

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

EMERGENCY RULE MAKING

Golden Nematode Quarantine

I.D. No. AAM-45-05-00006-E

Filing No. 1268

Filing date: Oct. 24, 2005

Effective date: Oct. 24, 2005

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

Action taken: Amendment of section 127.2 of Title 1 NYCRR.

Statutory authority: Agriculture and Markets Law, sections 18, 164 and 167

Finding of necessity for emergency rule: Preservation of general welfare.

Specific reasons underlying the finding of necessity: The rule amends the golden nematode quarantine in section 127.2 of 1 NYCRR by extending that quarantine to certain lands currently owned or operated by Martens Farms in the Town of Mentz in Cayuga County and to a field currently owned or operated by Hoeffner Farms in the Town of Fremont in Steuben County. The extension of the quarantine to certain lands currently owned or operated by Martens Farms is in response to the recent detection of golden nematode on that farm. The extension of the quarantine to a field

currently owned or operated by Hoeffner Farms is consistent with the most recent revisions to the federal regulations at 7 CFR sections 301.85-1 through 301.85-10 which extend the federal golden nematode quarantine to that field.

The golden nematode, *Globodera rostochiensis*, non-indigenous to the United States, is a microscopic eelworm native to Europe. It is one of the world's most destructive crop pests, which attacks potatoes, tomatoes and eggplants by boring into their roots. The resulting damage by the golden nematode affects the growth and crop yield of the plant and may result in the death of the plant. Once established in the soil, the golden nematode is easily spread to non-infested areas through the movement of the infested plants and infested soil. The golden nematode was discovered in Europe during the 19th century and was first detected in the United States on a potato farm on Long Island in 1941. The pest subsequently spread beyond that farm to other areas on Long Island. The emergence of this pest prompted the establishment of a cooperative federal-state golden nematode control program shortly after the end of World War II. The program was dedicated to the control of the golden nematode and included laboratory analysis, research, survey activities and quarantine enforcement. In 1967, the golden nematode was detected on a farm near the Town of Prattsburg in Steuben County and subsequently spread to parts of Cayuga, Genesee, Livingston, Orleans, Seneca and Wayne Counties. The establishment of federal and state golden nematode quarantines as well as restrictions on the movement of host materials played key roles in preventing the further spread of the golden nematode. As of 2002, the quarantines had effectively confined this pest to 6,000 acres of farmland in Nassau and Suffolk Counties on Long Island and the Counties of Cayuga, Genesee, Livingston, Orleans, Seneca, Steuben and Wayne in western New York State. However, the golden nematode has since been detected on a farm in the Town of Mentz in Cayuga County and a farm in the Town of Fremont in Steuben County. Accordingly, it is necessary to extend the golden nematode quarantine to the lands owned and operated by these farms.

Based on the facts and circumstances set forth above, the Department has determined that the immediate adoption of this rule is necessary for the preservation of the general welfare and that compliance with subdivision one of section 202 of the State Administrative Procedure Act would be contrary to the public interest. Since the federal quarantine has not yet been revised to address the recent detection of the golden nematode on certain lands currently owned or operated by the Martens Farm in the Town of Mentz in Cayuga County, the failure to immediately extend the State quarantine to those areas will promote the spread of this pest to uninfested areas within and outside New York State, through the movement of infested plants and infested soil. Although the federal quarantine has been extended to a field currently owned or operated by Hoeffner Farms in the Town of Fremont in Steuben County, that quarantine only addresses the interstate movement of infested plants and infested soil. Consequently, the failure to immediately extend the State quarantine to that field will promote the spread of this pest to uninfested areas within New York State. This would not only result in damage to potato, tomato and eggplant crops in New York and other states, but could also result in a federal quarantine or quarantines by other states which would cause economic hardship to the potato, tomato and eggplant producers and producers of soil-bearing commodities, such as nursery stock and onions, throughout New York State. The consequent loss of business to these producers would harm the agriculture industry which is important to New York State's economy and as such, would harm the general welfare. Given the potential for the spread of the golden nematode beyond the areas currently infested and the detrimental consequences that would have, it appears that this rule should be

implemented on an emergency basis and without complying with the requirements of subdivision one of section 202 of the State Administrative Procedure Act, including the minimum periods therein for notice and comment.

Subject: Host materials (potatoes, tomatoes and eggplants) and soil.

Purpose: To modify the golden nematode quarantine to prevent the further spread of this pest.

Text of emergency rule: The text of this rule is printed in a notice of Proposed Rule Making, I.D. No. AAM-45-05-00006-P, in this issue of the *State Register*.

This notice is intended to serve only as a notice of emergency adoption. This agency intends to adopt this emergency rule as a permanent rule and will publish a notice of proposed rule making in the *State Register* at some future date. The emergency rule will expire January 21, 2006.

Text of emergency rule and any required statements and analyses may be obtained from: Robert Mungari, Director, Division of Plant Industry, Department of Agriculture and Markets, 10B Airline Dr., Albany, NY 12235, (518) 457-2087

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

Are printed in a notice of Proposed Rule Making, I.D. No. AAM-45-05-00006-P, in this issue of the *State Register*.

NOTICE OF ADOPTION

Scrapies in Sheep and Goats

I.D. No. AAM-34-05-00002-A

Filing No. 1267

Filing date: Oct. 24, 2005

Effective date: Nov. 9, 2005

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

Action taken: Amendment of Part 62 of Title 1 NYCRR.

Statutory authority: Agriculture and Markets Law, sections 16, 18 and 72

Subject: Health requirements relative to scrapies in sheep and goats and requirements for the movement of sheep and goats.

Purpose: To incorporate by reference the current Federal regulations set forth in 9 CFR part 79.

Text or summary was published in the notice of proposed rule making, I.D. No. AAM-34-05-00002-P, Issue of August 24, 2005.

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

Text of rule and any required statements and analyses may be obtained from: John Huntley, DVM, Director, Division of Animal Industry, Department of Agriculture and Markets, 10B Airline Dr., Albany, NY 12235, (518) 457-3502

Assessment of Public Comment

The agency received no public comment.

PROPOSED RULE MAKING HEARING(S) SCHEDULED

Golden Nematode Quarantine

I.D. No. AAM-45-05-00006-P

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

Proposed action: Amendment of section 127.2 of Title 1 NYCRR.

Statutory authority: Agriculture and Markets Law, sections 18, 164 and 167

Subject: Host materials (potatoes, tomatoes and eggplants) and soil.

Purpose: To modify the golden nematode quarantine to prevent the further spread of this pest by extending that quarantine to certain lands currently owned or operated by Martens Farms in the Town of Mentz in Cayuga County and to a field currently owned or operated by Hoeffner Farms in the Town of Fremont in Steuben County.

Public hearing(s) will be held at: 11:00 a.m., Dec. 28, 2005 at Department of Agriculture and Markets, 10B Airline Dr., 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.

Text of proposed rule: Section 127.2 of Title 1 of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended by adding new subdivisions (l) and (m) to read as follows:

(l) *That area located in the Town of Fremont in Steuben County and bounded by a line beginning at a point on Babcock Road which intersects a farm road at latitude/longitude coordinates N42°26'12.5" W77°34'30.4" then west along the farm road to coordinates N42°26'12.2" W77°34'41.0", then south to coordinates N42°26'09.6" W77°34'40.9" then west to coordinates N42°26'09.4" W77°34'50.7" then south to coordinates N42°26'00.7" W77°34'50.3" then east to coordinates N42°25'59.9" W77°34'40.4", then south to coordinates N42°25'54.7" W77°34'40.0" then east to coordinates N42°25'56.3" W77°34'37.7" then northeast to coordinates N42°25'58.9" W77°34'35.0" then east to coordinates N42°25'58.9" W77°34'34.1" then north to N42°26'05.8" W77°34'32.5" then east to N42°26'05.7" W77°34'29.9" then north to the point of beginning.*

(m) *That area located in the Town of Mentz in Cayuga County currently owned or operated by Martens Farms which lies in an area bounded as follows: beginning at the intersection of Tow Path Road and Maiden Lane following Tow Path Road west to a point where it intersects with the Town of Mentz boundary, following north along Town of Mentz boundary to a point where it intersects with Maiden Lane, followed eastward back to the intersection of Maiden Lane and Tow Path Road, in the Town of Mentz in the county of Cayuga.*

Text of proposed rule and any required statements and analyses may be obtained from: Robert Mungari, Director, Division of Plant Industry, Department of Agriculture and Markets, 10B Airline Dr., Albany, NY 12235, (518) 457-2087

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

Public comment will be received until: Five days after the last scheduled public hearing required by statute.

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 amendments to section 127.2 of 1 NYCRR would extend the golden nematode quarantine to certain lands currently owned or operated by Martens Farms in the Town of Mentz in Cayuga County and to a field currently owned or operated by Hoeffner Farms in the Town of Fremont in Steuben County.

The proposed modification of the golden nematode 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 this injurious pest.

3. Needs and benefits:

The golden nematode, *Globodera rostochiensis*, non-indigenous to the United States, is a microscopic eelworm native to Europe. It is one of the world's most destructive crop pests, which attacks potatoes, tomatoes and eggplants by boring into their roots. The resulting damage by the golden nematode affects the growth and crop yield of the plant and may result in the death of the plant. Once established in the soil, the golden nematode is easily spread to non-infested areas through the movement of the infested plants and infested soil. The golden nematode was discovered in Europe during the 19th century and was first detected in the United States on a potato farm on Long Island in 1941. The pest subsequently spread beyond that farm to other areas on Long Island. The emergence of this pest prompted the establishment of a cooperative federal-state golden nematode control program shortly after the end of World War II. The program was

dedicated to the control of the golden nematode and included laboratory analysis, research, survey activities and quarantine enforcement. In 1967, the golden nematode was detected on a farm near the Town of Prattsburg in Steuben County and subsequently spread to parts of Cayuga, Genesee, Livingston, Orleans, Seneca and Wayne Counties. The establishment of federal and state golden nematode quarantines as well as restrictions on the movement of host materials played key roles in preventing the further spread of the golden nematode. As of 2002, the quarantines had effectively confined this pest to 6,000 acres of farmland in Nassau and Suffolk Counties on Long Island and the Counties of Cayuga, Genesee, Livingston, Orleans, Seneca, Steuben and Wayne in western New York State. However, the golden nematode has since been detected on a farm in the Town of Mentz in Cayuga County and a farm in the Town of Fremont in Steuben County. Accordingly, it is necessary to extend the golden nematode quarantine to certain lands owned or operated by these farms.

The effective control of the golden nematode within the areas of the State where this pest has been found is important to protect New York agriculture generally, and potato, tomato and eggplant producers in New York, specifically. The failure to extend the golden nematode quarantine to certain lands owned or operated by these two farms will promote the spread of this pest to uninfested areas through the movement of infested plants and infested soil. This would not only result in damage to potato, tomato and eggplant crops in New York and other states, but could also result in a federal quarantine or quarantines by other states which would cause economic hardship to the potato, tomato and eggplant producers and producers of soil-bearing commodities, such as nursery stock and onions, throughout New York State. It is estimated that there are 530 potato producers, 1,212 tomato producers and 124 eggplant producers in New York. They employ an estimated 2,420 people and generate 92.7-million dollars in revenue per year. The consequent loss of business to these producers would harm the agriculture industry which is vastly important to New York State's economy and as such, would harm the general welfare.

4. Costs:

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

Under the proposal, farming and construction equipment located on the two farms affected by the proposed extension of the quarantine would have to be cleaned and sanitized prior to leaving the quarantine zone. Depending upon the availability of resources and personnel, cleaning and sanitizing would be provided free of charge by the United States Department of Agriculture (USDA) and/or the Department. If, however, resources and personnel are not available at a given point in time, regulated parties would have to clean and sanitize their own equipment prior to leaving the quarantine zone. Regulated parties will incur an initial capital cost of \$400.00 for the purchase of a gasoline-powered power washer to clean and sanitize the equipment. It is estimated that one worker earning \$10.00 per hour can clean and sanitize equipment in one hour. Since a potato field is entered 11 times a growing season for purposes of planting, crop management and harvest, regulated parties would incur, at most, annual costs for continued compliance with the rule of \$110.00 (\$10.00 per hour x 11). Of course, these costs would be lower to the extent scheduling permits the USDA and/or the Department to clean and sanitize the equipment.

Any potatoes planted at the two farm locations affected by the proposed extension of the quarantine would have to be varieties which are resistant to the golden nematode and rotated, as required by Part 127 of the Regulations. The approved rotation allows growers to continue to produce potatoes on regulated (*i.e.* infested) acreage while maintaining populations of the golden nematode below a level at which the pest can spread. Since the cost for seeds of resistant varieties is comparable to that for seeds of non-resistant varieties, the two farms would not incur any additional costs in the purchase of potato seeds.

(d) Costs to the regulatory agency:

(i) The initial expenses the agency will incur in order to implement and administer the regulation: None. The Department already has gasoline powered power washers to clean and sanitize equipment.

(ii) It is anticipated that the Department would be able to use existing personnel to administer the proposed extension of the quarantine and to perform the necessary cleaning and sanitizing of equipment in the extended quarantine area. One inspector earning \$50.88 per hour, which includes base salary, overtime and fringe benefits, can clean and sanitize equipment in four (4) hours, which includes travel time to and from the farms. Accordingly, it would cost the Department approximately \$203.00 for each visit to clean and sanitize equipment.

5. Local government mandate: None.

6. Paper work: None.

7. Duplication: None.

8. Alternatives: None. The failure of the State to modify the quarantine to reflect the areas in which the golden nematode has been detected would result not only in damage to potato, tomato and eggplant crops in New York and other states, but could also result in a federal quarantine or quarantines by other states which would cause economic hardship to the potato, tomato and eggplant producers and producers of soil-bearing commodities, such as nursery stock and onions, throughout New York State.

9. Federal standards:

The proposed extension of the quarantine to certain lands currently owned or operated by Hoeffner Farm in the Town of Fremont in Steuben County is consistent with the most recent revisions to the federal regulations at 7 CFR sections 301.85-1 through 301.85-10. Accordingly, this part of the proposed amendment does not exceed any minimum standards for the same or similar subject areas. The proposed extension of the quarantine to certain lands currently owned or operated by Martens Farm in the Town of Mentz in Cayuga County is in response to the recent detection by the Department of golden nematode on that farm. The federal quarantine has not yet been revised to address this detection of the pest.

10. Compliance schedule: Immediate.

Regulatory Flexibility Analysis

1. Effect on small business:

The proposed amendment to section 127.2 of 1 NYCRR would extend the golden nematode quarantine to certain lands currently owned or operated by Martens Farms in the Town of Mentz in Cayuga County and to a field currently owned or operated by Hoeffner Farms in the Town of Fremont in Steuben County.

The proposed amendments would affect these two farms, both of which are small businesses.

It is anticipated that the rule will have no impact on local governments.

2. Compliance requirements:

Farming and construction equipment on the two farms affected by the proposed extension of the quarantine would have to be cleaned and sanitized prior to leaving the quarantine zone.

Any potatoes planted at the two farm locations affected by the proposed extension of the quarantine would have to be varieties which are resistant to the golden nematode and rotated, as required by Part 127 of the Regulations.

It is anticipated that the proposed amendments would have no impact on local governments.

3. Professional services:

In order to comply with the proposed amendments, the two farms would have to have their farming and construction equipment cleaned and sanitized before it leaves the quarantine zone. Depending upon the availability of resources and personnel, this service would be provided by the United States Department of Agriculture (USDA) and/or the Department. Otherwise, regulated parties would have to clean and sanitize their own equipment prior to leaving the quarantine zone.

It is anticipated that the proposed amendments would have no impact on local governments.

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:

Regulated parties would incur an initial capital cost of \$400.00 for the purchase of a gasoline-powered power washer to clean and sanitize the equipment.

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

Farming and construction equipment located on the two farms affected by the proposed extension of the quarantine would have to be cleaned and sanitized prior to leaving the quarantine zone. Depending upon the availability of resources and personnel, cleaning and sanitizing would be provided free of charge by the United States Department of Agriculture (USDA) and/or the Department. If, however, resources and personnel are not available at a given point in time, regulated parties would have to clean and sanitize their own equipment prior to leaving the quarantine zone. It is estimated that one worker earning \$10.00 per hour can clean and sanitize equipment in one hour. Since a potato field is entered 11 times a growing season for purposes of planting, crop management and harvest, regulated parties would incur, at most, annual costs for continued compliance with the rule of \$110.00 (\$10.00 per hour x 11). Of course, this cost would be lower to the extent scheduling permits the USDA and/or the Department to clean and sanitize the equipment.

