indicate that the two plastic zipper-lock bags per sample would cost less than \$1.00; a box of 100 disposable gloves costs approximately \$6.00; and a lockable refrigerator-freezer costs \$500. Costs to equip one individual sample collector or analyst with requisite personal protective equipment are estimated at a minimum of \$10 for one set of disposable outerwear comprised of gown, shoe covers and gloves, to a maximum of \$500 for a rechargeable self-contained breathing apparatus.

Costs related to security systems vary greatly, depending on the sophistication of the system (i.e., electronic or manual), and costs of maintenance and service contracts. According to estimates given by two manufacturers of card-key systems, one portal with card-key entry would cost \$5,000. One manufacturer of video surveillance equipment estimated that a labora-

tory installing a sixteen-camera system would incur costs of \$15,000. It is not possible to estimate operating and maintenance of security systems, since service contracts would vary according to the size of the system. Since no express requirements are in place for security equipment, a laboratory may control access to certain areas with stringent administrative controls, including sign-in logs and identification badges, at lower costs than a mechanical or electronic system.

Clinical laboratories seeking certification as environmental laboratories, as well as previously unregulated commercial concerns offering environmental testing (e.g., for anthrax on surfaces), will need to pay approval fees equivalent to first-year Department Environmental Laboratory Approval Program (ELAP) fees, estimated at \$550. Clinical laboratories and previously unregulated facilities may also incur compliance costs similar to those for existing environmental laboratories described above. Based on a written survey of clinical laboratories currently licensed in the category of microbiology pursuant to Public Health Law Article 5, Title V, the Department estimates that 73 percent of these laboratories have existing capability for critical agent testing and would not need to expend significant resources for biosafety facilities unless they need to purchase personal protective equipment and related items to comply with the more stringent safety practices for critical agents testing. Clinical laboratories that conduct toxicology analyses and environmental laboratories that conduct chemical testing (e.g., for environmental contaminants) already have in place adequate biosafety facilities for toxin testing and would not need to expend significant resources to meet this amendment's requisites.

Most clinical laboratories interested in testing environmental samples for biological critical agents already employ laboratory directors and testing personnel who qualify under the proposed educational and experiential criteria. The majority of environmental laboratories certified to perform microbiology testing limit that testing to low biosafety level work (e.g., potable water testing), and generally do not employ personnel meeting the proposed requirements. While these sites would not incur additional personnel costs for analysts because of the proposal's grandfathering provision, requirements for a technical director would entail some added costs. According to a survey published in 2001 by the American Council of Independent Laboratories, the mean hiring rate for scientists with a bachelor's degree and one to three years' experience is \$38,900. A person with these credentials would meet the proposal's minimum requirements for a technical director of a laboratory performing anthrax testing on environmental samples. Since the regulation was first filed, the Department has found that none of the environmental laboratories currently limiting their services to monitoring of sewage and water treatment facilities are interested in performing critical agent testing. The majority of environmental laboratories certified to perform chemical testing (e.g., for environmental contaminants) already employ personnel meeting the proposed requirements for toxin testing.

Rural laboratories applying for approval under these regulations will incur costs of approximately \$3.00 to \$20.00 to copy to the Department all policies and procedures relevant to critical agent testing. On occasion, a laboratory may incur costs for shipping presumptively positive samples to the Wadsworth Center or another designated facility for further testing. The cost of shipping an isolate of a microbiologic agent (e.g., a culture tube) by common carrier is estimated at between \$25 and \$50, depending on the need for keeping the agent's temperature constant with ice packs, for example. As an alternative, law enforcement officials, laboratory employees or couriers may be used for transporting samples at an anticipated maximum cost of \$350, assuming an 800-mile round trip and a \$25 hourly personnel wage.

Economic and Technological Feasibility:

The proposed regulation would present no economic or technological difficulties to facilities located in rural areas that are not already presented by undertaking these activities in a safe and reliable manner. Appropriate equipment and supplies to perform critical agent testing in a safe and reliable manner are currently available should a laboratory choose to begin testing in this specialty. The regulation does not require any laboratory, regardless of location, to undertake testing for critical agents.

Minimizing Adverse Impact:

This regulation only imposes requirements on laboratories choosing to undertake critical agent testing. Standards have been established at the absolute minimum necessary for safe and reliable testing. The department did not consider different compliance requirements or exceptions for facilities located in rural areas because of the importance of this type of testing to public health, safety and welfare.

Participation by Parties in Rural Areas:

In the development of these regulations, the Department had informal discussions with environmental and clinical laboratories concerning their interest in and capacity to perform critical agent testing. Few, if any, rural laboratories chose to participate in these discussions. The Department believes that the urgent need for public health and safety oversight in the area of critical agent testing obviates the need for extensive solicitation of regulated party input at this time.

Job Impact Statement

A Job Impact Statement is not required because it is apparent, from the nature and purpose of the proposed rule, that it will not have a substantial adverse impact on jobs and employment opportunities. The revision proposes minimum standards for a recently recognized specialty of environmental laboratory testing, i.e., critical agent testing. No requirement is imposed that a laboratory be certified in this specialty, and the Department expects that, of the small number of laboratories anticipated to seek certification in critical agent testing, few, if any, will need to take on additional capacity in the form of hiring new personnel. Therefore, this proposed amendment has no implications for job opportunities.

Industrial Board of Appeals

NOTICE OF ADOPTION

Inspection and Reproduction of Documents

I.D. No. IBA-11-04-00012-A

Filing No. 550

Filing date: May 11, 2004

Effective date: May 26, 2004

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following action:

Action taken: Amendment of section 65.52 of Title 12 NYCRR.

Statutory authority: Labor Law, section 101

Subject: Inspection and reproduction of documents.

Purpose: To clarify that the inspection and reproduction of any board documents will take place in the board's Albany office, and that any costs will be as set forth under section 73.5 of this Subchapter, concerning costs under F.O.I.L.

Text or summary was published in the notice of proposed rule making, I.D. No. IBA-11-04-00012-P, Issue of March 17, 2004.

Final rule as compared with last published rule: No changes.

Text of rule and any required statements and analyses may be obtained from: John G. Binseel, Industrial Board of Appeals, Empire State Plaza, Agency Bldg. 2, 20th Fl., Albany, NY 12223, (518) 474-4785, e-mail: USCJGB@labor.state.ny.us

Assessment of Public Comment

The agency received no public comment.

NOTICE OF ADOPTION

Joint Hearing of Proceedings

I.D. No. IBA-11-04-00013-A

Filing No. 551

Filing date: May 11, 2004

Effective date: May 26, 2004

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following action:

Action taken: Amendment of section 65.48 of Title 12 NYCRR.

Statutory authority: Labor Law, section 101

Subject: Joint hearing of proceedings.

Purpose: To clarify that joint hearing may be held where the same or similar facts are involved.

Text or summary was published in the notice of proposed rule making, I.D. No. IBA-11-04-00013-P, Issue of March 17, 2004.

Final rule as compared with last published rule: No changes.

Text of rule and any required statements and analyses may be obtained from: John G. Binseel, Industrial Board of Appeals, Empire

State Plaza, Agency Bldg. 2, 20th Fl., Albany, NY 12223, (518) 474-4785, e-mail: USCJGB@labor.state.ny.us

Assessment of Public Comment

The agency received no public comment.

NOTICE OF ADOPTION

Standards of Conduct

I.D. No. IBA-11-04-00014-A

Filing No. 559

Filing date: May 11, 2004

Effective date: May 26, 2004

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following action:

Action taken: Amendment of section 65.46 of Title 12 NYCRR.

Statutory authority: Labor Law, section 101

Subject: Standards of conduct.

Purpose: To clarify that the applicable and appropriate standards of conduct before the board are the same as applicable in the courts of the State of New York.

Text or summary was published in the notice of proposed rule making, I.D. No. IBA-11-04-00014-P, Issue of March 17, 2004.

Final rule as compared with last published rule: No changes.

Text of rule and any required statements and analyses may be obtained from: John G. Binseel, Industrial Board of Appeals, Empire State Plaza, Agency Bldg. 2, 20th Fl., Albany, NY 12223, (518) 474-4785, e-mail: USCJGB@labor.state.ny.us

Assessment of Public Comment

The agency received no public comment.

NOTICE OF ADOPTION

Exhibits

I.D. No. IBA-11-04-00015-A

Filing No. 558

Filing date: May 11, 2004

Effective date: May 26, 2004

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following action:

Action taken: Amendment of section 65.35 of Title 12 NYCRR.

Statutory authority: Labor Law, section 101

Subject: Exhibits.

Purpose: To clarify that a copy of each exhibit being offered into evidence at a hearing must be given by the offering party to any other parties, and the board.

Text or summary was published in the notice of proposed rule making, I.D. No. IBA-11-04-00015-P, Issue of March 17, 2004.

Final rule as compared with last published rule: No changes.

Text of rule and any required statements and analyses may be obtained from: John G. Binseel, Industrial Board of Appeals, Empire State Plaza, Agency Bldg. 2, 20th Fl., Albany, NY 12223, (518) 474-4785, e-mail: USCJGB@labor.state.ny.us

Assessment of Public Comment

The agency received no public comment.

NOTICE OF ADOPTION

Filing of Briefs; Oral Argument at Hearing

I.D. No. IBA-11-04-00016-A

Filing No. 560

Filing date: May 11, 2004

Effective date: May 26, 2004

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following action:

Action taken: Amendment of section 65.36 of Title 12 NYCRR.

Statutory authority: Labor Law, section 101

Subject: Filing of briefs and proposed findings with the board; oral argument at the hearing.

Purpose: To clarify that the hearing officer shall fix a reasonable time period for the filing of any briefs, and delete the provision that such time period may not exceed 30 days.

Text or summary was published in the notice of proposed rule making, I.D. No. IBA-11-04-00016-P, Issue of March 17, 2004.

Final rule as compared with last published rule: No changes.

Text of rule and any required statements and analyses may be obtained from: John G. Binseel, Industrial Board of Appeals, Empire State Plaza, Agency Bldg. 2, 20th Fl., Albany, NY 12223, (518) 474-4785, e-mail: USCJGB@labor.state.ny.us

Assessment of Public Comment

The agency received no public comment.

NOTICE OF ADOPTION

Deposition in Lieu of Oral Testimony

I.D. No. IBA-11-04-00017-A

Filing No. 557

Filing date: May 11, 2004

Effective date: May 26, 2004

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following action:

Action taken: Amendment of section 65.34 of Title 12 NYCRR.

Statutory authority: Labor Law, section 101

Subject: Deposition in lieu of oral testimony; application; procedures; form; rulings.

Purpose: To clarify that any request for the deposition of a witness in lieu of oral testimony will only be allowed in exigent circumstances.

Text or summary was published in the notice of proposed rule making, I.D. No. IBA-11-04-00017-P, Issue of March 17, 2004.

Final rule as compared with last published rule: No changes.

Text of rule and any required statements and analyses may be obtained from: John G. Binseel, Industrial Board of Appeals, Empire State Plaza, Agency Bldg. 2, 20th Fl., Albany, NY 12223, (518) 474-4785, e-mail: USCJGB@labor.state.ny.us

Assessment of Public Comment

The agency received no public comment.

NOTICE OF ADOPTION

Failure to Appear at a Scheduled Administrative Hearing

I.D. No. IBA-11-04-00018-A

Filing No. 556

Filing date: May 11, 2004

Effective date: May 26, 2004

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following action:

Action taken: Amendment of section 65.24 of Title 12 NYCRR.

Statutory authority: Labor Law, section 101

Subject: Failure to appear at a scheduled administrative hearing.

Purpose: To clarify that any request for reinstatement must be made within five days after the scheduled hearing date.

Text or summary was published in the notice of proposed rule making, I.D. No. IBA-11-04-00018-P, Issue of March 17, 2004.

Final rule as compared with last published rule: No changes.

Text of rule and any required statements and analyses may be obtained from: John G. Binseel, Industrial Board of Appeals, Empire State Plaza, Agency Bldg. 2, 20th Fl., Albany, NY 12223, (518) 474-4785, e-mail: USCJGB@labor.state.ny.us

Assessment of Public Comment

The agency received no public comment.

NOTICE OF ADOPTION

Postponement of a Scheduled Administrative Hearing

I.D. No. IBA-11-04-00019-A

Filing No. 561

Filing date: May 11, 2004

Effective date: May 26, 2004

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following action:

Action taken: Amendment of section 65.23 of Title 12 NYCRR.

Statutory authority: Labor Law, section 101

Subject: Postponement of a scheduled administrative hearing.

Purpose: To amend, from three days to seven days, the amount of time in advance that a party must request a non-emergency postponement of a scheduled administrative hearing.

Text or summary was published in the notice of proposed rule making, I.D. No. IBA-11-04-00019-P, Issue of March 17, 2004.

Final rule as compared with last published rule: No changes.

Text of rule and any required statements and analyses may be obtained from: John G. Binseel, Industrial Board of Appeals, Empire State Plaza, Agency Bldg. 2, 20th Fl., Albany, NY 12223, (518) 474-4785, e-mail: USCJGB@labor.state.ny.us

Assessment of Public Comment

The agency received no public comment.