Any potatoes planted at the two farm locations affected by the proposed extension of the quarantine would have to be varieties which are

resistant to the golden nematode and rotated, as required by Part 127 of the Regulations. The approved rotation allows growers to continue to produce potatoes on regulated (*i.e.* infested) acreage while maintaining populations of the golden nematode below a level at which the pest can spread. Since the cost for seeds of resistant varieties is comparable to that for seeds of non-resistant varieties, the two farms would not incur any additional costs in the purchase of potato seeds.

It is anticipated that the proposed amendments would have no impact on local governments.

5. Minimizing adverse impact:

The Department has designed the proposed amendments to minimize adverse economic impact on small businesses and local governments. The proposal minimizes adverse economic impact by limiting the modified quarantined areas to only those areas where the golden nematode has been detected. The proposed amendments also minimize adverse economic impact by providing that the USDA and/or Department would clean and sanitize farm and construction equipment free of charge, depending upon the availability of resources and personnel. 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 proposed amendments minimize adverse economic impact as much as is currently possible.

It is anticipated that the proposed amendments would have no impact on local governments.

6. Small business and local government participation:

The Department contacted the owners, operators and representatives of the two farms which are affected by the proposed extension of the quarantine. On June 12, 2003, the Department advised Steve Hoeffner of Hoeffner Farms that analysis of soil samples taken from his lands revealed evidence of infestation by golden nematode. On September 17, 2004, the Department advised Robert and Timothy Martens of Martens Farms that analysis of soil samples taken from their lands revealed evidence of infestation by golden nematode.

It is anticipated that the proposed amendments would have no impact on local governments.

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 proposal by small businesses and local governments has been addressed and such compliance has been determined to be feasible. Farming and construction equipment located on the two farms affected by the proposed extension of the quarantine would have to be cleaned and sanitized prior to leaving the quarantine zone. However, cleaning and sanitizing would be provided at no charge by USDA and/or the Department, depending upon the availability of resources and personnel. Any potatoes planted at the two farm locations affected by the proposed extension of the quarantine would have to be varieties which are resistant to the golden nematode and rotated, as required by Part 127 of the Regulations. The approved rotation would allow growers to continue to produce potatoes on regulated (*i.e.* infested) acreage while maintaining populations of the golden nematode below a level at which the pest can spread. Since the cost for seeds of resistant varieties is comparable to that for seeds of non-resistant varieties, the two farms would not incur any additional costs in the purchase of potato seeds.

It is anticipated that the proposed amendments would have no impact on local governments.

Rural Area Flexibility Analysis

1. Type and estimated numbers of rural areas:

The proposed amendments to section 127.2 of 1 NYCRR would extend the golden nematode quarantine to certain lands currently owned or operated by Martens Farms in the Town of Mentz in Cayuga County and to a field currently owned or operated by Hoeffner Farms in the Town of Fremont in Steuben County.

The proposed amendments would affect these two farms, both of which are in rural areas.

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

The proposed amendments would not require any reporting or record-keeping requirements for regulated parties.

With respect to compliance requirements, farming and construction equipment on the two farms affected by the proposed extension of the

quarantine will have to be cleaned and sanitized prior to leaving the quarantine zone. Depending on the availability of resources and personnel, this service will be provided by the United States Department of Agriculture (USDA) and/or the Department. Otherwise, regulated parties would have to clean and sanitize their own equipment prior to leaving the quarantine zone. Any potatoes planted at the two farm locations affected by the proposed extension of the quarantine will have to be varieties which are resistant to the golden nematode and rotated, as required by Part 127 of the Regulations. The approved rotation allows growers to continue to produce potatoes on regulated (*i.e.* infested) acreage while maintaining populations of the golden nematode below a level at which the pest can spread. Since the cost for seeds of resistant varieties is comparable to that for seeds of non-resistant varieties, the two farms will not incur any additional costs in the purchase of potato seeds.

3. Costs:

Farming and construction equipment located on the two farms affected by the proposed extension of the quarantine will have to be cleaned and sanitized prior to leaving the quarantine zone. However, cleaning and sanitizing would be provided free of charge by USDA and/or the Department, depending upon the availability of resources and personnel. If resources and personnel are not available at a given point in time, regulated parties would have to clean and sanitize their own equipment prior to leaving the quarantine zone. Regulated parties would incur an initial capital cost of \$400.00 for the purchase of a gasoline-powered power washer to clean and sanitize the equipment. It is estimated that one worker earning \$10.00 per hour can clean and sanitize equipment in one hour. Since a potato field is entered 11 times a growing season for purposes of planting, crop management and harvest, regulated parties would incur, at most, annual costs for continued compliance with the proposed amendments of \$110.00 (\$10.00 per hour x 11). Of course, these costs will be lower to the extent scheduling permits the USDA and/or the Department to clean and sanitize the equipment.

4. Minimizing adverse impact:

In conformance with State Administrative Procedure Act Section 202-bb(2), the proposed amendments were drafted to minimize adverse impact on all regulated parties, including those in rural areas. The proposal minimizes adverse economic impact by limiting the modified quarantined areas to only those areas where the golden nematode has been detected. The proposed amendments also minimize adverse economic impact by providing that the USDA and/or Department will clean and sanitize farm and construction equipment free of charge, depending upon the availability of resources and personnel. Given all of the facts and circumstances, it is submitted that the proposed amendments minimize adverse economic impact as much as is currently possible.

5. Rural area participation:

The Department contacted the owners, operators and representatives of the two farms which are affected by the proposed extension of the quarantine. Both farms are located in rural areas of the State. On June 12, 2003, the Department advised Steve Hoeffner of Hoeffner Farms that analysis of soil samples taken from his lands revealed evidence of infestation by golden nematode. On September 17, 2004, the Department advised Robert and Timothy Martens of Martens Farms that analysis of soil samples taken from their lands revealed evidence of infestation by golden nematode.

Job Impact Statement

The proposed amendments will not have a substantial adverse impact on jobs and employment opportunities. The proposed modification of the quarantine area is designed to prevent the spread of the golden nematode to other parts of the State. It is estimated that there are 530 potato producers, 1,212 tomato producers and 124 eggplant producers in New York. They employ an estimated 2,420 people and generate 92.7-million 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 golden nematode, the proposal will help to prevent such adverse economic consequences and in so doing, protect the jobs and employment opportunities associated with the production of potatoes, tomatoes and eggplant in New York State.

Banking Department

NOTICE OF ADOPTION

Authority of Banks and Trust Companies

I.D. No. BNK-30-05-00002-A
Filing No. 1262
Filing date: Oct. 20, 2005
Effective date: Nov. 9, 2005

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

Action taken: Addition of section 6.7 to Title 3 NYCRR.

Statutory authority: Banking Law, sections 10, 14 and 14-g

Subject: Additional authority of banks and trust companies to underwrite and deal in certain securities, including municipal bonds.

Purpose: To give New York State chartered banks and trust companies parity with national banks in underwriting and dealing in municipal revenue bonds and other government securities.

Text or summary was published in the notice of proposed rule making, I.D. No. BNK-30-05-00002-P, Issue of July 27, 2005.

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

Text of rule and any required statements and analyses may be obtained from: Sam L. Abram, Secretary to the Banking Board, Banking Department, One State St., New York, NY 10004-1417, (212) 709-1658, e-mail: sam.abram@banking.state.ny.us

Assessment of Public Comment

The Department received one comment. It was from a bankers' association and strongly supported the proposal. In addition to enhancing the competitive ability of State-chartered banks, the commenter noted that by increasing competition in the underwriting of local securities, the proposal could lead to increased liquidity and lower cost in the municipal securities market.

State Commission of Correction

NOTICE OF ADOPTION

Fire Prevention and Environmental Health and Safety

I.D. No. CMC-29-05-00005-A
Filing No. 1266
Filing date: Oct. 21, 2005
Effective date: Nov. 9, 2005

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

Action taken: Amendment of sections 7039.3, 7602.3, 7602.5, 7602.7 and 7602.8 of Title 9 NYCRR.

Statutory authority: Correction Law, section 45(6) and (15)

Subject: Fire prevention and environmental health and safety.

Purpose: To remove specific references to repealed New York State Fire Prevention and Building Codes.

Text or summary was published in the notice of proposed rule making, I.D. No. CMC-29-05-00005-P, Issue of July 20, 2005.

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

Text of rule and any required statements and analyses may be obtained from: Brian M. Callahan, Senior Attorney, Commission of Correction, 80 Wolf Rd., 4th Fl., Albany, NY 12205, (518) 485-2346, e-mail: Brian.Callahan@scoc.state.ny.us

Assessment of Public Comment

The agency received no public comment.

NOTICE OF ADOPTION

Inmate Exercise

I.D. No. CMC-29-05-00006-A
Filing No. 1265
Filing date: Oct. 21, 2005
Effective date: Nov. 9, 2005

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

Action taken: Amendment of sections 7002.9(a)(4), 7013.6(a)(4) and 7041.2(a)(8) of Title 9 NYCRR.

Statutory authority: Correction Law, section 45(6) and (15)

Subject: Inmate exercise.

Purpose: To change all regulatory references from inmate "recreation" to "exercise."

Text or summary was published in the notice of proposed rule making, I.D. No. CMC-29-05-00006-P, Issue of July 20, 2005.

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

Text of rule and any required statements and analyses may be obtained from: Brian M. Callahan, Senior Attorney, Commission of Correction, 80 Wolf Rd., 4th Fl., Albany, NY 12205, (518) 485-2346, e-mail: Brian.Callahan@scoc.state.ny.us

Assessment of Public Comment

The agency received no public comment.

NOTICE OF ADOPTION

Medical Examination of Intoxicated Prisoners

I.D. No. CMC-29-05-00007-A
Filing No. 1264
Filing date: Oct. 21, 2005
Effective date: Nov. 9, 2005

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

Action taken: Amendment of section 7503.1(b) of Title 9 NYCRR.

Statutory authority: Correction Law, section 45(6) and (15)

Subject: Medical examination of intoxicated prisoners.

Purpose: To remove a reference to a repealed provision of the New York State Penal Law.

Text or summary was published in the notice of proposed rule making, I.D. No. CMC-29-05-00007-P, Issue of July 20, 2005.

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

Text of rule and any required statements and analyses may be obtained from: Brian M. Callahan, Senior Attorney, Commission of Correction, 80 Wolf Rd., 4th Fl., Albany, NY 12205, (518) 485-2346, e-mail: Brian.Callahan@scoc.state.ny.us

Assessment of Public Comment

The agency received no public comment.

NOTICE OF ADOPTION

Agency Address

I.D. No. CMC-29-05-00008-A
Filing No. 1263
Filing date: Oct. 21, 2005
Effective date: Nov. 9, 2005

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

Action taken: Amendment of sections 7022.5(c), 7200.2(a), 7200.3, 7200.6(b), 7202.4(a), 7202.6 and 7202.11(a) of Title 9 NYCRR.

Statutory authority: Correction Law, section 45(6) and (15)

Subject: Agency address.

Purpose: To amend the Commission of Correction's listed address.

Text or summary was published in the notice of proposed rule making, I.D. No. CMC-29-05-00008-A, Issue of July 20, 2005.

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

Text of rule and any required statements and analyses may be obtained from: Brian M. Callahan, Senior Attorney, Commission of Correction, 80 Wolf Rd., 4th Fl., Albany, NY 12205, (518) 485-2346, e-mail: Brian.Callahan@scoc.state.ny.us

Assessment of Public Comment

The agency received no public comment.

Department of Economic Development

EMERGENCY RULE MAKING

Empire State Film Production Tax Credit Program

I.D. No. EDV-45-05-00001-E

Filing No. 1257

Filing date: Oct. 19, 2005

Effective date: Oct. 19, 2005

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

Action taken: Addition of Part 170 to Title 5 NYCRR.

Statutory authority: L. 2004, ch. 60

Finding of necessity for emergency rule: Preservation of general welfare.

Specific reasons underlying the finding of necessity: As a matter of public policy, the Legislature has determined that a tax credit to eligible qualified film production companies would provide incentive for films to be produced in New York State and thereby help stimulate the State economy. The rule is necessary because section 7(c) of chapter 60 of the Laws of 2004 mandates the department to promulgate regulations for the program to establish procedures for the allocation of tax credits and describing the application process, the due dates for the applications, the standards used to evaluate the applications and any other provisions deemed necessary and appropriate by Oct. 31, 2004. Such legislation provides that, notwithstanding any other provisions to the contrary in the State Administrative Procedure Act, the rules and regulations may be adopted on an emergency basis.

Subject: Empire State Film Production Tax Credit Program.

Purpose: To establish procedures for the allocation of tax credits and describe the application process, the due dates for the applications, the standards used to evaluate the application and any other provisions deemed necessary and appropriate; and clarify necessary and pertinent definitions to the program.

Substance of emergency rule: The empire state film production tax credit program generally provides film production companies with a tax credit equal to ten percent of qualified production costs incurred within New York State. Under the program an applicant may be eligible for a full benefit or partial benefit. If an applicant has 75% or more of their total production costs occur at a qualified New York facility and the production spends at least \$3 million during production, then the production qualifies for the full benefit which is a 10% tax credit on all qualified production expenditures. If 75% or more of total production costs occur at a qualified New York facility but the production spends less than \$3 million at the qualified facility, it must then shoot 75% or more of its location days in New York to qualify for the full 10% tax credit.

If 75% or more of a production total facility expenditures occur at a qualified facility but the production spends less than \$3 million and less than 75% of its total location shooting days are in New York, then the production qualifies for the 10% tax credit for expenditures at the qualified facility only.

This rule implements Chapter 60 of the Laws of 2004. Part 170 of Title 5 NYCRR is hereby created and is summarized as follows:

First, the rule makes clear that the Governor's Office for Motion Picture and Television development shall administer the empire state film production tax credit program. This proposed rule does not govern the New York city film production tax credit program eligibility in either the state or city program does not guarantee eligibility or receipt of a credit in the other.

Second, eligibility in the program is established through the definition of authorized applicant. In order to be eligible to apply for the program, a business must be a qualified film production company or sole proprietor

thereof that is scheduled to begin principal photography on a qualified film within 180 days after submitting its initial application to the Office and it must intend to shoot a portion of that photography on a stage at a qualified film production facility on a set or sets.

Third, a two part application process is created. An authorized applicant must complete an initial application, a document created by the Office which asks the applicant to project/estimate various expenditures at qualified film production facilities and shooting days in and outside of New York. The applicant must also meet with the Office to discuss the details of the application. The Office then reviews the initial application based on criteria set out in the proposed rule, including, the completeness of the application, whether or not it is premature (*i.e.*, incapable of photography starting within 180 days of the date of the application), and whether or not it meets the statutory requirements for qualification, including whether its projected qualified productions costs equal or exceed 75% of its total productions costs.

If the initial application is approved, the applicant (now referred to as an approved applicant) receives a certificate of conditional eligibility. This certificate assures the applicant that, pending successful completion of a final application, they are in line (though not guaranteed) to receive a tax credit. The certificate also contains the applicants' priority number, a number used by the Office to place the applicant in line for allocation of the tax credit purposes. Priority number is based on the applicant's effective date. Effective date is defined in the rule to mean the date the certification of conditional eligibility becomes effective. It is derived from the date the initial application is received by the Office. In the event an applicant does not begin principal and ongoing photography within 180 days of the submission of their initial application, effective date may be recalculated to correspond to the date one hundred eighty days prior to the date the approved applicant submits a notification of commencement of principal and ongoing photography to the Office. If the application is disapproved, the applicant receives notice of its rejection from the program and may reapply at a later date.

Fourth, the rule requires the approved applicant notify the Office on the date principal and ongoing photography begins on their production and supply a sign-off budget at this point. This additional budget data helps the Office get a better sense of the production expenses the applicant has and ultimately helps the Office estimate the potential credit the applicant may later be entitled to.

Fifth, within 60 days after the completion of production of their qualified film, the approved applicant must submit a final application to the Office. The final application is similar to the initial application, though it now contains actual expenditure data as opposed to expenditure projections. The Office then considers certain criteria in its review to determine whether the final application should be approved. Much like the criteria used for the initial application, this includes analysis of whether the application is complete, whether applicant actually shot principal photography on stage at a qualified film production facility on a set or sets, whether a qualified film was completed, and whether the actual qualified production costs equal or exceed 75% of the actual production costs on the film, etc.

The proposed rule allows the Office to request additional documentation, including receipts of qualified productions costs, to help the Office determine if the applicant meets the criteria. At this point, the applicant is either approved and issued a certificate of tax credit (stating the amount of tax credit they will be receiving) or provided a notice of disapproval.

Sixth, the proposed rule addresses the issue of the allocation of the empire state film production tax credits. The allocation is made in the order of priority based on the applicant's effective date. If an approved applicant's tax credit exceeds the amount of credits allowed in a given year, their credit will be allocated on a priority basis in the immediately succeeding calendar year. Also, the proposed rule makes explicit the fact that allocation and receipt of the tax credit are subject to availability of state funds for the program.

Seventh, the proposed rule requires applicants to maintain records of qualified production costs used to calculate their potential or actual benefit under the program for a period of 3 years. Such records may be requested by the Office upon reasonable notice.

Finally, the proposed rule creates an appeal process. Applicants who have had their initial or final applications disapproved, or who have a disagreement over the dollar amount of their tax credit have the right to appeal.

This notice is intended to serve only as a notice of emergency adoption. This agency does not intend to adopt the provisions of this emergency rule as a permanent rule. The rule will expire January 16, 2006.

Text of emergency rule and any required statements and analyses may be obtained from: Thomas P. Regan, Department of Economic Development, Counsel's Office, 30 S. Pearl St., Albany, NY 12245, (518) 292-5120, e-mail: tregan@empire.state.ny.us

Regulatory Impact Statement

STATUTORY AUTHORITY:

Section (7)(c) of Chapter 60 of the laws of 2004 requires the Commissioner of Economic Development to promulgate rules and regulations by October 31, 2004 to establish procedures for the allocation of the empire state film production tax credit, including provisions describing the application process, the due dates for such applications, the standards used to evaluate the applications, and the documentation provided to taxpayers to substantiate to the State Department of Taxation and Finance the amount of the tax credit for the program itself. Such legislation provides that, notwithstanding any other provisions to the contrary in the State Administrative Procedure Act, the rules and regulations may be adopted on an emergency basis.

LEGISLATIVE OBJECTIVES:

The proposed rule is in accord with the public policy objectives the Legislature sought to advance by creating a tax credit program for the film industry. This program is an attempt to create an incentive for film industry to bring productions to New York State as opposed to other competitive markets, such as Toronto. It is the public policy of the State to offer a tax credit that will help provide incentive for the film industry to bring productions to the State. The proposed rule helps to further such objectives by establishing an application process for the program, clarifying portions of the Program through the creation of various definitions and describing the credit allocation process itself.

NEEDS AND BENEFITS:

The proposed rule is required to be promulgated by October 31, 2004 (see section 7(c) of Chapter 60 of the Laws of 2004). It is necessary to properly administer the tax credit program. The statute itself does not set out the specifics of the program; rather, it deals primarily with its creation and calculation of the actual tax credit. There are several administrative benefits that would be derived from this proposed rule making. First, the proposed rule establishes a clear and precise application process, complete with due process as there is an opportunity for applicants to appeal from denials of applications or a disagreement regarding the actual amount of the tax credit. Second, the proposed rule describes in detail the standards to be used to evaluate the initial and final applications created under this program. Third, it describes the documentation that will be provided to taxpayers to substantiate to the State Tax and Finance Department the amount of the tax credits allocation. Finally, it clarifies some existing definitions and creates several new definitions in order to help facilitate an effective and efficient administration of the program.

COSTS:

I. Costs to private regulated parties (the Business applicants): None. The proposed regulation will not impose any additional costs to the film industry.

II. Costs to the regulating agency for the implementation and continued administration of the rule: There could be additional costs to the Department of Economic Development associated with the proposed rule making as the Office may need an additional employee to help with the program's new created administrative process. Such costs are estimated to be \$40,000 to \$50,000 in annual salary for an employee's with a background in production accounting.

III. Costs to the State government: The program shall not allocate more than \$25 million in any calendar year. The program sunsets on January 1, 2008 so the overall cost to the State is \$100 million.

IV. Costs to local governments: None. The proposed regulation will not impose any additional costs to local government.

LOCAL GOVERNMENT MANDATES:

None.

PAPERWORK:

The proposed rule creates an application process for eligible applicants, including the creation of an initial and final application, certain tax certificates and forms relating to film expenditures.

DUPLICATION:

The proposed rule will not duplicate or exceed any other existing Federal or State statute or regulation.

ALTERNATIVES:

No alternatives were considered in regard to creating a new regulation in response to the statutory requirement. The Department of Economic Development, through its Governor's Office for Motion Picture and Television Development, did an extraordinary amount of outreach to various interested parties before submitting this proposed rule. For example, the Department met with seven representatives from episodic television, seven representatives from the independent film industry and seven representatives from large studio films to seek industry input. In addition, the Department met with three film industry accountants, five industry tax attorneys and approximately seven studio representatives to solicit their comments. Furthermore, the Department was in close contact with representatives from the State Tax and Finance Department and the New York City Office for Motion Pictures to coordinate the details of the proposed rule.

FEDERAL STANDARDS:

There are no federal standards in regard to the empire state film production tax credit program; it is purely a state program that offers a state tax credit to eligible applicants. Therefore, the proposed rule does not exceed any Federal standard.

COMPLIANCE SCHEDULE:

The effected State agencies (Economic Development) and the business applicants will be able to achieve compliance with the proposed regulation as soon as it is implemented. In terms of compliance schedule, the statute (Chapter 60 of the Laws of 2004) was signed into law on August 20, 2004. All film production expenditures that date back to this date will be eligible for inclusion in the tax credit calculation. The statute gave the Department until October 31, 2004 to promulgate regulations to implement the program. The program applies to taxable years beginning on or after January 1, 2004 and expires on January 1, 2008.

Regulatory Flexibility Analysis

Participation in the empire state film production tax credit program is entirely at the discretion of qualified film production companies. Neither Chapter 60 of the Laws of 2004 nor the proposed regulations impose any obligation on any local government or business entity to participate in the program. The proposed regulation does not impose any adverse economic impact or their compliance requirements on small businesses or local governments. In fact, the proposed regulation may have a positive economic impact on small businesses due to the possibility that these businesses may enjoy a film production tax credit if they qualify for the program's tax credit.

Because it is evident from the nature of the proposed rule that it will have either no impact, or a positive impact, on small businesses and local government, no further affirmative steps were needed to ascertain that fact and none were taken. Accordingly, a regulatory flexibility analysis for small business and local government is not required and one has not been prepared.

Rural Area Flexibility Analysis

This program is open to participation from all qualified film production companies, which is defined by statute to include a corporation, partnership or sole proprietorship making and controlling a qualified film in New York. The location of the companies is irrelevant, so long as they meet the necessary qualifications of the definition. This program may impose responsibility on statewide businesses that are qualified film production companies, in that they must undertake an application process to receive the empire state film production tax credit. However, the proposed regulation will not have a substantial adverse economic impact on rural areas. Accordingly, a rural flexibility analysis is not required and one has not been prepared.

Job Impact Statement

The proposed regulation creates the application process for the empire state film production tax credit program. As a tax credit program, it is designed to positively impact the film industry doing business in New York State and have a positive impact on job creation. The proposed regulation will not have a substantial adverse impact on jobs and employment opportunities. Because it is evident from the nature of the proposed rule making that it will have either no impact, or a positive impact, on job and employment opportunities, no further affirmative steps were needed to ascertain that fact and none were taken. Accordingly, a job impact statement is not required and one has not been prepared.

EMERGENCY RULE MAKING

Empire Zones Program

I.D. No. EDV-45-05-00009-E

Filing No. 1270

Filing date: Oct. 25, 2005

Effective date: Oct. 25, 2005

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

Action taken: Amendment of Parts 10 through 14 of Title 5 NYCRR.

Statutory authority: General Municipal Law, art. 18-B, section 959

Finding of necessity for emergency rule: Preservation of general welfare.

Specific reasons underlying the finding of necessity: The reforms enacted in L. 2005, ch. 63 require reconfiguration of the existing Empire Zones by January 1, 2006. Immediate guidance to affected parties is required.

Subject: Empire Zones Program.

Purpose: To conform the regulations to existing statute and recent statutory amendments L. 2005, ch. 63 and clarify and improve administrative procedures.

Substance of emergency rule: The emergency rule is the result of changes to Article 18-B of the General Municipal Law pursuant to Chapter 63 of the Laws of 2005, as well as a comprehensive review of administrative procedures and existing regulations. The amended laws require the existing Empire Zones to identify revised zone boundaries that is, placement of zone acreage into "distinct and separate contiguous areas"—to the Department of Economic Development by January 1, 2006. The existing regulations are affected by this requirement, but at the same time the zones need immediate guidance which requires amending the existing regulations in an accelerated fashion. At the same time, the existing regulations contain several outdated references, and the Department has also taken the opportunity to improve its administrative procedures. The Empire Zone regulations contained in 5 NYCRR Parts 10 through 14 are hereby amended as follows:

First, pursuant to Chapter 63 of the Laws of 2000 and Chapter 63 of the Laws of 2005, the emergency rule would reflect the name change of the program from Economic Development Zones to the Empire Zones and add reference to three new tax benefits: the Qualified Empire Zone Enterprise ("QEZE") Real Property Tax Credit, QEZE Tax Reduction Credit, and the QEZE Sales and Use Tax Exemption. The emergency rule also reflects the eligibility of agricultural cooperatives for Empire Zone tax credits and the QEZE Real Property Tax Credit.

Second, the emergency rule would conform the regulations to existing statutory terminology, definitions and practices. For example, an incorrect reference to a local empire zone administrator is being corrected to read local empire zone certification officer or simply, the local empire zone, if applicable. Pursuant to statute, the chief executive officer must ensure that the information on a designation application is accurate and complete, not the local legislative body. The requirements for a shift resolution did not contain all the criteria as set forth in statute. Certain regulatory provisions regarding application for zone designation were not in accord with the statute, such as whether certain information must be contained in local law rather than the application itself. In addition, tracking the statutory changes from Chapter 63 of the Laws of 2005, census tract zones are renamed "investment zones", county-created zones are renamed "development zones", and the new term "cost-benefit analysis" is defined. The emergency regulation also tracks the amended statute's deletion of the category of contributions to a qualified Empire Zone Capital Corporation from those businesses eligible for the Zone Capital Credit.

Third, the emergency rule would amend the Department's discretionary provision that limits the designation of nearby lands in investment zones to 320 acres. Such regulatory limitations are arbitrary and unnecessarily exceed or are inconsistent with State statute, and at the same time place undue limits on the reconfiguration of zones; municipalities cannot effectively utilize zone acreage to create opportunities for business investment and job growth in economically distressed areas that are not necessarily located in eligible or contiguous census tracts. At the same time, the Department is required to provide guidance in regulation on placement of nearby zone lands, and cannot countenance abuse of the program's requirements on acreage placement. Thus, placement of nearby lands can exceed 320 acres provided that the municipality demonstrates that (1) there

is insufficient existing or planned infrastructure within eligible or contiguous tracts to accommodate business development in a highly distressed area, or to accommodate development of strategic businesses or (2) placing up to 960 acres in eligible or contiguous census tracts would be inconsistent with open space and wetland protection or (3) there are insufficient lands available for further business development within eligible or contiguous census tracts or (4) lands previously designated in the eligible or contiguous census tracts that were otherwise suitable for development and have not had any appreciable commercial activity or capital investment or (5) changes to eligible census tracts as a result of the 2000 Census, combined with the requirement in the amended statute that the distinct and separate contiguous areas accommodate already designated lands, alter the amount of nearby acreage used and available for development.

Fourth, the emergency rule clarifies the statutory requirement from Chapter 63, L. 2005 that development zones (formerly county zones) create up to three areas within their reconfigured zones as investment (formerly census tract) zones. The rule would require that 75% of the acreage used to define these investment zones be included within an eligible or contiguous census tract. Furthermore, the rule would not require a development zone to place investment zone acreage within a municipality in that county if that particular municipality already contained an investment zone, and the only eligible census tracts were contained within that municipality. The purpose of this is to fulfill the intent of the new statutory amendments that the counties place a substantial portion of the zone acreage within eligible or contiguous census tracts, and this provision follows essentially the same method for concentrating acreage within distressed areas as the General Municipal Law employed for census tract zones.

Fifth, the emergency rule tracks the statutory requirements that zones reconfigure their existing acreage in up to three (for investment zones) or six (for development zones) distinct and separate contiguous areas, and that zones can allocate up to their total allotted acreage at the time of designation. These reconfigured zones must be presented to the Empire Zones Designation Board for unanimous approval. The emergency rule makes clear that zones may not necessarily designate all of their acreage into three or six areas or use all of their allotted acreage, however, any subsequent additions after their official redesignation by the Designation Board will still require unanimous approval by that Board.

Sixth, the emergency rule tracks the new statutory requirement that certain defined "regionally significant" projects can be located outside of the new distinct and separate contiguous areas. There are four categories of projects identified in Chapter 63; only one category of applications, manufacturers projecting the creation of 50 or more jobs, are allowed to progress before the identification of the distinct and separate contiguous areas and/or the approval of certain regulations by the Empire Zones Designation Board. The emergency rule identifies a timetable for meeting the minimum job creation requirement: 25% of the minimum jobs required to meet the definition of regionally significant project within 2 years of the date of designation of the project as regionally significant, 50% of the minimum jobs within 3 years, 75% of the minimum jobs within 4 years, and 100% of the minimum jobs within 5 years. Failure to achieve a milestone would trigger a decertification process.

Seventh, the emergency rule elaborates on the "demonstration of need" requirement mentioned in Chapter 63 of the Laws of 2005 for the addition (for both investment and development zones) of an additional distinct and separate contiguous area. A zone can demonstrate the need for a fourth or, as the case may be, a seventh distinct and separate contiguous area if (1) there is insufficient existing or planned infrastructure within the three (or six) distinct and separate contiguous areas to (a) accommodate business development and there are other areas of the applicant municipality that can be characterized as economically distressed and/or (b) accommodate development of strategic businesses as defined in the local development plan, or (2) placing all acreage in the other three or six distinct and separate contiguous areas would be inconsistent with open space and wetland protection, or (3) there are insufficient lands available for further business development within the other distinct and separate contiguous areas.

Eight, the emergency rule clarifies Chapter 63's permission for zone-certified businesses which will be located outside of the distinct and separate contiguous areas to receive zone benefits until decertified. The area which will be "grandfathered" shall be limited to the expansion of the certified business within the parcel or portion thereof that was originally located in the zone before redesignation. Each zone must identify any such business by December 30, 2005.

Ninth, the emergency rule tracks Chapter 63's requirement that new zone development plans, created in the conjunction with the new distinct

and separate contiguous areas to be approved by the Empire Zones Designation Board, are to be approved by the Department within 90 days of submission. The emergency rule defines the date of submission for each zone as the date of approval of the distinct and separate contiguous areas by the Empire Zones Designation Board.

Tenth, the emergency rule fulfills the requirements of Chapter 63 to subject all businesses applying for zone benefits to meet a "cost-benefit analysis". The cost-benefit analysis is to be included in the zone development plan by the applicant municipality. The definition included in the emergency rule lays out the basic formula for calculating the benefits received to the costs incurred.

Eleventh, the emergency rule clarifies the status of community development projects as a result of the reconfiguration of the zones pursuant to Chapter 63. The current regulations require the community development projects to be located in an Empire Zone in order for investments in those projects to qualify for tax benefits. Drawing distinct and separate contiguous areas around community development projects would severely limit the ability of Empire Zones to include as many eligible businesses as possible into the new distinct and separate contiguous areas. Community development projects are not necessarily required to be certified. There is a strong public policy preference for these projects and there is an expectation by their sponsors that they continue to offer tax credits to contributors until fundraising for the projects are completed. To that end, all community development projects approved by the Department before April 1, 2005 would be considered to be located within its respective Empire Zone, and a community development project will be considered to be located in the Empire Zone if it can demonstrate that a zone has been working with the project before April 1, 2005 for the purpose of submitting a boundary revision for inclusion in to the Zone that would include job creation.