NOTICE OF ADOPTION

Withdrawal of Petition or Application

I.D. No. IBA-11-04-00020-A

Filing No. 555

Filing date: May 11, 2004

Effective date: May 26, 2004

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following action:

Action taken: Amendment of section 65.15 of Title 12 NYCRR.

Statutory authority: Labor Law, section 101

Subject: Withdrawal of petition or application.

Purpose: To simplify the procedure used in withdrawing a petition or application previously filed with the board, by recognizing that any party may withdraw an appeal at any time, and remove the procedural requirement that a party must apply for approval to withdraw.

Text or summary was published in the notice of proposed rule making, I.D. No. IBA-11-04-00020-P, Issue of March 17, 2004.

Final rule as compared with last published rule: No changes.

Text of rule and any required statements and analyses may be obtained from: John G. Binseel, Industrial Board of Appeals, Empire State Plaza, Agency Bldg. 2, 20th Fl., Albany, NY 12223, (518) 474-4785, e-mail: USCJGB@labor.state.ny.us

Assessment of Public Comment

The agency received no public comment.

NOTICE OF ADOPTION

Form of Pleadings

I.D. No. IBA-11-04-00021-A

Filing No. 554

Filing date: May 11, 2004

Effective date: May 26, 2004

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following action:

Action taken: Amendment of section 65.11 of Title 12 NYCRR.

Statutory authority: Labor Law, section 101

Subject: Form of pleadings filed with the board.

Purpose: To simplify the format to be used for any pleading filed with the board.

Text or summary was published in the notice of proposed rule making, I.D. No. IBA-11-04-00021-P, Issue of March 17, 2004.

Final rule as compared with last published rule: No changes.

Text of rule and any required statements and analyses may be obtained from: John G. Binseel, Industrial Board of Appeals, Empire State Plaza, Agency Bldg. 2, 20th Fl., Albany, NY 12223, (518) 474-4785, e-mail: USCJGB@labor.state.ny.us

Assessment of Public Comment

The agency received no public comment.

NOTICE OF ADOPTION

Computation of Time Periods

I.D. No. IBA-11-04-00022-A

Filing No. 553

Filing date: May 11, 2004

Effective date: May 26, 2004

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following action:

Action taken: Amendment of section 65.3 of Title 12 NYCRR.

Statutory authority: Labor Law, section 101

Subject: Computation of time period prescribed within the rules.

Purpose: To standardize response time periods in the rules, and introduce into the rules an addition to the CPLR (section 2103[b][6]), which recognizes service of interlocutory papers by overnight delivery services.

Text or summary was published in the notice of proposed rule making, I.D. No. IBA-11-04-00022-P, Issue of March 17, 2004.

Final rule as compared with last published rule: No changes.

Text of rule and any required statements and analyses may be obtained from: John G. Binseel, Industrial Board of Appeals, Empire State Plaza, Agency Bldg. 2, 20th Fl., Albany, NY 12223, (518) 474-4785, e-mail: USCJGB@labor.state.ny.us

Assessment of Public Comment

The agency received no public comment.

NOTICE OF ADOPTION

Application

I.D. No. IBA-11-04-00023-A

Filing No. 552

Filing date: May 11, 2004

Effective date: May 26, 2004

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following action:

Action taken: Amendment of section 65.1 of Title 12 NYCRR.

Statutory authority: Labor Law, section 101

Subject: Application of the board's rules.

Purpose: To emphasize and clarify that, in applying the board's rules to proceedings filed pursuant to Labor Law section 101, time periods which have been prescribed by statute cannot be extended.

Text or summary was published in the notice of proposed rule making, I.D. No. IBA-11-04-00023-P, Issue of March 17, 2004.

Final rule as compared with last published rule: No changes.

Text of rule and any required statements and analyses may be obtained from: John G. Binseel, Industrial Board of Appeals, Empire State Plaza, Agency Bldg. 2, 20th Fl., Albany, NY 12223, (518) 474-4785, e-mail: USCJGB@labor.state.ny.us

Assessment of Public Comment

The agency received no public comment.

Office of Mental Health

EMERGENCY RULE MAKING

Patients Committed to the Custody of the Commissioner

I.D. No. OMH-15-04-00002-E

Filing No. 548

Filing date: May 11, 2004

Effective date: May 11, 2004

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following action:

Action taken: Amendment of Part 540 of Title 14 NYCRR.

Statutory authority: Mental Hygiene Law, sections 7.09(b)-(c) and 31.04(a); and Criminal Procedure Law, art. 730

Finding of necessity for emergency rule: Preservation of public safety.
Specific reasons underlying the finding of necessity: This rule is necessary to streamline the currently lengthy and involved process of making determinations regarding fitness to stand trial and return to court of patients against whom criminal charges are pending.

Subject: Patients committed to the custody of the commissioner.

Purpose: To establish a faster and more appropriate process for determination of fitness to stand trial and return to court of a patient against whom criminal charges are pending.

Substance of emergency rule: Part 540 currently provides that the clinical director of a State operated forensics facility may apply to the court for the return of a patient in the custody of his or her facility where that patient's mental status has changed in terms of their capability of understanding the court proceedings and participating in their own defense. The current regulation involves a review by the hospital forensic committee in accordance with requirements of Section 540.9. This rule will streamline the process of making determinations regarding the fitness to stand trial and the return to court of the patients involved. It will establish that the clinical director is responsible for determining whether a patient remains an incapacitated person or is fit to stand trial. It outlines that the clinical director may designate certain facility psychiatrists to examine the patient and prepare a report and recommendation to the clinical director. While the clinical director will review and consider these recommendations, he or she need not follow them.

This notice is intended to serve only as a notice of emergency adoption. This agency intends to adopt the provisions of this emergency rule as a permanent rule, having previously published a notice of proposed rule making, I.D. No. OMH-15-04-00002-P, Issue of April 14, 2004. The emergency rule will expire July 9, 2004.

Text of emergency rule and any required statements and analyses may be obtained from: Dan Odell, Bureau of Policy, Legislation and Regulation, Office of Mental Health, 44 Holland Ave., Albany, NY 12229, (518) 473-6945, e-mail: dodell@omh.state.ny.us

Regulatory Impact Statement

1. Statutory authority: §§ 7.09(b), 7.09(c) and Section 31.04(a) of the Mental Hygiene Law grant the Commissioner of the Office of Mental Health the authority and responsibility to adopt regulations that are necessary and proper to implement matters under his jurisdiction, the authority to administer the forensic psychiatric program, and the power to adopt regulations for quality control, respectively. Article 730 of the Criminal Procedure Law establishes the role of the Commissioner of Mental Health in the process of determining the fitness to stand trial.

2. Legislative objectives: Article 7 and Article 31 of the Mental Hygiene Law reflect the Commissioner's authority to establish regulations regarding mental health programs. Article 730 of the Criminal Procedure Law reflects the role of the Commissioner of Mental Health in the process of determining the fitness to stand trial.

3. Needs and benefits: This amendment will streamline proper decision making regarding changes in custody status of patients who have been committed to the custody of an Office of Mental Health (OMH) forensic facility by a criminal court after having been found to have a mental illness which renders them incapable of understanding the court proceedings against them or participating in their own defense. OMH has a responsibility to take steps, in the interest of public safety, to see that these individuals are kept at the appropriate level of custody and are promptly returned to the court when their mental status changes.

Currently Part 540 provides that the clinical director may apply to the court for the return of a patient in the custody of his or her facility where that patient's mental status has changed in terms of their capability of understanding the court proceedings and participating in their own defense. The current regulation involves a review by the hospital forensic committee in accordance with requirements of Section 540.9. The hospital forensic committee reviews, due to difficulty of scheduling and additional paperwork, often consume a period of several weeks. This adds unnecessarily to the patient's length of stay and delays the defendant's ability to face a fair and speedy trial. It also results in over crowding as patients who might otherwise return to court await the committee's action. This situation has become critical and immediate action is necessary to address it.

This rule will streamline the process of making determinations regarding the fitness to stand trial and the return to court of the patients involved. It will establish that the clinical director is responsible for determining whether a patient remains an incapacitated person or is fit to stand trial. It outlines that the clinical director may designate certain facility psychiatrists to examine the patient and prepare a report and recommendation to

the clinical director. While the clinical director will review and consider these recommendations, he or she need not follow them.

In summary, this amendment streamlines the process of determining fitness to stand trial. It supports sound decision making and it maintains the final decision making authority of the clinical director. This new process will meet all the requirements and expectations of the court orders involved.

4. Costs: It is estimated that this amendment could result in a savings of at least 2,000 hours of staff time per year at Mid-Hudson Forensic Psychiatric Center. It is also estimated that by streamlining this process there will be a reduction at that facility in patient length of stay, averaging between 14 to 21 days and resulting in a savings to the State of at least \$100,000 in associated costs.

There will also be significant savings to local governments. As required by subdivision (c) of Section 43.03 of the Mental Hygiene Law, the costs of care of patients receiving services while being held pursuant to order of a criminal court must be paid by the county in which such court is located. OMH currently provides services to approximately 350 patients admitted under Article 730 of the Criminal Procedure Law. Counties are currently billed at a rate of \$301.00 per day of inpatient service. Based on an estimated 14 to 21 days reduction in length of stay the annual savings to counties, on a statewide basis, will be between \$1,475,000 to \$2,212,000.

5. Local government mandates: These regulatory amendments will not result in any additional imposition of duties or responsibilities upon county, city, town, village, school or fire districts. This regulation applies only to state-operated forensic facilities.

6. Paperwork: This rule should decrease and simplify the paperwork requirements.

7. Duplication: These regulatory amendments do not duplicate existing State or federal requirements.

8. Alternatives: The only alternative to the regulatory amendment which was considered was inaction. This alternative was rejected. This change is critical and is needed immediately to address census and staffing issues, improve treatment for patients, and provide for a safer environment for patients and staff.

9. Federal standards: The regulatory amendments do not exceed any minimum standards of the federal government for the same or similar subject areas.

10. Compliance schedule: These regulatory amendments will be effective upon their adoption.

Regulatory Flexibility Analysis

A Regulatory Flexibility Analysis for Small Businesses and Local Governments is not being submitted with this notice because the amended rule will not impose any adverse economic impact on small businesses, or local governments. There will be significant savings to local governments. As required by subdivision (c) of Section 43.03 of the Mental Hygiene Law, the costs of care of patients receiving services while being held pursuant to order of a criminal court must be paid by the county in which such court is located. OMH currently provides services to approximately 350 patients admitted under Article 730 of the Criminal Procedure Law. Counties are currently billed at a rate of \$301.00 per day of inpatient service. Based on an estimated 14 to 21 days reduction in length of stay the annual savings to counties, on a statewide basis, will be \$1,475,000 to \$2,212,000.

Rural Area Flexibility Analysis

A Rural Area Flexibility Analysis is not being submitted with this notice because the amended rules will not impose any adverse economic impact on rural areas. This rule will have a positive economic impact on rural counties.

There will be significant savings to rural county governments. As required by subdivision (c) of Section 43.03 of the Mental Hygiene Law, the costs of care of patients receiving services while being held pursuant to order of a criminal court must be paid by the county in which such court is located. OMH provides services to approximately 350 patients admitted under Article 730 of the Criminal Procedure Law. Counties are currently billed at a rate of \$301.00 per day of inpatient service. Based on an estimated 14 to 21 days reduction in length of stay the annual savings to counties, on a statewide basis, will be between \$1,475,000 to \$2,212,000.

Rural counties have been especially concerned about these costs since they can have a proportionately larger budget impact and are difficult to plan for or to address in the local budget process.

Job Impact Statement

A Job Impact Statement is not being submitted with this notice because it is apparent from the nature and purpose of this rule that it involves procedural changes to custody determinations regarding patients at state operated forensic facilities and will not have any adverse impact on jobs

and employment activities. It will have a positive impact on staffing at Mid-Hudson Forensic Psychiatric Center by reducing the amount of staff time necessary to conduct reviews and prepare documentation regarding custody determinations under Criminal Procedure Law Article 730.

Department of Motor Vehicles

NOTICE OF ADOPTION

Drinking Driver Program

I.D. No. MTV-10-04-00023-A

Filing No. 547

Filing date: May 11, 2004

Effective date: May 26, 2004

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following action:

Action taken: Amendment of Part 134 of Title 15 NYCRR.

Statutory authority: Vehicle and Traffic Law, sections 215(a), 1196(1) and (6)

Subject: Drinking Driver Program.

Purpose: To increase the fees.

Text or summary was published in the notice of proposed rule making, I.D. No. MTV-10-04-00023-P, Issue of March 10, 2004.

Final rule as compared with last published rule: No changes.

Text of rule and any required statements and analyses may be obtained from: Michele Welch, Counsel's Office, Department of Motor Vehicles, Empire State Plaza, Swan St. Bldg., Rm. 526, Albany, NY 12228, (518) 474-0871, e-mail: mwelc@dmv.state.ny.us

Assessment of Public Comment

The Department received a comment from the NYS Drinking Driver Program Director's Association expressing the support and appreciation from its full membership for the advancement of the proposed regulatory change.

The Department also received a comment from one DDP provider who suggested making DDP attendance mandatory for first-time drunk driving offenders. The commenter also expressed full support for the development of a student workbook.