Twelfth, the emergency rule would revise the application process in order to ensure timely action and improve efficiency and accountability. For example, the proposed process would no longer require the applicant to submit an application to both the Department and the Department of Labor. In addition, the proposed process allows the applicant to cure incomplete or deficient applications within a set time period.

Lastly, the emergency rule would add certain programmatic information that is helpful to zone administrators, applicants, and practitioners such as the method for determining the effective dates for certifications and boundary revisions.

The full text of the rule is available at www.empire.state.ny.us

This notice is intended to serve only as a notice of emergency adoption. This agency does not intend to adopt the provisions of this emergency rule as a permanent rule. The rule will expire January 22, 2006.

Text of emergency rule and any required statements and analyses may be obtained from: Donald T. Ross, Deputy Commissioner and General Counsel, Department of Economic Development, 30 S. Pearl St., Albany, NY 12245, (518) 292-5120, e-mail dtross@empire.state.ny.us

Regulatory Impact Statement

STATUTORY AUTHORITY:

Section 959(a) of the General Municipal Law authorizes the Commissioner of Economic Development to adopt rules and regulations governing the criteria of eligibility for empire zone designation, the application process, and the joint certification of a business enterprise.

LEGISLATIVE OBJECTIVES:

The rulemaking accords with the public policy objectives the Legislature sought to advance because the majority of such revisions are in direct response to recent statutory amendments and the remaining revisions conform the regulations to existing statute or clarify administrative procedures of the program. It is the public policy of the State to offer special incentives and assistance that will promote the development of new businesses, the expansion of existing businesses and the development of human resources within areas designated as Empire Zones. The proposed amendments help to further such objectives by enabling the Department of Economic Development to administer the program in a more efficient manner.

NEEDS AND BENEFITS:

The emergency rule is required in order to bring the regulations into accord with statute and to improve the overall administration and effectiveness of the program. There are several benefits that would be derived from this emergency rulemaking. First, the emergency regulations would conform to statutory provisions and thereby eliminate potential confusion to the practitioner. Second, the emergency rule would clarify the application process to ensure timely action and improve efficiency and accountability.

COSTS:

I. Costs to private regulated parties (the Business applicants): None. The emergency regulation will not impose any additional costs to the business applicants beyond the existing program. In fact, there may be a cost savings due to a clearer application and the ability to cure application deficiencies rather than being immediately denied.

II. Costs to the regulating agency for the implementation and continued administration of the rule: While there will be additional costs to the Department of Economic Development associated with the emergency rule making, this is a result of the statutory changes which the emergency regulation language tracks or interprets. All existing Empire Zones have to revise their boundaries as a result of the statutory changes, with certain exceptions tied to specific types of business or the timing of certain applications. This results in more paperwork and additional staff time over the course of the next twelve months as the program is reconfigured. However, over time staff and paperwork costs will be minimized because the statutory changes have clarified eligibility for the program and the revised regulations have made procedures for processing applications easier to understand.

III. Costs to the State government: None. There will be no additional costs to New York State as a result of the emergency rule making.

IV. Costs to local governments (the Local Zone administration): None. The emergency regulation will not impose any additional costs to the local zone administration beyond any additional costs associated with implementing the statutory requirements which reform the program. In the long term, there may be some cost savings in regards to staff time due to a clarification of program requirements.

LOCAL GOVERNMENT MANDATES:

None. Local governments are not mandated to participate in the Empire Zones Program. If a local government chooses to participate, there is a cost associated with local administration. However, this emergency rule does not impose any additional costs to the local governments beyond any additional costs associated with implementing the statutory requirements which reform the program.

PAPERWORK:

The emergency rule does create additional paperwork, insofar as the various Empire Zones have to refile applications to reconfigure their Zone acreage, identify regionally significant projects and "grandfathered" businesses where necessary, and process boundary revisions before deadlines enumerated in statute which are reproduced verbatim from the statute.

DUPLICATION:

The emergency rule will not duplicate or exceed any other existing Federal or State statute or regulation.

ALTERNATIVES:

No alternatives were considered with regard to amending the regulations in response to statutory revisions. Certain alternatives to policies seeking to be adopted were considered in certain subject areas where the Legislature provided some room for interpretation; for example, acreage devoted to existing businesses outside of the reconfigured zone areas, creation of investment zones within development zones, the placement of "nearby" acreage, the location of "grandfathered" businesses and the continuation of community development projects. In each case, interpretation was geared to preserving, to the extent possible, the expectation of benefits for existing zone businesses, making zone reconfiguration as clear as possible for existing zones, and enabling zone acreage to be utilized in the most effective manner. Finally, with regard to the application process, an alternative was considered to include more time for review of the application at the State level. This alternative was rejected because it was determined that certification of a business, which has a complete and sufficient application, should not be delayed.

FEDERAL STANDARDS:

There are no federal standards in regard to the Empire Zones program; it is purely a state program that offers, among other things, state and local tax credits. Therefore, the emergency rule does not exceed any Federal standard.

COMPLIANCE SCHEDULE:

The affected State agencies (Economic Development and Labor), local zone administration and the business applicants will be able to achieve compliance with the emergency regulation as soon as it is implemented.

Regulatory Flexibility Analysis

Participation in the Empire Zones Program is entirely at the discretion of each eligible municipality and business enterprise. Neither General Municipal Law Article 18-B nor the emergency regulations impose an obligation on any local government or business entity to participate in the program. The emergency regulation does not impose any adverse economic impact, reporting, recordkeeping, or other compliance requirements

on small businesses and/or local governments. In fact, the emergency regulations may have a positive economic impact on the small businesses and local governments that do participate due to clarifying changes, the added flexibility and a new application process. The administrative structure of the program was designed to offer a streamlined application and approval process by extracting only essential information from the applicants. In addition, the changes to the regulations that track changes in statute and result in a reconfiguration of zones will actually enhance the ability of businesses yet to apply which are located in distressed areas to receive program benefits. Local governments will have the additional short-term burden of taking the legal and administrative steps necessary to reconfigure their zones, but this is a statutorily imposed burden, not solely a regulatory one. Because it is evident from the nature of the emergency rule that it will have either no substantive impact, or a positive impact, on small businesses and local governments, no further affirmative steps were needed to ascertain that fact and none were taken. Accordingly, a regulatory flexibility analysis for small businesses and local government is not required and one has not been prepared.

Rural Area Flexibility Analysis

The program is a statewide program. There are eligible municipalities and businesses in rural areas of New York State. However, participation is entirely at the discretion of eligible applicant municipalities and eligible business enterprises. The program does impose some responsibility on those municipalities and businesses which participate in the program such as submitting applications and reports. The emergency rule will not impose any additional reporting, record keeping or other compliance requirements on public or private entities in rural areas. Therefore, the emergency regulation will not have a substantial adverse economic impact on rural areas or reporting, record keeping or other compliance requirements on public or private entities in such rural areas. Accordingly, a rural area flexibility analysis is not required and one has not been prepared.

Job Impact Statement

The emergency regulation relates to the Empire Zones Program. The Empire Zones Program itself is a job creation incentive. The emergency regulation will not have a substantial adverse impact on jobs and employment opportunities. In fact, the regulations, which result from statutory-based reforms, will enable the program to better fulfill its mission: job creation and investment for economically distressed areas. At the same time, businesses currently receiving benefits will not have their status jeopardized as a result of the regulations. Because it is evident from the nature of the emergency amendment that it will have either no impact, or a positive impact, on job and employment opportunities, no further affirmative steps were needed to ascertain that fact and none were taken. Accordingly, a job impact statement is not required and one has not been prepared.

poses to amend subdivision (gg) of section 100.2 of the Regulations of the Commissioner of Education, effective February 1, 2006. The following is a summary of the provisions of the proposed rule.

In general, subdivision (gg) of section 100.2 is amended to establish clearer definitions of terms and incidents, a ranking of the seriousness of incidents, and a common discipline standard to be used for the reporting of incidents. The amendments also establish the use of a school violence index as a comparative measure of the level of school violence in a school. The substantive amendments are as follows:

Section 100.2(gg)(1) is amended to provide a ranking of the seriousness of incidents and additional clarity to the definitions of physical and serious physical injury, sex offenses, robbery, arson, kidnapping, reckless endangerment, minor assaults, intimidation, burglary, criminal mischief, larceny, riot, weapons possession, drug and alcohol use, possession, or sale, and other disruptive incidents.

Section 100.2(gg)(2) is amended to provide instructions regarding the recording and reporting of offenses and the discipline standard to use in determining if an incident should be reported.

Section 100.2(gg)(3) is amended to establish a time frame for school districts to submit the summary of violent and disruptive incident reports.

Section 100.2(gg)(4) is amended to provide the types of incidents that shall be included in the report.

Section 100.2(gg)(8) is added to establish the use of a school violence index commencing with the 2005-2006 school year as a comparative measure of the level of violence in a school.

Text of proposed rule and any required statements and analyses may be obtained from: Anne Marie Koschnick, Legal Assistant, Office of Counsel, Education Department, Albany, NY 12234, (518) 473-8296, e-mail: legal@mail.nysed.gov

Data, views or arguments may be submitted to: James A. Kadamus, Deputy Commissioner for Elementary, Middle, Secondary and Continuing Education, Education Department, Rm. 875, Education Bldg. Annex, Albany, NY 12234, (518) 474-5915, e-mail: jkadamus@mail.nysed.gov

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

Regulatory Impact Statement

1. STATUTORY AUTHORITY:

Education Law section 101 continues the existence of the Education Department, with the Board of Regents at its head and the Commissioner of Education as the chief administrative officer, and charges the Department with the general management and supervision of public schools and the educational work of the State.

Education Law section 207 grants general rule-making authority to the Board of Regents to carry into effect the laws and policies of the State relating to education.

Education Law section 305(1) empowers the Commissioner of Education to be the chief executive officer of the State system of education and the Board of Regents and authorizes the Commissioner to enforce laws relating to the educational system and to execute educational policies determined by the Board of Regents. Education Law section 305(2) authorizes the Commissioner to have general supervision over all schools subject to the Education Law.

Education Law section 2802 authorizes the Commissioner of Education to promulgate regulations establishing a statewide uniform violent incident reporting system which public school districts, boards of cooperative educational services (BOCES), charter schools and county vocational education and extension boards shall follow to annually report to the Commissioner information concerning violent and disruptive incidents that occurred in the prior school year.

Chapter 402 of the Laws of 2005 amended Education Law section 2801(1) to define school function to mean "a school-authorized extra-curricular event or activity regardless of where such event or activity takes place, including any event or activity that may take place in another state."

2. LEGISLATIVE OBJECTIVES:

The proposed amendment is consistent with the above statutory authority and is necessary to improve the violent and disruptive incident reporting system required by Education Law section 2802.

3. NEEDS AND BENEFITS:

The proposed amendment is necessary to provide a ranking, standard for reporting, and more concise definition of reportable offenses as required by the uniform violent and disruptive incident reporting system for the reporting of incidents by school districts, BOCES, charter schools and county vocational education and extension boards, as required by Education Law section 2802, and thereby assure to the extent practicable that the reports are uniform and comparable throughout the State with respect to

Education Department

PROPOSED RULE MAKING NO HEARING(S) SCHEDULED

Uniform Violent and Disruptive Incident Reporting System

I.D. No. EDU-45-05-00008-P

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

Proposed action: Amendment of section 100.2(gg) of Title 8 NYCRR.

Statutory authority: Education Law, sections 101 (not subdivided), 207 (not subdivided), 305(1) and (2), 2801(1) and 2802(2), (3), (4) and (6); and L. 2005, ch. 402

Subject: Uniform violent and disruptive incident reporting system.

Purpose: To provide a ranking, standard for reporting, and more concise definition of reportable offenses as required by the uniform violent and disruptive incident reporting system for the reporting of incidents by school districts, BOCES, charter schools and county vocational education and extension boards, as required by Education Law section 2802, and establish the use of a school violence index as a comparative measure of the level of school violence in a school.

Substance of proposed rule (Full text is posted at the following State website: www.emsc.nysed.gov): The State Education Department pro-

the type of incidents reported and the actions taken in response to such incidents.

4. COSTS:

(a) Costs to State government: None.

(b) Costs to local government: The proposed amendment is necessary to implement Education Law section 2802 and does not impose any cost on local governments beyond those imposed by the statute. School districts, BOCES, charter schools and county vocational education and extension boards will continue to collect certain information on violent and disruptive incidents as part of existing recordkeeping procedures. The Department will provide a reporting form. The number of staff required to attend staff development will determine the costs associated with the amendment. It is estimated that this amendment will require one day of staff development per district. At an estimated cost of \$1,000 per district, the cumulative cost is \$700,000.

(c) Costs to private regulated parties: None.

(d) Costs to the regulating agency for implementation and continued administration of this rule: Violent and disruptive incident report summary sheets are received from each of the approximately 4,000 New York State school buildings. The costs associated with entry, analysis and verification of data requires the efforts of two full time equivalent (FTE) positions for two to three months. This is in addition to the staff development that must be offered to district staff that requires one FTE position for approximately two months. The total cost is approximately \$30,000.

5. LOCAL GOVERNMENT MANDATES:

The proposed amendment is necessary to provide a ranking, standard for reporting, and more concise definition of reportable offenses as required by the uniform violent and disruptive incident reporting system for the reporting of incidents by school districts, BOCES, charter schools and county vocational education and extension boards, as required by Education Law section 2802, and thereby assure to the extent practicable that the reports are uniform and comparable throughout the State with respect to the type of incidents reported and the actions taken in response to such incidents.

6. PAPERWORK:

The paper work requirements are the same for a school district, BOCES, charter schools or county vocational education and extension board. They must collect and maintain information on each violent or disruptive incident. This information may be kept in hard copy or electronic form and must be maintained at the building or program level in accordance with applicable retention schedules prescribed by the Commissioner.

Each school district, BOCES, charter school and county vocational education and board shall annually submit its report on violent or disruptive incidents, in the manner prescribed by the Commissioner, on or before the basic educational data system (BEDS) reporting deadline or such other date as determined by the Commissioner.

7. DUPLICATION:

The proposed amendment does not duplicate, overlap or conflict with State and federal rules or requirements, and is necessary to improve the uniform violent incident reporting system necessary to implement Education Law section 2802.

8. ALTERNATIVES:

The alternative of retaining the existing regulation was considered and rejected. The proposed amendment was deemed necessary to assure, to the extent practicable, that uniform and comparable data is collected and maintained throughout the State with respect to the type of incidents reported and the actions taken in response to such incidents, by providing a ranking, standard for reporting, and more concise definition of reportable offenses by school districts, BOCES, charter schools and county vocational education and extension boards as part of a uniform violent and disruptive incident reporting system, as required by Education Law section 2802.

The alternative of ranking the reportable incidents strictly in accordance with the ranking of seriousness of offenses used in the criminal justice system was considered but rejected. The Penal Law rankings are made for purposes of sentencing and determinations of lesser-included offenses under the State's criminal justice system, and if applied literally to the reporting of incidents occurring in a school setting would create a risk that certain incidents, such as other sex offenses, would be under-reported.

9. FEDERAL STANDARDS:

There are no related Federal standards.

10. COMPLIANCE SCHEDULE:

It is anticipated that regulated parties will be able to achieve compliance with this amendment by its effective date.

Regulatory Flexibility Analysis

Small Businesses:

The proposed amendment applies to school districts, boards of cooperative educational services (BOCES), charter schools and county vocational education and extension boards and relates to a change in reporting requirements of violent and disruptive incidents as part of a Uniform Violent Incident Reporting System pursuant to Education Law section 2802. The proposed amendment does not impose any adverse economic impact, reporting, recordkeeping or any other compliance requirements on small businesses. Because it is evident from the nature of the proposed amendment that it does not affect small businesses, no further measures were needed to ascertain that fact and none were taken. Accordingly, a regulatory flexibility analysis for small businesses is not required and one has not been prepared.

Local Governments:

1. EFFECT OF RULE:

The proposed amendment applies to all school districts, boards of cooperative educational services (BOCES), charter schools and county vocational education and extension boards in the State.

2. COMPLIANCE REQUIREMENTS:

The proposed amendment is necessary to provide a ranking, standard for reporting, and more concise definition of reportable offenses as required by the uniform violent and disruptive incident reporting system for the reporting of incidents by school districts, BOCES, charter schools and county vocational education and extension boards, as required by Education Law section 2802, and thereby assure to the extent practicable that the reports are uniform and comparable throughout the State with respect to the type of incidents reported and the actions taken in response to such incidents.

The paper work requirements are the same for a school district, BOCES, charter schools or county vocational education and extension board. They must collect and maintain information on each violent or disruptive incident. This information may be kept in hard copy or electronic form and must be maintained at the building or program level in accordance with applicable retention schedules prescribed by the Commissioner.

Each school district, BOCES, charter school and county vocational education and board shall annually submit its report on violent or disruptive incidents, in the manner prescribed by the Commissioner, on or before the basic educational data system (BEDS) reporting deadline or such other date as determined by the Commissioner.

The proposed amendment will not impose any additional professional services requirements on school districts, BOCES and county vocational education and extension boards.

3. PROFESSIONAL SERVICES:

The proposed amendment will not impose any additional professional services requirements on school districts, BOCES, charter schools or county vocational education and extension boards.

4. COMPLIANCE COSTS:

The proposed amendment is necessary to improve the violent and disruptive incident reporting system required by Education Law section 2802. It does not impose any cost on local governments beyond those imposed by the statute. School districts, BOCES, charter schools and county vocational education and extension boards collect certain information on violent and disruptive incidents as part of existing recordkeeping procedures. The Department provides a reporting form. The actual costs will vary due to the number of staff requiring staff development. It is estimated that implementation of this regulation will result in each district allowing staff to attend staff development. The cost at \$1,000 per district is approximately \$700,000.

5. ECONOMIC AND TECHNOLOGICAL FEASIBILITY:

The proposed amendment does not impose any additional technological requirements. Economic feasibility is addressed under the Compliance Costs section above.

6. MINIMIZING ADVERSE IMPACT:

The proposed amendment improves the reporting system required by Education Law section 2802. Because these statutory requirements specifically apply to school districts, BOCES, charter schools and county vocational education and extension boards it is not possible to exempt them from the proposed amendment's requirements or impose a lesser standard. The proposed amendment has been carefully drafted to meet statutory requirements and Regents policy while minimizing the impact on school districts, BOCES, charter schools and county vocational education and extension boards.

7. LOCAL GOVERNMENT PARTICIPATION:

The State Education Department solicited the input of members of the education community (including teachers, administrators, members of boards of education, community members and others) through the Committee of Practitioners.

Comments on the proposed amendment were solicited from school districts through the offices of the district superintendents of each supervisory district in the State.

Comments were also solicited through the New York State Division of Criminal Justice Services.

Rural Area Flexibility Analysis

1. TYPES AND ESTIMATED NUMBER OF RURAL AREAS:

The proposed amendment applies to all school districts, boards of cooperative educational services (BOCES), charter schools and county vocational education and extension boards in the State, including the 44 rural counties with less than 200,000 inhabitants and the 71 towns in urban counties with a population density of 150 per square mile or less.

2. REPORTING, RECORDKEEPING AND OTHER COMPLIANCE REQUIREMENTS; AND PROFESSIONAL SERVICES:

The proposed amendment is necessary to provide a ranking, standard for reporting, and more concise definition of reportable offenses as required by the uniform violent and disruptive incident reporting system for the reporting of incidents by school districts, BOCES, charter schools and county vocational education and extension boards, as required by Education Law section 2802, and thereby assure to the extent practicable that the reports are uniform and comparable throughout the State with respect to the type of incidents reported and the actions taken in response to such incidents.

The paper work requirements are the same for a school district, BOCES, charter schools or county vocational education and extension board. They must collect and maintain information on each violent or disruptive incident. This information may be kept in hard copy or electronic form and must be maintained at the building or program level in accordance with applicable retention schedules prescribed by the Commissioner.

Each school district, BOCES, charter school and county vocational education and board shall annually submit its report on violent or disruptive incidents, in the manner prescribed by the Commissioner, on or before the basic educational data system (BEDS) reporting deadline or such other date as determined by the Commissioner.

The proposed amendment will not impose any additional professional services requirements on school districts, BOCES and county vocational education and extension boards.

3. COMPLIANCE COSTS:

The proposed amendment is necessary to improve the violent and disruptive incident reporting system required by Education Law section 2802 and does not impose any cost on local governments beyond those imposed by the statute. School districts, BOCES, charter schools and county vocational education and extension boards collect certain information on violent and disruptive incidents as part of existing recordkeeping procedures. The Department provides a reporting form. The actual costs vary according to the number of staff requiring staff development. It is estimated that this amendment will result in staff from each district requiring one day for staff development at an estimated cost of \$1,000 per day. This results in a cumulative costs for 700 districts of \$700,000.

4. MINIMIZING ADVERSE IMPACT:

The proposed amendment is necessary to improve the violent and disruptive incident reporting system required by Education Law section 2802. Because these statutory requirements specifically apply to school districts, BOCES, charter schools and county vocational education and extension boards in the State, it is not possible to exempt school districts, BOCES, charter schools or county vocational education and extension boards in rural areas from the proposed amendment's requirements or establish different compliance and reporting requirements. The proposed amendment has been carefully drafted to meet statutory requirements and Regents policy while minimizing the impact on school districts, BOCES, charter schools and county vocational education and extension boards.

5. RURAL AREA PARTICIPATION:

The State Education Department solicited the input of members of the education community (including teachers, administrators, members of boards of education, community members and others) through the Committee of Practitioners.

Comments on the proposed amendment were solicited from school districts through the offices of the district superintendents of each supervisory district in the State.

Comments were also solicited through the New York State Division of Criminal Justice Services.

Comments on the proposed amendment were also solicited from the Department's Rural Advisory Committee, whose membership includes school districts and BOCES located in rural areas.

Job Impact Statement

The proposed amendment applies to school districts, boards of cooperative educational services (BOCES), charter schools and county vocational education and extension boards and relates to reporting requirements of violent and disruptive incidents as part of a Uniform Violent Incident Reporting System pursuant to Education Law section 2802. The proposed amendment will not have an adverse impact on jobs or employment opportunities. Because it is evident from the nature of the proposed amendment that it will have no impact on jobs or employment opportunities, no further steps were needed to ascertain those facts and none were taken. Accordingly, a job impact statement is not required and one has not been prepared.

Department of Health

EMERGENCY RULE MAKING

Newborn Screening Panel

I.D. No. HLT-34-05-00001-E

Filing No. 1259

Filing date: Oct. 19, 2005

Effective date: Oct. 19, 2005

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

Action taken: Amendment of sections 69-1.1 through 69-1.3 of Title 10 NYCRR.

Statutory authority: Public Health Law, section 2500-a

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

Specific reasons underlying the finding of necessity: New York Public Health Law Section 2500-a authorizes the Commissioner of Health to designate additional diseases or conditions for inclusion in the newborn screening program test panel by regulation. This regulatory amendment adds 33 conditions all inherited metabolic disorders -- to the current 11 that comprise New York State's newborn screening test panel, pursuant to existing Subpart 69-1.2. The Department of Health finds that immediate adoption of this rule is necessary to preserve the public health, safety and general welfare, and that compliance with State Administrative Procedure Act (SAPA) Section 202(1) for this rulemaking would be contrary to the public interest and welfare.

Proposed addition of 33 new conditions would triple the number of conditions included in the screening panel, currently 11, *i.e.*, ten genetic/congenital disorders and one infectious disease. The potential positive effect on public health of this action is best illustrated by the fact that many conditions in the expanded screening panel proposed by this amendment have several variants or subtypes with different clinical presentations, which, if each were counted as a separate disorder, would translate into the Newborn Screening Program's ability to detect more than 71 serious but treatable neonatal conditions. Immediate implementation of the proposed expanded panel is both feasible and obligatory; the necessary technology (*i.e.*, tandem mass spectrometry (MS/MS) instrumentation) is already in operation following previous screening panel expansions.

A system for follow-up and ensuring access to necessary treatment for identified infants is fully established and adequately staffed. The proposed new conditions will be identified by the Program's collecting and analyzing more data from MS/MS examination of each newborn's dried blood spot specimen than currently done. Now that the Program is technically proficient in MS/MS testing and experienced in spectrometric data collection and interpretation, failure to expand testing immediately would mean infants would go untested, undetected, and may thus suffer irreversible medical harm and even death. Although individually each of the 33 conditions is rare, it is expected that in the aggregate their prevalence will approach that of PKU - approximately 1 in 18,000 births. Therefore,

mandatory inclusion of the 33 additional conditions under the implementing regulations is rigorously time-constrained.

To avoid unnecessary and potentially detrimental delay in full implementation of the expanded screening profile, the amended regulatory language of 10 NYCRR Sections 69-1.1 through 69-1.3 of Subpart 69-1 is hereby adopted by emergency promulgation.

Subject: Newborn screening panel.

Purpose: To add 33 disorders to the newborn screening panel.

Text of emergency rule: Section 69-1.1 of Subpart 69-1 is amended as follows:

Section 69-1.1 Definitions. As used in this Part:

(a) Testing laboratory means the Wadsworth Center Laboratory of Newborn Screening and Genetic Services, New York State Department of Health, Empire State Plaza, Albany, [NY] *New York* 12201.

[(1)](n) Biohazardous specimen means a specimen collected from an infant who may have, or whose mother may have, an infectious disease agent transmissible by blood contact as determined by the infectious disease officer of the responsible institution.]

[(m)](l) Repeat specimen means an additional satisfactory specimen required by the testing laboratory.

[(n)](m) Specialized care center means a health care facility established under article 28 of the Public Health Law which is approved by the department and certified by the Wadsworth Center [for Laboratories and Research] to provide treatment and/or services to children identified by the testing laboratory.

[(o)](n) HIV specialized care center means a health care facility established under article 28 of the Public Health Law which: (1) is designated as an AIDS Center for [provision of] *providing* care to women and children; or (2) receives state and/or federal funds [to provide] *for* comprehensive treatment and services to HIV-exposed newborns identified by the testing laboratory, and to [their] *the newborns'* mothers and [their] families.

[(p)](o) Department means the New York State Department of Health. Section 69-1.2 of Subpart 69-1 is amended as follows:

Section 69-1.2 Diseases and conditions tested. (a) Unless a specific exemption is granted by the State Commissioner of Health, the testing required by section 2500-a and section 2500-f of the Public Health Law shall be [done] *performed* by the testing laboratory according to recognized clinical laboratory procedures.

(b) Diseases and conditions to be tested *for* shall include: [phenylketonuria, branched-chain ketonuria, homocystinuria, galactosemia, homozygous sickle cell disease, hypothyroidism, biotinidase deficiency, human immunodeficiency virus (HIV) exposure and infection, cystic fibrosis, congenital adrenal hyperplasia, and medium-chain acyl-CoA dehydrogenase deficiency (MCADD).]

- argininemia (ARG);*
- argininosuccinic acidemia (ASA);*
- biotinidase deficiency;*
- branched-chain ketonuria, also known as maple syrup urine disease (MSUD);*
- carnitine palmitoyl transferase Ia deficiency (CPT-IA);*
- carnitine palmitoyl transferase II deficiency (CPT-II);*
- carnitine-acylcarnitine translocase deficiency (CAT);*
- carnitine uptake defect (CUD);*
- citrullinemia (CIT);*
- cobalamin A, B cofactor deficiency (Cbl A,B);*
- congenital adrenal hyperplasia (CAH);*
- cystic fibrosis (CF);*
- dienoyl-CoA reductase deficiency (DE REDUCT);*
- galactosemia;*
- glutaric acidemia type I (GA-I);*
- hemoglobinopathies, including homozygous sickle cell disease;*
- homocystinuria;*
- human immunodeficiency virus (HIV) exposure and infection;*
- 3-hydroxy-3-methylglutaryl-CoA lyase deficiency (HMG);*
- hyperammonemia/ornithinemia/citrullinemia (HHH);*
- hypermethioninemia (HMET);*
- hypothyroidism;*
- isobutyryl-CoA dehydrogenase deficiency (IBG or IBCD);*
- isovaleric acidemia (IVA);*
- long-chain 3-hydroxyacyl-CoA dehydrogenase deficiency (LCHADD);*
- malonic aciduria (MAL);*
- medium-chain acyl-CoA dehydrogenase deficiency (MCADD);*
- medium-chain ketoacyl-CoA thiolase deficiency (MCKAT);*

- medium/short-chain hydroxyacyl-CoA dehydrogenase deficiency (M/SCHAD);*
- 2-methylbutyryl-CoA dehydrogenase deficiency (2MBG);*
- 3-methylcrotonyl-CoA carboxylase deficiency (3-MCC);*
- 3-methylglutaconic aciduria (3MGA);*
- 2-methyl 3-hydroxy butyryl-CoA dehydrogenase deficiency (2M3HBA);*
- methylmalonic acidemia (Cbl C, D);*
- methylmalonyl-CoA mutase deficiency (MUT);*
- mitochondrial acetoacetyl-CoA thiolase deficiency (BKT);*
- mitochondrial trifunctional protein deficiency (TFP);*
- multiple acyl-CoA dehydrogenase deficiency (MADD, also known as GA-II);*
- multiple carboxylase deficiency (MCD);*
- phenylketonuria (PKU);*
- propionic acidemia (PA);*
- short-chain acyl-CoA dehydrogenase deficiency (SCADD);*
- tyrosinemia (TYR); and*
- very long-chain acyl-CoA dehydrogenase deficiency (VLCADD).*

Section 69-1.3 of Subpart 69-1 is amended as follows:

Section 69-1.3 Responsibilities of the chief executive officer. The chief executive officer shall ensure that a satisfactory specimen is submitted to the testing laboratory for each newborn born in the hospital, or admitted to the hospital within the first twenty-eight (28) days of life [with] *from whom* no specimen [having] *has* been previously collected, and that the following procedures are carried out:

(a) The infant's parent is informed of the purpose and need for newborn screening, and given newborn screening educational materials provided by the testing laboratory.

(h) [Biohazardous specimens shall be thoroughly] *Thoroughly* dried [and then individually sealed in a transparent, plastic bag. The outside of the plastic bag shall be labeled as a biohazardous specimen] *specimens shall be submitted in accordance with instructions provided by the testing laboratory.*

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-34-05-00001-P, Issue of August 24, 2005. The emergency rule will expire December 17, 2005.

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: regsna@health.state.ny.us

Summary of Regulatory Impact Statement

Statutory Authority:

Public Health Law (PHL) Section 2500-a requires institutions caring for infants 28 days of age or under to cause newborns to be tested for phenylketonuria, branched-chain ketonuria, homocystinuria, galactosemia, homozygous sickle cell disease, hypothyroidism, and other conditions to be designated by the Commissioner of Health. Specifically, PHL Section 2500-a (a) provides statutory authority for the Commissioner of Health to designate in regulation other diseases or conditions for newborn testing in accordance to the Department's mandate to prevent infant and child mortality, morbidity, and diseases and disorders of childhood.

Legislative Objectives:

In enacting PHL Section 2500-a, the Legislature intended to promote public health through mandatory screening of New York State newborns to detect those with serious but treatable neonatal conditions and to ensure their referral for medical intervention. This proposal, which would add 33 conditions all inherited metabolic disorders to the list of ten genetic/congenital disorders and one infectious disease currently in regulation, is in keeping with the Legislature's public health aims of early identification and timely medical intervention for all the State's youngest citizens.

Needs and Benefits:

Data compiled from New York State's Newborn Screening Program and other states' programs have shown that timely intervention and treatment for metabolic disorders can drastically improve affected infants' survival chances and quality of life. Advancing technology, emerging medical treatments and rising public expectations for this critical public health program demand that the panel of screening conditions be expanded at this time through this amendment of Subpart 69-1.2, which would add 33 inherited metabolic disorders to the scope of newborn screening services already provided by the Department. For ease of readability, all

conditions -- those in the existing screening panel and the proposed 33 additional conditions -- have been arranged alphabetically in a column format.

The 33 conditions all inborn errors of metabolism can be grouped according to the resulting abnormality: organic acidemias; fatty acid oxidation disorders; urea cycle disorders; and amino acid disorders. Although individually each of the conditions is rare, it is expected that in the aggregate their prevalence will approach that of PKU - approximately 1 in 18,000 births. Infants may die during an early clinical episode, and children who survive severe clinical episodes may experience varying degrees of central nervous system dysfunction, including developmental delay and other abnormalities. However, many inborn errors of metabolism can be effectively treated when detected early, primarily through dietary intervention and avoidance of metabolic stressors such as fasting, especially during childhood illness. Without newborn screening a child may not be recognized with a metabolic disorder until he/she develops cognitive or behavioral symptoms, and/or is admitted to the hospital with seizures, ataxia, movement disorder, stroke, coma or other afflictions. Early diagnosis of the error can make the difference between lifelong impairment and healthy development.