Response: There is no statutory authority to mandate DDP attendance for first time drunk offenders. Furthermore, the comments pertaining to mandatory DDP attendance are outside the scope of this rule.

Another DDP provider recommended that the DDP fee be increased by an additional \$5. The provider also expressed support for the workbook, but added that the addition of a workbook for the program for a cost may add to the provider's tight budget. The provider expressed doubt that a third party contractor could produce the workbooks for \$5. The provider had questions about what would happen to a student who is dropped from the program and has not paid the program fee, but was given a workbook or who transfers from another program.

Response: After meeting with DDP providers several times and analyzing fiscal information from the DDP providers, the Department determined that the proposed \$50 increase was an appropriate amount necessary to defray the actual expenses of the DDP. The Department had considered increasing the DDP fee by a smaller amount, but it was determined that such an inconsequential increase would not significantly affect the DDP providers. The Department has also conducted research to determine that a workbook can be produced for the proposed \$5 fee.

Section 134.14 of the Commissioner's Regulations (a)(2) provides that the portion of the DDP fee required for enrollment in a program shall be paid by the applicant prior to entry into the program to the entity authorized by the Department to conduct a rehabilitation program, and that such fee shall not be refundable unless the person is denied enrollment in the program upon his application. The regulation also provides that no portion of the fee shall be refundable by reason of the participant's withdrawal or expulsion from the program.

If the participant is unable to complete the program in the agency where he/she began, a transfer fee will be paid to the new DDP, as per section

134.14(c) of the Commissioner's Regulations. The enrollee is entitled to keep the workbook if he/she has paid the enrollment fee and can take that workbook to the re-entry program.

NOTICE OF ADOPTION

Drivers' Schools

I.D. No. MTV-11-04-00028-A

Filing No. 546

Filing date: May 11, 2004

Effective date: May 26, 2004

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following action:

Action taken: Amendment of section 76.15(e) of Title 15 NYCRR.

Statutory authority: Vehicle and Traffic Law, sections 215(a) and 394(8)

Subject: Drivers' schools.

Purpose: To eliminate the fixed expiration date of June 30th for driving school instructor certificates and establish September 30th as the date of expiration for such certificates.

Text or summary was published in the notice of proposed rule making, I.D. No. MTV-11-04-00028-P, Issue of March 17, 2004.

Final rule as compared with last published rule: No changes.

Text of rule and any required statements and analyses may be obtained from: Michele Welch, Counsel's Office, Department of Motor Vehicles, Empire State Plaza, Swan St. Bldg., Rm. 526, Albany, NY 12228, (518) 474-0871, e-mail: mwelc@dmv.state.ny.us

Assessment of Public Comment

The agency received no public comment.

Public Service Commission

NOTICE OF ADOPTION

Plattsburgh Airbase Redevelopment Corporation and its Electric Customers

I.D. No. PSC-43-03-00034-A

Filing date: May 5, 2004

Effective date: May 5, 2004

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following action:

Action taken: The commission, on May 5, 2004, adopted an order in Case 03-E-1463, authorizing revisions to New York State Electric & Gas Corporation's (NYSEG) schedule for electric service, P.S.C. No. 115.

Statutory authority: Public Service Law, section 66(12)

Subject: Tariff filing by New York State Electric & Gas Corporation.

Purpose: To convert Plattsburgh Airbase Redevelopment Corporation (PARC) and its customers from PARC rates to NYSEG tariff rates.

Substance of final rule: The Commission approved New York State Electric & Gas Corporation's tariff filing to transition Plattsburgh Airbase Redevelopment Corporation and its customers to NYSEG tariff rates over a two year period.

Final rule compared with proposed rule: No changes.

Text of rule may be obtained from: Central Operations, Public Service Commission, Bldg. 3, 14th Fl., Empire State Plaza, Albany, NY 12223-1350, by fax to (518) 474-9842, by calling (518) 474-2500. An IRS employer ID no. or social security no. is required from firms or persons to be billed 25 cents per page. Please use tracking number found on last line of notice in requests.

Assessment of Public Comment

An assessment of public comment is not submitted with this notice because the rule is within the definition contained in section 102(2)(a)(ii) of the State Administrative Procedure Act. (03-E-1463SA1)

NOTICE OF ADOPTION

Mini Rate Increase by Hamilton Municipal Utilities Commission

I.D. No. PSC-06-04-00010-A
Filing date: May 7, 2004
Effective date: May 7, 2004

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following action:

Action taken: The commission, on May 5, 2004, adopted an order in Case 04-E-0072 approving revisions to Hamilton Municipal Utilities Commission's tariff schedule, P.S.C. No. 1—Electricity.

Statutory authority: Public Service Law, section 66(12)

Subject: Tariff filing for mini rate increase.

Purpose: To support increasing labor costs and future capital projects and purchases.

Substance of final rule: The Commission approved a request by Hamilton Municipal Utilities Commission (Hamilton) to increase its annual revenues of \$299,999 or 13.2% and authorized Hamilton to use a \$260,547 transmission refund from New York State Electric & Gas Corporation to offset the costs of capital projects, subject to the terms and conditions set forth in the order.

Final rule compared with proposed rule: No changes.

Text of rule may be obtained from: Central Operations, Public Service Commission, Bldg. 3, 14th Fl., Empire State Plaza, Albany, NY 12223-1350, by fax to (518) 474-9842, by calling (518) 474-2500. An IRS employer ID no. or social security no. is required from firms or persons to be billed 25 cents per page. Please use tracking number found on last line of notice in requests.

Assessment of Public Comment

An assessment of public comment is not submitted with this notice because the rule is within the definition contained in section 102(2)(a)(ii) of the State Administrative Procedure Act. (04-E-0072SA1)

NOTICE OF ADOPTION

Expired Tariff Options by Niagara Mohawk Power Corporation

I.D. No. PSC-09-04-00014-A
Filing date: May 5, 2004
Effective date: May 5, 2004

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following action:

Action taken: The commission, on May 5, 2004, adopted an order in Case 04-E-0156, allowing Niagara Mohawk Power Corporation (Niagara Mohawk) to amend its tariff schedule, P.S.C. No. 207.

Statutory authority: Public Service Law, section 66(12)

Subject: Tariff filing to modify Niagara Mohawk's electric tariff schedule.

Purpose: To eliminate sections of Niagara Mohawk's tariff schedule that have expired and are no longer applicable to customers.

Substance of final rule: The Commission approved a request by Niagara Mohawk Power Corporation (Niagara Mohawk) to remove expired tariff options from S.C. No. 3A — Large General Service — Time of Use Rates and S.C. No. 12 — Special Contract Rates contained in Niagara Mohawk's tariff schedule, P.S.C. 207.