Overall, the potential positive effect on public health of the proposed screening panel is significant. It is best illustrated by considering that many of the conditions in the expanded screening panel proposed by this amendment carry several variants or subtypes, each with a different clinical presentation, which, if viewed as separate disorders, would translate into the Newborn Screening Program's ability to detect more than 71 serious but treatable neonatal conditions.

This amendment would also codify the Program's practice of reporting clinically significant abnormalities of hemoglobin detected concurrently with homozygous sickle cell disease. In addition, this amendment would append an acronym in regulation to each condition for which an acronym is commonly used (*e.g.*, PKU for phenylketonuria). Such linkage will facilitate recognition by primary care physicians and laypersons, most of whom are unfamiliar with the full, complex scientific names of these relatively rare metabolic conditions, and will make the regulation's express terms consistent with acronyms used in the Program's administrative forms and educational materials. This amendment also proposes to modify paragraph (h) of Section 69-1.3 to include in regulation current procedures for use and labeling of mailers for forwarding newborn specimens to the Department, procedures that are consistent with United States Postal Service (USPS) regulations, as amended effective January 1, 2004. The Program's new specimen collection form folds over to cover the dried blood spot specimens with a protective flap preprinted with the universal biohazard symbol. Therefore, the existing requirement in Section 69-1.3(h) for enclosing the specimen in a transparent plastic bag and labeling the package by hand is no longer necessary and must be deleted.

Since the Program introduced the new specimen collection form, which provides packaging at a safety level suitable for biohazardous specimens, the facility's infection control officer is no longer required to consider the possible infectious status of the infant or his/her mother to determine how a specimen should be submitted. Therefore, this amendment would also delete from Section 69-1.1 the definition for biohazardous specimen, and modify Section 69-1.3(h) accordingly as it is no longer necessary to make such a distinction in packaging specimens.

Costs:

Costs to Private Regulated Parties:

Regulated parties that are birthing facilities will incur no new costs related to collection and submission of blood specimens to the Program, since the dried blood spot specimens now collected and mailed to the program for other currently available testing would also be tested for the additional disorders proposed by this amendment.

The Program estimates that, following implementation of this proposal, 2,700 newborns will screen positive for one or more of the new conditions annually, and will require either repeat screening or referral to facilities and practitioners, depending on whether the value of the initial screening result for the condition's marker is close to the empirically determined cutoff point for positive, or significantly above that point. Cost figures that follow are based on this high-end estimate for presumptive positives and an estimated maximum number of infants needing immediate referral. The Department has revised its estimate of the number of infants expected to screen positive annually based on the results of a two-pronged approach: the Program's four months' experience with screening approximately 85,000 specimens for the 20-test panel mandated by the emergency rulemaking effective October 28, 2004; and a shorter-term, parallel study on 2,000 residual newborn specimens stripped of all identifiers and ana-

lyzed for any one of the 13 conditions added by emergency rulemaking effective April 25, 2005. Both undertakings used preliminary values for the cutoff point (marker level) for considering a specimen positive, values that intentionally maximize the number of presumptive positives. As the Program gains experience testing and verifies clinical outcomes, it is reasonable to expect that cutoff points will be adjusted to reduce the number of false positives to as few as possible, while retaining the capability to capture all true positives and eliminate false negatives.

Approximately 500 of the 2,700 screen-positive infants are expected to show marker levels significantly above the cutoff for positive and will be referred immediately for clinical assessment; repeat specimens will be requested from the remaining 2,200 screen-positive infants. Of the repeat specimens submitted, about 20 percent will be screen-positive on the repeat specimen and require referral for clinical assessment. The Department estimates that, on average, each of the seven metabolic centers would be referred an additional three infants per week for clinical assessment and possible additional testing to confirm or refute screening results.

Birthing facilities would likely incur minimal additional costs related to fulfilling their responsibilities for ensuring collection of a repeat specimen and referral of identified infants. Such costs would be limited to human resources costs of approximately 2.0 person-hours for arranging collection of a second specimen and its forwarding to the Department. On average, each birthing facility can expect to handle 4.5 additional infants in need of referral to a metabolic center per year as a result of screening tests conducted pursuant to this proposal. This increase is expected to have little effect on the facility's workload since currently the number of infants referred to all facilities annually ranges from 350 to 500; therefore, no additional staff would be required at these institutions to comply with this proposal. Any facility can calculate its specific cost impact based on its annual number of births and expenses applying the following factors: an estimated rate of ten screen-positive infants per 1,000 births; and a referral rate of 3.5 infants per 1,000 births.

Facilities and practitioners would incur human resources costs per referral of approximately \$300 for: medical evaluation, including confirmatory testing in some cases; ongoing care; and treatment supplies and dietary supplements. However, given the low specificity of the screening tests, the Department anticipates that as many as 98 percent of referred infants will ultimately be found not to be afflicted with the target condition, based on clinical assessment and laboratory tests.

Regulated parties will incur additional human resources costs of two to five person-hours and an estimated \$450 per affected infant, for providing post-evaluation and ongoing medical management services to the approximately two percent of screen-positive infants whose disorders are confirmed.

Infants who screen positive for one or more of the 33 new metabolic conditions will require laboratory tests and comprehensive-level office visits at a metabolic center to determine final diagnosis. The cost of these services is estimated to range from \$261,000 to \$754,000 annually, applying the prevailing rate of \$300 for a comprehensive-level office visit, and, for the various laboratory tests that may be required, charges ranging from \$150 to \$1,000. The number and kind of laboratory tests, and therefore testing costs, will vary greatly, depending on the type of metabolic disorder, the specific condition under consideration and the availability of definitive laboratory methods, such as mutation analysis by DNA-based genetic tests.

The Department expects that costs of medical services and supplies will be reimbursed by all payor mechanisms now covering the care of children identified with conditions currently in the newborn screening panel. Payors include indemnity health plans, managed care organizations, New York State's medical assistance program (Medicaid), Child Health Plus, and Children with Special Health Care Needs programs.

Many of the costs associated with medical management of a child affected with a metabolic disorder are not attributable solely to the proposed regulation, as most would have been incurred at some point following diagnosis, if targeted testing had been sought at the primary care level for children in whom the disorder was not fatal shortly after birth. Although early diagnosis through the proposed rule may result in increased overall lifetime health care costs for patients who would have died in the absence of screening, *e.g.*, those with propionic acidemia, substantial cost savings are likely to be accrued from avoided complications. Early diagnosis and treatment may prevent or lessen irreversible organ damage, and thereby reduce costs related to caring for affected individuals incurred by New York's health care and education systems. Furthermore, early detection affords those affected with the opportunity for improved quality of life, a benefit that cannot be quantified.

Costs for Implementation and Administration of the Rule:**Costs to State Government:**

Although funding for the State's Newborn Screening Program requires State expenditures, proactively treating congenital abnormalities may save money by avoiding more financially burdensome medical costs and institutional services.

State-operated facilities providing birthing services, infant follow-up and medical care would incur costs and savings as described for regulated parties. The Medicaid Program would also experience costs equal to the 25-percent State share for treatment and medical care of affected Medicaid-eligible children. However, Medicaid would also benefit from cost savings, since early diagnosis avoids medical complications, thereby reducing the average length of hospital stays and need for expensive high-technology health care services.

Costs to the Department:

Costs incurred by the Department's Wadsworth Center for performing newborn screening tests, providing short- and long-term follow-up, and supporting continuing research in neonatal and genetic diseases are covered by State budget appropriations recently augmented by dedicated line-item funding for program expansion.

A system for follow-up and assurance of access to necessary treatment for identified infants is fully established. In order to accommodate testing panel expansions effective October 28, 2004, the Department bolstered staffing in the Program's follow-up unit to handle the increased number of screen-positive results and interface with medical practitioners and facilities, by redeploying staff and filling three positions with an annual value of \$138,381. The Department has requested permission to fill one clerical and eight scientific/clinical positions with a total annual value of \$565,365. The requested positions would allow the Department to meet public demands for a reduction in both the time required to generate screening test results and the number of infants with false positive screen test results, by conducting testing and data entry during weekday evening hours and on weekends and by assisting in development of molecular tests to better differentiate infants in need of immediate referral from infants whose marker levels may have been temporarily elevated or otherwise falsely positive. The Department also expects that staffing costs attributable to hiring a physician, which are included in the cost figures identified above, would translate to long-term cost savings across all affected parties. The physician would provide review of screen test results, thereby potentially reducing both the number of infants requiring testing of a second specimen and the number of infants requiring referral to metabolic centers for medical evaluation and testing.

Costs to Local Government:

Local government-operated facilities providing birthing services, infant follow-up and medical care would incur the costs and savings described for private regulated parties. County governments would also incur costs equal to the 25-percent county share for treatment and medical care of affected Medicaid-eligible children, and realize cost savings as described above for State-operated facilities.

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 a facility, such as a hospital, caring for infants 28 days of age or under and, therefore, is subject to these regulations to the same extent as a private regulated party.

Paperwork:

No increase in paperwork would be attributable to activities related to specimen collection, and reporting and filing of test results, as the number and type of forms now used for these purposes will not change. Facilities that submit newborn specimens will sustain minimal to no increases in paperwork, specifically, only that necessary to conduct and document follow-up and/or referral.

Duplication:

These rules do not duplicate any other law, rule or regulation.

Alternative Approaches:

Potential delays in detection of serious but treatable neonatal conditions until onset of clinical symptoms would result in increased infant morbidity and mortality, as well as higher health care costs, and are therefore unacceptable. Given the decided public health benefits of preventing adverse clinical outcomes in affected infants, the Department has determined that there are no alternatives to requiring newborn screening for these conditions.

Federal Standards:

There are no existing federal standards for medical screening of newborns.

Compliance Schedule:

The director of the Newborn Screening Program has participated in discussions with representatives of the Governor's Office, the Health Commissioner's Office and the Department's Public Affairs Group to optimize coordinated notification and implementation of this proposed newborn test panel expansion. Educational materials for parents and health care professionals have been updated with information on the expanded screening panel.

The Department is continuing to work with the Newborn Screening Task Force, comprised of directors of specialty care centers, payors, national experts in newborn screening quality assurance, and health care professionals, for ongoing assessment of the scope of needed follow-up services, and their availability at specialized care centers and other health care settings. The Program is collaborating with various Department offices, including the Office of Medicaid Management and the Office of Managed Care, to ensure adequate reimbursement and coverage inclusiveness for required follow-up services, and confirmatory, diagnostic and monitoring testing.

The Commissioner of Health is expected to notify all New York State-licensed physicians by letter informing them of this newborn screening panel expansion. The letter will also be distributed to hospital CEOs and their designees responsible for newborn screening, as well as other affected parties.

There appears to be no potential for organized opposition. Consequently, regulated parties should be able to comply with these regulations as of their effective date.

Regulatory Flexibility Analysis**Effect on Small Businesses and Local Governments:**

This proposed amendment to add 33 conditions all inherited metabolic disorders to the list of ten genetic/congenital disorders and one infectious disease for which every newborn in New York State must be tested will affect hospitals; alternative birthing centers; and physician and midwifery practices operating as small businesses or operated by local government, provided such facilities care for infants 28 days of age or under, or are required to register the birth of a child. The Department estimates that ten hospitals and one birthing center in the State meet the definition of a small business. Local government, including the New York City Health and Hospitals Corporation, operates 21 hospitals. No metabolic center is operated by a local government or as a small business. New York State licenses 67,790 physicians and certifies 350 licensed midwives, some of whom, specifically those in private practice, operate as small businesses. It is not possible, however, to estimate the number of these medical professionals operating an affected small business, primarily because the number of physicians directly involved in delivering infants cannot be ascertained.

Compliance Requirements:

The Department expects that affected facilities, and medical practices operated as small businesses or by local governments, will experience minimal additional regulatory burdens in complying with the amendment's requirements, as functions related to mandatory newborn screening are already embedded in established policies and practices of affected institutions and individuals. Activities related to collection and submission of blood specimens to the State's Newborn Screening Program will not change, since newborn dried blood spot specimens now collected and mailed to the Program for other currently performed testing would also be used for the additional tests proposed by this amendment. However, birthing facilities and at-home birth attendants (*i.e.*, licensed midwives) would be required to follow up infants screening positive for any one or more of the conditions proposed for addition to the State's panel, and assume responsibility for referral for medical evaluation and additional testing as appropriate for each infant's medical status. The anticipated increased burden is expected to have minimal effect on the ability of small businesses or local government-operated facilities to comply, as no such facility would experience an increase of more than two per week in the number of infants requiring referral. Therefore, the Department expects that regulated parties will be able to comply with these regulations as of their effective date, upon filing with the Secretary of State.

Professional Services:

No need for additional professional services is anticipated. Although increased numbers of repeat specimens and referrals are foreseen, affected facilities' existing professional staff should be able to assume the minimal increase in workload. Infants with positive screening tests for one or more of the disorders included in this amendment would be referred to the

facility physician already designated to receive positive screening results for MCADD and PKU.

Compliance Costs:

Birth facilities operated as small businesses and by local governments, and practitioners who are small business owners (*i.e.*, private practicing licensed midwives who assist with at-home births) will incur no new costs related to collection and submission of blood specimens to the State Newborn Screening Program, since the dried blood spot specimens now collected and mailed to the Program for other currently available testing would also be used for the additional tests proposed by this amendment. However, such facilities, and, to a lesser extent, at-home birth attendants, would likely incur minimal costs related to following up infants screening positive for one or more of the 33 disorders proposed for addition to the newborn screening panel, primarily because testing proposed under this regulation is expected to result in, on average, fewer than one screen-positive infant per week at each of the 11 birthing facilities that are small businesses. Communicating the need and/or arranging referral for medical evaluation of one additional identified infant would take 1.0 person-hour, and is expected to be able to be accomplished with existing staff.

Providers, such as clinical specialists (*i.e.*, medical geneticists), and primary and ancillary care providers (*i.e.*, pediatricians, nutritionists and physical therapists), some of whom operate small businesses, would incur costs for first response and ongoing care of affected infants, as well as treatment supplies and dietary supplements. Specifically, such providers would incur human resources costs of approximately \$300 for an initial comprehensive medical evaluation of one infant with an abnormal screening test result. However, given the low specificity of screening tests to ensure no false-negative test results, the Department anticipates that as many as 98 percent of infants will be found to not have the target condition, based on clinical assessment and relatively simple confirmatory tests.

Hospitals and independent providers will incur additional costs for providing post-evaluation and ongoing medical management services to the approximately two percent of screen-positive infants whose disorders are confirmed. Human resources costs for post-confirmation services of two to five person-hours, involving medical geneticists, genetic counselors and nutritionists, have been estimated at \$450 per affected infant, including \$300 for a comprehensive-level visit and \$150 for a genetic or nutritional counseling session.

The Department expects that costs of medical services and supplies will be reimbursed by all payor mechanisms now covering the care of children identified with conditions in the present newborn screening panel, as well as the care of children diagnosed with a metabolic disorder by targeted testing at the primary care level. Payors include indemnity health plans, managed care organizations, and New York State's medical assistance program (Medicaid Program), Child Health Plus and Children with Special Health Care Needs programs. The Department also expects that medical care providers will claim reimbursement from one or more of these payors at a rate equal to the usual and customary charge, thereby recouping costs.

Overall health care costs for definitive diagnosis and comprehensive medical management of affected individuals will vary significantly, primarily depending on the condition and the services and supplies required for sustaining some level of continued health. Many of the costs associated with medical management of a child affected with a metabolic disorder are not attributable solely to the proposed regulation, as most such expenses would have been incurred at some point following diagnosis, by targeted testing at the primary care level. Although the proposed rules' speeding early diagnosis may result in increased overall lifetime care and treatment costs for patients who would have died in the absence of screening, *e.g.*, those with propionic acidemia, substantial cost savings are likely to be accrued from prevented medical complications to set off against treatment costs. Early diagnosis and treatment may prevent or lessen irreversible organ damage, and thereby reduce costs related to caring for affected individuals incurred by New York's health care and education system infrastructure. Furthermore, early detection affords affected individuals the opportunity for improved quality of life, a benefit that cannot be quantified.

Economic and Technological Feasibility:

The proposed regulation would present no economic or technological difficulties to any small businesses and local governments affected by this amendment.

Minimizing Adverse Impact:

The Department did not consider alternate, less stringent compliance requirements, or regulatory exceptions for facilities operated as small businesses or by local government, because of the importance of the

proposed testing to statewide public health and welfare. These amendments will not have an adverse impact on the ability of small businesses or local governments to comply with Department requirements for mandatory newborn screening, as full compliance would require minimal enhancements to present collection, reporting, follow-up and recordkeeping practices.

Small Business and Local Government Participation:

The requirements proposed by this amendment are in effect as an emergency rule. Notification of the amendment already occurred prior to and concurrent with statewide implementation of the expanded newborn screening panel.

Rural Area Flexibility Analysis

Types of Estimated Numbers of Rural Areas:

Rural areas are defined as counties with a population under 200,000; and, for counties with a population larger than 200,000, rural areas are defined as towns with population densities of 150 or fewer persons per square mile. Forty-four counties in New York State with a population under 200,000 are classified as rural, and nine other counties include certain townships with population densities characteristic of rural areas.

This proposed amendment to add 33 conditions all inherited metabolic disorders to the list of ten genetic/congenital disorders and one infectious disease for which every newborn in the State must be tested will affect hospitals, alternative birthing centers, and physician and midwifery practices located in rural areas, provided such facilities care for infants 28 days of age or under, or are required to register the birth of a child. The Department estimates that 54 hospitals and birthing centers operate in rural areas, and another 30 birthing facilities are located in counties with low-population density townships. Although they are well distributed throughout the State, no specialized care center operates in a rural area. New York State licenses 67,790 physicians and certifies 350 licensed midwives, some of whom are engaged in private practice in areas designated as rural; however, the number of professionals practicing in rural areas cannot be estimated because licensing agencies do not maintain records of licensees' employment addresses.

Reporting, Recordkeeping and other Compliance Requirements:

The Department expects that facilities and medical practices affected by this amendment and operating in rural areas will experience minimal additional regulatory burdens in complying with the amendment's requirements, as activities related to mandatory newborn screening are already part of established policies and practices of affected institutions and individuals. Collection and submission of blood specimens to the State's Newborn Screening Program will not be altered by this amendment, since the dried blood spot specimens now collected and mailed to the program for other currently available newborn testing would also be used for the additional tests proposed by this amendment. However, birthing facilities and at-home birth attendants (*i.e.*, licensed midwives) would be required to follow up infants screening positive for one of the 33 disorders proposed for addition to the panel, and assume responsibility for referral for medical evaluation and additional testing as appropriate for each infant's medical status. This requirement is expected to affect minimally the ability of rural facilities to comply, as no such facility would experience an increase of more than two per week in infants requiring referral. Therefore, the Department anticipates that regulated parties in rural areas will be able to comply with these regulations as of their effective date, upon filing with the Secretary of State.

Professional Services:

No need for additional professional services is anticipated. Although small increases in the number of repeat specimens and referrals are foreseen, affected facilities' existing professional staff are expected to be able to assume the resulting minimal increase in workload. Infants with a positive screening test for one or more of the disorders included in this amendment will be referred to the facility physician already designated to receive positive screening results for MCADD and PKU.

Compliance Costs:

Birth facilities operating in rural areas and practitioners in private practice in rural areas (*i.e.*, licensed midwives who assist with at-home births) will incur no new costs related to collection and submission of blood specimens to the State's Newborn Screening Program, since the dried blood spot specimens now collected and mailed to the program for other currently available testing would also be used for the additional tests proposed by this amendment. However, such facilities and, to a lesser extent, at-home birth attendants would likely incur minimal costs related to follow-up of infants screening positive for one of the metabolic disorders, since the proposed added testing is expected to result in no more than one more referral per week. Communicating the need and/or arranging referral

for medical evaluation of one additional identified infant would take 1.0 person-hour, and is expected to be able to be accomplished with existing staff.

Rural providers, including clinical specialists (*i.e.*, medical geneticists) and primary and ancillary care providers (*i.e.*, pediatricians, nutritionists and physical therapists), would incur costs for first response and ongoing care of identified infants, as well as treatment supplies and dietary supplements. Specifically, such medical professionals would incur human resources costs of approximately \$300 for an initial comprehensive medical evaluation of each infant with an abnormal screening result. However, given the low specificity of screening tests to ensure no false negative results, the Department anticipates that as many as 98 percent of infants will be ultimately found to not be afflicted with the target condition, based on clinical assessment practices and relatively simple confirmatory tests.

To the extent specialized services are delivered in a rural area, hospitals and independent providers in rural areas will incur additional costs for post-evaluation and ongoing medical management services to the approximately two percent of screen-positive infants whose disorders are confirmed. Human resources costs of two to five person-hours for post-confirmation services, involving medical geneticists, genetic counselors and nutritionists, have been estimated at \$450 per affected infant, including \$300 for a comprehensive-level office visit, and \$150 for a genetic or nutritional counseling session.

The Department expects that costs of medical services and supplies will be reimbursed by all payor mechanisms now covering the care of children identified with conditions already in the newborn screening panel, as well as children diagnosed with one of the metabolic disorders proposed for addition to the State panel by means of targeted testing at the primary care level. Payors include indemnity health plans, managed care organizations, and New York State's medical assistance program (Medicaid), Child Health Plus and Children with Special Health Care Needs programs. The Department also expects that medical care providers will claim reimbursement from one or more of these payors at a rate equal to the usual and customary charge, thereby recouping costs.

Overall health care costs for definitive diagnosis and comprehensive medical management of affected individuals will vary significantly, primarily by the condition, and the services and supplies required for sustaining some level of continued health. Many of the costs associated with medical management of a child affected with a metabolic disorder are not attributable solely to the proposed regulation, as most would have been incurred at some point following diagnosis by targeted testing at the primary care level. Although early diagnosis provided through the proposed rule may result in increased overall lifetime costs for patients who would have died in the absence of screening, *e.g.*, those with propionic acidemia, substantial cost savings are likely to be accrued from prevented complications to offset treatment costs. Early diagnosis and treatment may prevent or lessen irreversible organ damage, and thereby reduce costs related to caring for affected individuals incurred by New York's health care and education system infrastructure. Moreover, early detection affords affected individuals with the opportunity for improved quality of life, a benefit that cannot be quantified.

Minimizing Adverse Impact:

The Department did not consider less stringent compliance requirements or regulatory exceptions for facilities located in rural areas because of the importance of expanded infant testing to statewide public health and welfare. These amendments will not have an adverse impact on the ability of regulated parties in rural areas to comply with Department requirements for mandatory newborn screening, as full compliance would entail minimal changes to present collection, reporting, follow-up and recordkeeping practices.

Rural Area Participation:

The requirements proposed by this amendment are in effect as an emergency rule. Notification of the amendment already occurred prior to and concurrent with statewide implementation of the expanded newborn screening panel.

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 amendment proposes the addition of 33 conditions all inherited metabolic disorders -- to the scope of newborn screening services already provided by the Department. It is expected that, of the small number of regulated parties that will experience moderate rather than minimal impact on their workload, few, if any, will need to hire new personnel. Therefore, this proposed amendment carries no adverse implications for job opportunities.

EMERGENCY RULE MAKING

New York State Prescription Form

I.D. No. HLT-45-05-00002-E

Filing No. 1258

Filing date: Oct. 19, 2005

Effective date: Oct. 19, 2005

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

Action taken: Addition of Part 910 and amendment of sections 80.84, 85.21, 85.22, 85.23 and 85.25 of Title 10 NYCRR and amendment of sections 505.3, 528.1 and 528.2 of Title 18 NYCRR.

Statutory authority: Public Health Law, section 21

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 is necessary to protect the public health and safety and to meet statutory requirements. The budget proposal enacting Section 21 contains explicit authority for the Commissioner to promulgate emergency regulations. This was done recognizing the need to provide for a proper transition period for the use of statewide forged proof prescriptions, which under the regulations will be for a period of 18 months. Without the regulations the program is required to be enacted in 60 days which would be detrimental to both practitioners and the public.

Immediate adoption of these regulations is necessary to allow the gradual implementation of Section 21 of Public Health Law, achieve the health care cost savings and to enhance the quality of health care by preventing drug diversion resulting from forged or stolen prescriptions.

The practitioner groups affected by this proposal, PSSNY, MSSNY and the Health Plan Association of New York were consulted during budget negotiations. Their concerns are addressed in the statutory proposal set forth in the state budget and in these regulations.

Subject: New York State prescription form.

Purpose: To enact a serialized official New York State prescription form.

Substance of emergency rule: Part 910 (10 NYCRR)

These regulations are being proposed on an emergency basis to implement Section 21 of the Public Health Law. The purpose of the law is to combat and prevent prescription fraud by requiring the use of an official New York State prescription for all prescribing done in this state. Official prescriptions contain security features that will curtail alterations and forgeries that divert drugs to black market sale to unsuspecting patients and cost New York's Medicaid program and private insurers tens of millions of dollars annually in fraudulent claims.

The emergency regulations consist of a new Part 910 to Title 10 NYCRR. Section 910.1 defines terms used in the Part. Section 910.2 states requirements for practitioner prescribing, including that for the 18 month period stipulated in the law, either an official prescription or a practitioner's personal prescription is valid for prescribing. Section 910.3 covers registration with the Department, which practitioners and healthcare facilities are required to do to order official prescriptions. Section 910.4 states the manner in which official prescriptions will be issued by the Department, while section 910.5 lists the practitioner and facility requirements for safeguarding the official prescriptions against theft, loss or unauthorized use. Section 910.6 states pharmacy requirements for dispensing official prescriptions and out-of-state prescriptions, which may be dispensed in lieu of an official prescription. Section 910.6 also states pharmacy requirements for submission of official prescription data to the Department.

Both 10 NYCRR and 18 NYCRR have been revised to reflect the above regulations, update outdated/obsolete sections and to allow for greater flexibility for changes in law. The following changes have been proposed:

Section 505.3 (18 NYCRR)

- Language included to reflect use of facsimile prescriptions.
- Language included to allow electronically transmitted prescriptions.
- Language included to mandate that all claims for payments of drugs or supplies under the MA program shall contain the serial number of the Official NYS Prescription Form.
- Delete language prohibiting telephone orders for OTCs.
- Language amended—telephone prescriptions for non-controlled substances WILL NOT require a follow-up hard copy prescription (even with refills).

- Delete Estimated Acquisition Cost—defined in Social Services Law 367-a(9)(b)(ii).

- Delete language referencing “triplicate” prescriptions and update to language consistent with Official NYS Prescription Form and Article 33 of the Public Health Law.

- Delete language referencing other Sections that have been deleted (i.e. 10 NYCRR 85.25).

- Delete language referencing dispensing fees—in Social Services Law 367-a(9)(d).

- Language is added to reference prescription drugs filled in compliance with 6810 of the Education Law, Article 33 of the Public Health Law and new 10 NYCRR Part 910.

Part 528 (18 NYCRR)

- Section 528.1 is deleted—obsolete listing of non-prescription drugs covered under the MA program. Listing of reimbursable drugs and rate is available on-line at the NYS eMedNY website.

- Section 528.2 is deleted—language regarding “dispensing fees include routine delivery charges” is moved to 18 NYCRR 505.3(f)(6). Compounding fee language in 18 NYCRR 505.3 [6] (3) .

Part 85 (10 NYCRR)

- Section 85.21 amended—OTC List—quantities and dosage forms have been deleted to allow greater flexibility in coverage. Remove OTC categories that are no longer marketed.

- Section 85.22 amended—establishment of OTC prices amended to more accurately reflect OTC pricing (Ad Hoc Committee is obsolete) and removal of references to deleted Sections (i.e., 18 NYCRR 528.2 and 10 NYCRR 85.25).

- Section 85.23 deleted—Revisions to list of OTCs and Maximum Reimbursable Prices in Social Services Law 365-a(4)(a).

- Section 85.25 deleted—Prescription drug list covered under MA—obsolete. Drug list available on line at NYS eMedNY website.

Part 80 (10 NYCRR)

- Section 80.84(b)(1) is amended to remove the requirement that a group practice of physicians providing treatment of opiate dependence with buprenorphine be limited to 30 patients at any one time. The amendment makes New York State regulations consistent with the federal Drug Addiction Treatment Act, which was amended on August 2, 2005 to remove the 30 patient limit for group practices treating opiate dependence with buprenorphine.

This notice is intended to serve only as a notice of emergency adoption. This agency intends to adopt this emergency rule as a permanent rule and will publish a notice of proposed rule making in the *State Register* at some future date. The emergency rule will expire January 16, 2006.

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:

Section 3308(2) of the Public Health Law authorizes and empowers the Commissioner to make any regulations necessary to supplement the provisions of Article 33 of the Public Health Law in order to effectuate its purpose and intent.

The state budget for SFY 2004-2005 enacted new Section 21 of the Public Health Law which mandates a statewide official prescription form for all prescriptions written in New York for the purpose of curtailing prescription fraud and enhancing patient safety. The law permits the Commissioner to promulgate emergency regulations in furtherance of this new section of law.

Legislative Objectives:

Article 33 of the Public Health Law, officially known as the New York State Controlled Substances Act, was enacted in 1972 to govern and control the possession, prescribing, manufacturing, dispensing, administering and distribution of controlled substances within New York. New Section 21 of the Public Health law mandates a statewide official prescription, supports electronic prescribing and facilitates the dispensing process.

Needs and Benefits:

This regulation will support the enactment of an official New York State prescription form, which will deter fraud by curtailing theft or copying of prescriptions by individuals engaged in drug diversion. These regulations have been drafted after discussions with such provider groups as the State Health Plan Association, Medical Society of the State of New York and the Pharmacist Society of the State of New York. The simplification and provider beneficial provisions include:

- (1) Allowing electronic prescribing in the State Medical Assistance (Medicaid) program;

- (2) Eliminating the fee to practitioners and institutions for official prescriptions;

- (3) Eliminating the requirement that practitioners send written follow-up prescriptions to pharmacies for oral prescriptions in the Medicaid program;

- (4) Allowing oral prescribing of OTC medications in the Medicaid program and eliminating the requirement for hard copy orders for Medicaid OTC drugs;

- (5) Eliminating the requirement that pharmacists write the DEA number of the pharmacy on the official prescription;

- (6) Bar coding of the serial number on the official prescription to expedite the dispensing process; and

- (7) Eliminating multiple prescription forms practitioners currently use to prescribe drugs.

The regulations also define the requirements for using the official prescription and provide for an 18-month period where both existing prescription forms and the official prescription can be used. This will allow for a transition period for practitioners, institutions and pharmacists.

These regulations are found in amendments to 18 NYCRR Sections 505.3; 528.1; 528.2; and in the newly promulgated regulations in 10 NYCRR Part 910.

Technical amendments are also being made to 10 NYCRR Sections 85.21, 85.22, 85.23 and 85.25 to conform with the intent of Section 21 of the Public Health Law.

Costs:

Costs to Regulated Parties:

This program is being funded by an assessment on the State Insurance Department. The current fee to practitioners and institutions for the official prescription has been eliminated. Private insurers and the Medicaid program will realize millions of dollars in savings due to the reduction of fraudulent prescription claims.

The allowance for electronic prescribing in the Medicaid program and the expedition of the dispensing process through the use of bar coding will save valuable professional time for practitioners and pharmacists.

The slight expenditure to pharmacies for software adjustments, due to minor changes in reporting requirements, will be offset by funds through a grant administered by the Department.

Costs to State and Local Government:

There will be no costs to state or local government.

Costs to the Department of Health:

There will be no additional costs to the Department.

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:

No additional paperwork is required. The use of a single prescription form for controlled substances and non-controlled substances will simplify paperwork and record keeping for practitioners and institutions. Currently, practitioners use their own prescription form as well as the official prescription. The official prescription will replace existing prescriptions that are currently used in addition to the official prescription. Encouragement of electronic prescribing and dispensing as well as the elimination of the requirement for a written follow up prescription on oral prescriptions in the Medicaid Program will significantly reduce paperwork requirements for practitioners, institutions and pharmacists.

Duplication:

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

Alternatives:

There are no alternatives that would support the approach to be taken under the regulations. The limitation on reporting requirements by pharmacies (only for controlled substances and Medicaid prescriptions as opposed to requiring reporting on all prescriptions) was done after consultation with affected provider organizations.