Final rule compared with proposed rule: No changes.

Text of rule may be obtained from: Central Operations, Public Service Commission, Bldg. 3, 14th Fl., Empire State Plaza, Albany, NY 12223-1350, by fax to (518) 474-9842, by calling (518) 474-2500. An IRS employer ID no. or social security no. is required from firms or persons to be billed 25 cents per page. Please use tracking number found on last line of notice in requests.

Assessment of Public Comment

An assessment of public comment is not submitted with this notice because the rule is within the definition contained in section 102(2)(a)(ii) of the State Administrative Procedure Act. (04-E-0156SA1)

PROPOSED RULE MAKING HEARING(S) SCHEDULED

Deferral and Allocation of Property Tax Refund by United Water New York, Inc.

I.D. No. PSC-21-04-00017-P

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following proposed rule:

Proposed action: The Public Service Commission is considering whether to approve or reject, in whole or in part, a petition filed by United Water New York, Inc. for allocation of a \$84,489.80 property tax refund received from the Ramapo School District.

Statutory authority: Public Service Law, sections 89-C(3) and 113(2)

Subject: Deferral and allocation of property tax refund.

Purpose: To determine accounting and allocation of property tax refund received by United Water New York, Inc.

Public hearing(s) will be held at: 10:00 a.m., June 18, 2004 at Three Empire State Plaza, Third Fl., Albany, NY.

Accessibility: All public hearings have been scheduled at places reasonably accessible to persons with a mobility impairment.

Interpreter Service: Interpreter services will be made available to deaf persons, at no charge, upon written request submitted within reasonable time prior to the scheduled public hearing. The written request must be addressed to the agency representative designated in the paragraph below.

Substance of proposed rule: On July 22, 2003 United Water New York, Inc. (UWNY) informed the Public Service Commission that it received property tax refunds in the amount of \$84,489.80. The company proposes to follow guidelines outlined in the multi-year Settlement Agreement in Case 94-W-0486, and would defer \$63,367 for subsequent return to its customers and retain \$21,122. The Commission will consider whether to approve or reject, in whole or in part, the United Water New York, Inc. proposal.

Text of proposed rule may be obtained from: Margaret Maguire, Public Service Commission, Bldg. 3, Empire State Plaza, Albany, NY 12223-1350, (518) 474-3204

Data, views or argument may be submitted to: Jaelyn A. Brilling, Acting Secretary, Public Service Commission, Bldg. 3, Empire State Plaza, Albany, NY 12223-1350, (518) 474-6530

Public comment will be received until: 45 days after publication of this notice.

Regulatory Impact Statement, Regulatory Flexibility Analysis, Rural Area Flexibility Analysis and Job Impact Statement

Statements and analyses are not submitted with this notice because the proposed rule is within the definition contained in section 102(2)(a)(ii) of the State Administrative Procedure Act. (03-W-1170SA2)

PROPOSED RULE MAKING NO HEARING(S) SCHEDULED

Verizon Performance Assurance Plan by Metropolitan Telecommunications

I.D. No. PSC-21-04-00013-P

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following proposed rule:

Proposed action: The commission is considering the request of Metropolitan Telecommunications to clarify the appropriate performance level to produce a score of "-2" for Verizon performance assurance plan metric OR 10-02, "percent of PON exceptions resolved within 10 business days" as set forth in the order amending performance assurance plan in Case 99-C-0949, issued Jan. 24, 2003.

Statutory authority: Public Service Law, sections 91(1) and 94(2)

Subject: Verizon performance assurance plan metric OR 10-02.

Purpose: To clarify the appropriate performance level.

Substance of proposed rule: The Commission is considering whether to approve or reject, in whole or in part, the request of Metropolitan Telecommunications to clarify the appropriate performance level to produce a score of "-2" for Verizon Performance Assurance Plan Metric OR 10-02, "Percent of PON Exceptions Resolved Within 10 Business Days," as set forth in the Order Amending Performance Assurance Plan in Case 99-C-0949, issued January 24, 2003.

Text of proposed rule may be obtained from: Margaret Maguire, Public Service Commission, Bldg. 3, Empire State Plaza, Albany, NY 12223, (518) 474-3204

Data, views or arguments may be submitted to: Jaclyn A. Brilling, Acting Secretary, Public Service Commission, Bldg. 3, Empire State Plaza, Albany, NY 12223-1350, (518) 474-6530

Public comment will be received until: 45 days after publication of this notice.

Regulatory Impact Statement, Regulatory Flexibility Analysis, Rural Area Flexibility Analysis and Job Impact Statement

Statements and analyses are not submitted with this notice because the proposed rule is within the definition contained in section 102(2)(a)(ii) of the State Administrative Procedure Act.

(99-C-0949SA11)

**PROPOSED RULE MAKING
NO HEARING(S) SCHEDULED**

Financing of Ongoing Operations at 50 MW Coal-Fired Generation Facility by Black River Generation LLC

I.D. No. PSC-21-04-00014-P

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following proposed rule:

Proposed action: The commission is considering a petition from Black River Generation LLC requesting approval of a working capital facility for the financing of ongoing operations at its 50 MW coal-fired generation facility located near Watertown, NY.

Statutory authority: Public Service Law, section 69

Subject: Financing of ongoing operations at 50 MW coal-fired generation facility.

Purpose: To approve a working capital facility.

Substance of proposed rule: The Commission is considering a petition from Black River Generation LLC requesting approval of a working capital facility for the financing of ongoing operations at its 50 MW coal-fired generation facility located near Watertown, NY. The Commission may adopt, modify or reject, in whole or in part, the relief requested.

Text of proposed rule may be obtained from: Margaret Maguire, Public Service Commission, Bldg. 3, Empire State Plaza, Albany, NY 12223, (518) 474-3204

Data, views or arguments may be submitted to: Jaclyn A. Brilling, Acting Secretary, Public Service Commission, Bldg. 3, Empire State Plaza, Albany, NY 12223-1350, (518) 474-6530

Public comment will be received until: 45 days after publication of this notice.

Regulatory Impact Statement, Regulatory Flexibility Analysis, Rural Area Flexibility Analysis and Job Impact Statement

Statements and analyses are not submitted with this notice because the proposed rule is within the definition contained in section 102(2)(a)(ii) of the State Administrative Procedure Act.

(04-E-0594SA1)

**PROPOSED RULE MAKING
NO HEARING(S) SCHEDULED**

Metering by Niagara Mohawk Power Corporation

I.D. No. PSC-21-04-00015-P

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following proposed rule:

Proposed action: The Public Service Commission is considering whether to approve or reject, in whole or in part, or modify, a proposal by Niagara Mohawk Power Corporation to make various changes to its rates, charges, rules and regulations contained in its tariff schedule, P.S.C. No. 207—electricity, to become effective Aug. 2, 2004.

Statutory authority: Public Service Law, section 66(12)

Subject: Metering.

Purpose: To modify customer-requested enhanced metering.

Substance of proposed rule: Niagara Mohawk Power Corporation (the company) proposes to modify Rule No. 25.2 — Customer-Requested Enhanced Metering to become effective August 2, 2004. The revisions will clarify that any customer, regardless of whether they are a customer who

has their commodity service supplied by the company or an ESCO, be allowed to request any type of enhanced metering.

Text of proposed rule may be obtained from: Margaret Maguire, Public Service Commission, Bldg. 3, Empire State Plaza, Albany, NY 12223, (518) 474-3204

Data, views or arguments may be submitted to: Jaclyn A. Brilling, Acting Secretary, Public Service Commission, Bldg. 3, Empire State Plaza, Albany, NY 12223-1350, (518) 474-6530

Public comment will be received until: 45 days after publication of this notice.

Regulatory Impact Statement, Regulatory Flexibility Analysis, Rural Area Flexibility Analysis and Job Impact Statement

Statements and analyses are not submitted with this notice because the proposed rule is within the definition contained in section 102(2)(a)(ii) of the State Administrative Procedure Act.

(04-E-0597SA1)

**PROPOSED RULE MAKING
NO HEARING(S) SCHEDULED**

Sublease of Real Property by The Brooklyn Union Gas Company d/b/a KeySpan Energy Delivery New York, et al.

I.D. No. PSC-21-04-00016-P

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following proposed rule:

Proposed action: The Public Service Commission is considering whether to approve or reject, in whole or in part, a petition filed by The Brooklyn Union Gas Company d/b/a KeySpan Energy Delivery New York (KeySpan) and Consolidated Edison Company of New York, Inc. (Con Edison) for: (1) approval under section 70 of the Public Service Law of a sublease of a portion of a leased KeySpan building to Con Edison; (2) approval of the proposed accounting and rate treatment for the transaction; and (3) related relief.

Statutory authority: Public Service Law, sections 5(b)-(c), 65(1), 66(1), (2), (5), (8)-(12) and 70

Subject: Sublease of real property, accounting and rate treatment for the transaction, and related matters.

Purpose: To consider the proposed sublease, accounting and rate treatment and related matters.

Substance of proposed rule: The Public Service Commission is considering whether to approve or reject, in whole or in part, the sublease of a portion of the first floor leased by The Brooklyn Union Gas Company d/b/a KeySpan Energy Delivery New York (KeySpan) at One Metrotech Center, Brooklyn, New York to Consolidated Edison Company of New York, Inc. (Con Edison). Con Edison proposes to establish a Walk-In Center at this location, where its utility customers may transact business with Con Edison care professionals. By this petition, the parties seek approval of this sublease to permit Con Edison to occupy the premises. The Commission is also considering KeySpan's proposed accounting and rate treatment for the transaction, including its proposal to use the revenues generated from this transaction to defray operation and maintenance expenses, and other related issues.

Text of proposed rule may be obtained from: Margaret Maguire, Public Service Commission, Bldg. 3, Empire State Plaza, Albany, NY 12223, (518) 474-3204

Data, views or arguments may be submitted to: Jaclyn A. Brilling, Acting Secretary, Public Service Commission, Bldg. 3, Empire State Plaza, Albany, NY 12223-1350, (518) 474-6530

Public comment will be received until: 45 days after publication of this notice.

Regulatory Impact Statement, Regulatory Flexibility Analysis, Rural Area Flexibility Analysis and Job Impact Statement

Statements and analyses are not submitted with this notice because the proposed rule is within the definition contained in section 102(2)(a)(ii) of the State Administrative Procedure Act.

(04-M-0155SA1)

**PROPOSED RULE MAKING
NO HEARING(S) SCHEDULED**

Tariff Filing by Misty Hills Water Corporation

I.D. No. PSC-21-04-00018-P

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following proposed rule:

Proposed action: The Public Service Commission is considering whether to approve or reject, in whole or in part, or modify, a proposal filed by Misty Hills Water Corporation to make various changes in the rates, charges, rules and regulations contained in its tariff schedule, P.S.C. No. 2—Water, effective Aug. 1, 2004.

Statutory authority: Public Service Law, section 89-c(10)

Subject: Tariff filing.

Purpose: To replace Misty Hills Water Corporation's current water tariff with an electronic tariff.

Substance of proposed rule: On April 27, 2004, Misty Hills Water Corporation (Misty Hills or the company), electronically filed an updated tariff schedule, P.S.C. No. 2 — Water, effective August 1, 2004, to replace its current water tariff schedule, P.S.C. No. 1 — Water. The new updated electronic tariff includes the rates, charges, rules and regulations under which the company will operate. Some of the changes include a change in the definition of bill delinquency, establishment of a late payment charge and a returned check charge, a modification to the written notice of discontinuance of service provision stating that it contains information required by 16 NYCRR Section 533.3, and language changes in its escrow account statement to conform with the standardized language used in updated escrow account statements. The restoration of service charge changes from \$25 at all times to \$50 during normal business hours (8:00 a.m. to 4:00 p.m., Monday through Friday), \$75 outside of normal business hours Monday through Friday and \$100 on weekends or public holidays. Misty Hills has 49 customers, and is located in the Town of Patterson, Putnam County. Misty Hill's tariff is available on the Commission's Home Page on the World Wide Web (www.dps.state.ny.us) — located under the file room — Tariffs. The Commission may approve or reject, in whole or in part, or modify the company's request.

Text of proposed rule may be obtained from: Margaret Maguire, Public Service Commission, Bldg. 3, Empire State Plaza, Albany, NY 12223, (518) 474-3204

Data, views or arguments may be submitted to: Jaclyn A. Brillig, Acting Secretary, Public Service Commission, Bldg. 3, Empire State Plaza, Albany, NY 12223-1350, (518) 474-6530

Public comment will be received until: 45 days after publication of this notice.

Regulatory Impact Statement, Regulatory Flexibility Analysis, Rural Area Flexibility Analysis and Job Impact Statement

Statements and analyses are not submitted with this notice because the proposed rule is within the definition contained in section 102(2)(a)(ii) of the State Administrative Procedure Act.

(04-W-0549SA1)

**PROPOSED RULE MAKING
NO HEARING(S) SCHEDULED**

Tariff Filing by Hilltop Meadows Water-Works Corp.

I.D. No. PSC-21-04-00019-P

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following proposed rule:

Proposed action: The Public Service Commission is considering whether to approve or reject, in whole or in part, or modify, a proposal filed by Hilltop Meadows Water-Works Corp. to make various changes in the rates, charges, rules and regulations contained in its tariff schedule, P.S.C. No. 3—Water, effective Aug. 1, 2004.

Statutory authority: Public Service Law, section 89-c(10)

Subject: Tariff filing.

Purpose: To replace Hilltop Meadows Water-Works Corp.'s current water tariff with an electronic tariff.

Substance of proposed rule: On April 27, 2004, Hilltop Meadows Water-Works Corp. (Hilltop Meadows or the company), electronically filed an updated tariff schedule, P.S.C. No. 3 — Water, effective August 1, 2004, to replace its current tariff schedule, P.S.C. No. 2 — Water. The new updated electronic tariff includes the rates, charges, rules and regulations under which the company will operate. The electronic tariff schedule is identical in substance to Hilltop Meadows' current Commission approved tariff except for the language changes contained in its escrow account statement to conform with the standardized language used in updated escrow account statements. In addition, the restoration of service charge changes from \$25 at all times to \$50 during normal business hours

(8:00 a.m. to 4:00 p.m., Monday through Friday), \$75 outside of normal business hours Monday through Friday and \$100 on weekends or public holidays. Hilltop Meadows has 49 customers, and is located in the Town of Southeast, Putnam County. Hilltop Meadows' tariff is available on the Commission's Home Page on the World Wide Web (www.dps.state.ny.us) — located under the file room — Tariffs. The Commission may approve or reject, in whole or in part, or modify the company's request.

Text of proposed rule may be obtained from: Margaret Maguire, Public Service Commission, Bldg. 3, Empire State Plaza, Albany, NY 12223, (518) 474-3204

Data, views or arguments may be submitted to: Jaclyn A. Brillig, Acting Secretary, Public Service Commission, Bldg. 3, Empire State Plaza, Albany, NY 12223-1350, (518) 474-6530

Public comment will be received until: 45 days after publication of this notice.

Regulatory Impact Statement, Regulatory Flexibility Analysis, Rural Area Flexibility Analysis and Job Impact Statement

Statements and analyses are not submitted with this notice because the proposed rule is within the definition contained in section 102(2)(a)(ii) of the State Administrative Procedure Act.

(04-W-0550SA1)

**PROPOSED RULE MAKING
NO HEARING(S) SCHEDULED**

Water Service by Saratoga Water Services, Inc. (Saratoga)

I.D. No. PSC-21-04-00020-P

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following proposed rule:

Proposed action: The Public Service Commission is considering whether to approve or reject, in whole or in part, or modify, a petition filed by Saratoga Water Services, Inc. requesting approval of an agreement for the provision of water service and for a waiver of certain tariff provisions and a waiver of 16 NYCRR Parts 501 and 502.

Statutory authority: Public Service Law, section 89-b

Subject: Water service.

Purpose: To approve an agreement for the provision of water service, waive certain tariff provisions and waive 16 NYCRR Parts 501 and 502.

Substance of proposed rule: On April 29, 2004, Saratoga Water Services, Inc. (Saratoga) filed a petition and on May 4, 2004 filed an amendment to the petition, requesting approval of an agreement between Saratoga and Charter Concord Const., Inc. (Charter) for the provision of water service by Saratoga to a real estate subdivision known as Highpointe of Malta PDD being constructed by Charter in the Town of Malta, Saratoga County. The petition also requested waiver of the requirements of inconsistent tariff provisions and waiver of 16 NYCRR Parts 501 and 502, concerning water main extensions. The agreement takes into account that all costs and associated charges arising out of the company's expansion will be borne by the developer, Charter. Saratoga currently provides water service to approximately 1,600 customers and is located in the Towns of Malta and Stillwater, Saratoga County. The Commission may approve or reject, in whole or in part, or modify the company's request.

Text of proposed rule may be obtained from: Margaret Maguire, Public Service Commission, Bldg. 3, Empire State Plaza, Albany, NY 12223, (518) 474-3204

Data, views or arguments may be submitted to: Jaclyn A. Brillig, Acting Secretary, Public Service Commission, Bldg. 3, Empire State Plaza, Albany, NY 12223-1350, (518) 474-6530

Public comment will be received until: 45 days after publication of this notice.

Regulatory Impact Statement, Regulatory Flexibility Analysis, Rural Area Flexibility Analysis and Job Impact Statement

Statements and analyses are not submitted with this notice because the proposed rule is within the definition contained in section 102(2)(a)(ii) of the State Administrative Procedure Act.

(04-W-0560SA1)

**PROPOSED RULE MAKING
NO HEARING(S) SCHEDULED**

Water Service by Saratoga Water Services, Inc. (Saratoga)

I.D. No. PSC-21-04-00021-P

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following proposed rule:

Proposed action: The Public Service Commission is considering whether to approve or reject, in whole or in part, or modify, a petition filed by Saratoga Water Services, Inc. requesting approval of an agreement for the provision of water service and for a waiver of certain tariff provisions and a waiver of 16 NYCRR Parts 501 and 502.

Statutory authority: Public Service Law, section 89-b

Subject: Water service.

Purpose: To approve an agreement for the provision of water service, waive certain tariff provisions and waive 16 NYCRR Parts 501 and 502.

Substance of proposed rule: On April 29, 2004, Saratoga Water Services, Inc. (Saratoga) filed a petition and on May 4, 2004 filed an amendment to the petition, requesting approval of an agreement between Saratoga and Parade Ground Village Partnership for the provision of water service by Saratoga to a planned subdivision being constructed by Parade Ground Village Partnership (Parade Ground) in the Town of Malta, Saratoga County. The petition also requested waiver of the requirements of inconsistent tariff provisions and waiver of 16 NYCRR Sections 501 and 502, concerning water main extensions. The agreement takes into account that all costs and associated charges arising out of the company's expansion will be borne by the developer, Parade Ground. Saratoga currently provides water service to approximately 1,600 customers and is located in the Towns of Malta and Stillwater, Saratoga County. The Commission may approve or reject, in whole or in part, or modify the company's request.

Text of proposed rule may be obtained from: Margaret Maguire, Public Service Commission, Bldg. 3, Empire State Plaza, Albany, NY 12223, (518) 474-3204

Data, views or arguments may be submitted to: Jaclyn A. Brillling, Acting Secretary, Public Service Commission, Bldg. 3, Empire State Plaza, Albany, NY 12223-1350, (518) 474-6530

Public comment will be received until: 45 days after publication of this notice.

Regulatory Impact Statement, Regulatory Flexibility Analysis, Rural Area Flexibility Analysis and Job Impact Statement

Statements and analyses are not submitted with this notice because the proposed rule is within the definition contained in section 102(2)(a)(ii) of the State Administrative Procedure Act.

(04-W-0561SA1)