Federal Standards:

The regulatory amendment does not exceed any minimum standards of the federal government.

Compliance Schedule:

These regulations will become effective immediately upon filing a Notice of Emergency Adoption with the Secretary of State.

Regulatory Flexibility Analysis

Effect of Rule on Small Business and Local Government:

This proposed rule will affect practitioners, pharmacists, retail pharmacies, hospitals and nursing homes.

According to the New York State Department of Education, Office of the Professions, as of April 2003, there were approximately 120,000 licensed and registered practitioners authorized to prescribe and order prescription drugs. According to the New York State Board of Pharmacy, there are a total of approximately 4,500 pharmacies in New York State. According to the New York State Education Department's Office of the Professions as of April 2003 there were approximately 18,000 licensed and registered pharmacists in New York.

Compliance Requirements:

The regulations follow the newly enacted Section 21 of the Public Health Law and require the use of the official New York State Prescription form. In addition to curtailing fraud and diversion, these regulations will expedite the prescribing and dispensing process. Practitioners, institutions and pharmacists will benefit from the following amendments;

- (1) Allowing electronic prescribing in the State Medical Assistance (Medicaid) program;
- (2) Eliminating the fee to practitioners and institutions for official prescriptions;
- (3) Eliminating the requirement that practitioners send written follow-up prescriptions to pharmacies for oral prescriptions in the Medicaid program;
- (4) Allowing oral prescribing of OTC medications in the Medicaid program and eliminating the requirement for hard copy orders for Medicaid OTC drugs;
- (5) Eliminating the requirement that pharmacists write the DEA number of the pharmacy on the official prescription;
- (6) Bar coding of the serial number on the official prescription to expedite the dispensing process; and
- (7) Eliminating multiple prescription forms practitioners currently use to prescribe drugs.

Currently, dispensing data is required from all Schedule II and benzodiazepines prescriptions. The only new requirement is the submission of dispensing data from the original dispensing of all controlled substances.

Professional Services:

No additional professional services are necessary.

Compliance Costs:

Pharmacies may require minor adjustments in computer software programming due to additional prescription data submission requirements; however, this cost will be offset through the distribution of grant funds awarded to the Department for the enhancement of its prescription monitoring program by the federal Bureau of Justice Assistance.

Economic and Technological Feasibility:

The proposed rule is both economically and technologically feasible. The process utilizes existing electronic systems for reporting of dispensing by pharmacies. The regulations encourage the use of electronic prescribing by practitioners. Electronic prescribing is not only more efficient than the current paper process, it is also a secure procedure that will reduce prescription fraud. Electronic prescribing will protect the public health and result in substantial savings to the Medicaid program and private insurance as well as enhancing public safety.

Minimizing Adverse Impact:

The regulations require only a minimal increase in reporting requirements. These requirements were negotiated with organizations representing the affected groups. The use of bar coding, the elimination of written follow up prescriptions for oral prescriptions for the Medicaid program and the encouragement of electronic prescribing minimize any adverse impact.

Small Business and Local Government Participation:

During the drafting of the statute which is the basis of these regulations, the Department met with the Pharmacist Society of the State of New York (PSSNY), the Medical Society of the State of New York (MSSNY) and the Health Plan Association of New York. The regulations were drafted considering their comments. Local governments are not affected.

Rural Area Flexibility Analysis

Types and Estimated Numbers of Rural Areas:

The proposed rule will apply to participating pharmacies, practitioners and institutions located in all rural areas of the state. Outside of major cities and metropolitan population centers, the majority of counties in New York contain rural areas. These can range in extent from small towns and villages and their surrounding areas, to locations that are sparsely populated.

Compliance Requirements:

The only compliance requirements are the use of the official prescription provided free of charge and additional minimal reporting requirements by pharmacies. The regulations are in furtherance of new Section 21 of the Public Health Law authorizing a statewide official prescription aimed at reducing fraud. Additionally, the regulations assist practitioners and pharmacies by making the prescribing and dispensing process more efficient through the use of electronic prescribing.

Professional Services:

None necessary.

Compliance Costs:

None.

Economic and Technological Feasibility:

The proposed rule is both economically and technologically feasible. The process will utilize existing electronic systems for reporting of dispensing information by pharmacies. The regulations encourage the use of electronic prescribing, which is more efficient and more secure than a paper process. Electronic prescribing will also enhance patient safety through a reduction in medication error due to legibility issues.

Minimizing Adverse Impact:

The regulations require only a minimal increase in reporting requirements. This requirement is minimized by permitting pharmacies to scan the bar code of the prescription serial number onto the Medicaid claim form also through the allowance of electronic prescribing. Additionally, the benefits on regulated entities resulting from these regulations and described herein outweigh any adverse impact.

Rural Area Participation:

During the drafting of this regulation, the Agency met with and solicited comments from pharmacist, health plan and practitioner associations who represent these professions in rural areas. No particular issues relating to the effect of this program on rural areas was expressed.

Job Impact Statement

Nature of Impact:

This proposal will not have a negative impact on jobs and employment opportunities. In benefiting the public health by ensuring that drug diversion does not occur through the use of forged or stolen prescriptions, the proposed amendments are not expected to either increase or decrease jobs overall. The fiscal savings to public and private insurers will result in an economic benefit to these groups and could have a positive influence on jobs. Additionally, the anticipated time saved by practitioners and pharmacists will benefit all parties involved as well as patients.

**EMERGENCY
RULE MAKING**

HIV Laboratory Test Reporting

I.D. No. HLT-45-05-00003-E

Filing No. 1260

Filing date: Oct. 19, 2005

Effective date: Oct. 19, 2005

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

Action taken: Amendment of Part 63 of Title 10 NYCRR.

Statutory authority: Public Health Law, sections 2130, 2139 and 2786(1)

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

Specific reasons underlying the finding of necessity: Section 63.4(a)(4)(i).

On February 11, 2005, the Commissioner of New York City Department of Health and Mental Health (NYCDOHMH) announced that a highly drug resistant strain of human immunodeficiency virus (HIV) had been diagnosed in a NYC resident who had not previously undergone antiviral drug treatment. This patient, believed to be infected within the last 20 months, experienced a very rapid progression to AIDS, raising fears that a new highly drug resistant strain of rapidly progressive HIV is being transmitted in New York State (NYS).

This three drug-class resistant HIV strain may not respond to three of four classes of anti-retroviral medication, greatly limiting treatment options. This level of drug resistance is often seen in patients that have been on treatment for many years but is thought to be rare among patients who are newly diagnosed or who have never received antiretroviral therapy. Currently little information exists on a population basis regarding where and to what extent these drug resistance HIV strains are occurring among treated and untreated patients, and among patients newly diagnosed with HIV.

This event highlights the critical need for the HIV surveillance system of the NYS Department of Health (NYSDOH) to be strengthened in order to provide population-based information about emergent major threats to those with or at risk for HIV/AIDS. Specifically, information is needed on incidence and drug resistance in the population that will establish an early warning system for resistance to particular drugs, especially among newly infected individuals. Information on resistance in the population and sub-populations will also guide public health officials in 1) establishing and/or maintaining prevention efforts for groups at highest risk for acquisition of HIV that may be difficult to treat and 2) in maintaining sufficient resources for care of persons with AIDS that have a viral strain that is highly resistant to antiretroviral treatment. Aggregate information on resistance patterns in NYS is necessary to better inform physicians in clinical practice on how to manage patients in their community particularly when treating newly diagnosed, symptomatic patients and administering post exposure antiretroviral prophylaxis following possible exposure to HIV of unknown source.

To accomplish this, a comprehensive, population-based HIV surveillance system that incorporates surveillance for HIV incidence and HIV drug resistance must be established as soon as possible. The existing NYS HIV Reporting System provides a foundation for this system, but must be expanded to include: 1) the reporting of all nucleic acid (RNA or DNA) detection test results and all CD4 lymphocytes test results for more complete information on the magnitude of the HIV epidemic in NYS and the number and proportion of people with HIV in care for HIV infection; and 2) the results of HIV subtype and drug resistance testing.

Section 63.11.

This is a critical time for all barriers to HIV testing and drug resistance testing to be eliminated. HIV testing must be encouraged and facilitated. The current informed consent and HIV release forms contained in Section 63.11 must be revised to accurately reflect changes in test technologies and advances in treatment that have occurred since the writing of the original regulations. Further, federal privacy regulations promulgated under the Health Insurance Portability and Accountability Act ("HIPAA") require changes in the HIV release form for all providers who are covered by the federal law. These forms will be removed from Section 63.11, revised and placed on the department's website, enabling prompt, convenient updating to keep pace with future changes in HIV testing and treatment. Removal of the text of these forms from Section 63.11 and use of web-based forms, which are current, clear and simplified, is necessary and urgent.

Specifically, a more accurate up-to-date consent form will facilitate HIV antibody testing and resistance testing as well as incidence testing to monitor the HIV epidemic. The new consent form also provides the opportunity for individuals to consent at one point in time to a course of medically recommended HIV testing (e.g., during pregnancy) for which they are being counseled. The language on the consent form has been greatly simplified to make it easier for individuals to understand and easier for providers to use. Its use will streamline counseling and thus reduce barriers to testing. The simplification of the form will be in conjunction with an education campaign aimed at providers to streamline counseling to the extent possible that is consistent with the law.

As noted, the authorization for release of confidential HIV related information must be up-dated to conform to federal privacy regulations. Patients will be confused if they attempt to use the existing form to obtain the release of their records from HIPAA covered providers. All hospitals and the majority of providers are covered by HIPAA and can no longer honor the release form which now appears in Section 63.11.

Subject: HIV laboratory test reporting.

Purpose: To expand laboratory reporting to include viral load and CD4 test results and HIV drug resistance testing.

Text of emergency rule: Subparagraph (i) of Section 63.4(a)(4) is amended to read as follows:

(4)(i) Laboratories performing diagnostic tests shall report to the Commissioner cases of initial determinations or diagnoses of HIV infection, HIV-related illness and AIDS on a schedule to be specified by the Commissioner. Laboratories shall report the following: confirmed positive HIV antibody test results, [positive] HIV nucleic acid (RNA or DNA) detection test results, all CD4 lymphocyte counts [less than 500 cells per microliter or less than 29 percent of total lymphocytes] unless the test was known to be performed for reasons other than HIV infection or HIV-related illness, *HIV subtype and antiviral drug resistance testing in a format designated by the Commissioner*, and the results of other tests as may be determined by the Commissioner to indicate a diagnosis of HIV infection, HIV-related illness or AIDS.

Section 63.11 is hereby REPEALED and section 63.12 is renumbered section 63.11.

This notice is intended to serve only as a notice of emergency adoption. This agency intends to adopt this emergency rule as a permanent rule and will publish a notice of proposed rule making in the *State Register* at some future date. The emergency rule will expire January 16, 2006.

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 2139 requires the Commissioner to promulgate rules and regulations as shall be necessary and proper to effectuate the purposes of Article 21, Title III relating to the reporting and tracking of HIV/AIDS.

PHL Section 2130 requires that physicians and laboratories performing diagnostic tests or making a medical diagnosis immediately report determinations or diagnoses of HIV and AIDS. Such reports shall include information concerning the case "as shall be required by the Commissioner."

PHL Section 2786 authorizes the State Commissioner of Health to develop and/or approve forms for informed consent and for the release of confidential HIV-related information.

Legislative Objectives:

PHL Sections 2130 and 2139 were enacted to permit the Department of Health to conduct epidemiologic surveillance for HIV/AIDS: to record, monitor and evaluate the progression of the HIV/AIDS epidemic in the state. Confidential reporting allows the health department to assess the spread of the disease in various localities and among risk group, thereby enabling focused prevention efforts and the targeting of scarce health resources where they can be most effective.

The New York State Legislature mandated the Department's development of model forms and approval of forms in order to standardize and ensure compliance with elements of informed consent, set forth in Section 2781, and disclosure provisions outlined in Section 2782.

Needs and Benefits:

A decade ago, the course of the AIDS epidemic in New York State began to change dramatically due to the increasing use and effectiveness of highly active antiretroviral therapy (HAART), and use of viral load and HIV resistance laboratory tests to monitor the effectiveness of therapy. The decrease in AIDS diagnoses and deaths and the improving immunologic status of many persons living with HIV due to use of HAART has been accompanied by the development of mutations leading to anti-retroviral drug resistance. Although these mutations are commonly seen in persons who have received prior retroviral therapy without complete suppression of HIV viral load, population-based data are not available on the extent of resistance in the treated population. It is also not known to what extent resistant mutations are transmitted from one person to another, leading to decreased treatment options in those newly infected and diagnosed with HIV.

With the recent documentation of a HIV strain with resistance to three drug classes and rapid progression to AIDS in a NYC man newly diagnosed with HIV, the need for a comprehensive surveillance system designed to provide this information on a population basis is pressing. Expanding the existing NYS population based HIV surveillance system to incorporate surveillance of both HIV incident infection and HIV drug resistance will provide data not only on the level of HIV drug resistance among the treated population but also on transmission of HIV strains that are highly drug resistant among the newly diagnosed population. It will allow the examination of geographic differences and trends overtime in resistance patterns. These aggregate data will be extremely valuable to physicians, providing them with information on the resistance patterns that will help guide HIV treatment practices. They will also help public health agencies charged with making the best use of resources to develop effective prevention and care programs.

HIV viral load suppression is necessary to prevent the development of HIV drug resistance. Since June 2000, laboratories have reported detectable viral load test results to the Department. The inclusion of non-detectable viral loads in the surveillance system offers a valuable population-based assessment of the suppression of viral load and therefore the risk for the development of drug resistance. If the goal to avoid drug resistance is not being met at a population level, then viral load information will allow interventions to be designed that target the problems that are allowing

resistant strains to proliferate (*i.e.*, direct transmission of resistant strains, lack of entry into medical care, and/or inadequate viral load suppression even with medical care).

One of the original intents of the legislature in passing PHL Article 21 was to provide more case information to better track the HIV epidemic in New York State. The "Memorandum in Support, the New York State Senate," Session Laws of 1998, Chapter 163, p. 1631 states: "This legislation has the potential to save countless lives while assuring that infected and exposed individuals are given a chance to get tested and treated at the earliest possible stage in the progression of disease. In addition, making HIV a reportable disease will enable public health officials to more accurately track the spread of the epidemic into different communities, thus allowing them to direct treatment, prevention and educational funding into those communities most affected by the disease."

The use of HAART has increased the percentage of HIV-infected patients with undetectable viral loads and high CD4 counts. Requiring the reporting of undetectable viral loads and all CD4 lymphocyte counts (the names of persons undergoing CD4 testing for non-HIV related reasons will be deleted from the HIV/AIDS Registry) will provide a more complete picture of the epidemic, including the proportion of infected persons whose HIV is optimally controlled (undetected viral load and high CD4 count) and who are in ongoing medical care in different regions of the state. This information will assist in defining the complete HIV spectrum of disease at the population level in New York State, identifying trends in control of disease across time, and evaluating areas of the state where access to care may be an issue.

With the availability of HAART, it is more important than ever that barriers to HIV diagnostic testing be reduced. The Department is undertaking a broad initiative to make HIV testing routine in medical settings and to streamline the counseling and consent process. With respect to the HIV test consent form, testing must be further encouraged and made a standard part of medical care in NYS. The current forms contained in Section 63.11 are no longer accurate due to changes and options in test technologies and advances in treatment. Further, the release form does not reflect the requirements of new federal privacy regulations.

Specifically, the need to repeal the existing HIV consent form results from the evolution of HIV testing technologies. Rapid HIV antibody tests now available can provide a negative or preliminary positive result during a single appointment, often in less than an hour. Other testing technologies involving various body fluids are now available. The current consent form is focused on the ELISA and Western Blot tests and needs to be streamlined. Further, with treatment advances, it is timely to update the consent form to emphasize routine testing for disease monitoring that occurs in medical care (*e.g.* viral load and resistance testing). Various testing protocols, consisting of one or more tests now exist and need to be accommodated by a consolidated informed consent form; for example, testing and follow-up testing during pregnancy as recommended by the NYSDOH and the Center for Disease Control and Prevention (CDC). In 2004, the Department distributed a special version of the consent forms to permit a follow up test later in pregnancy, with a single consent form. Also, viral load and other tests to monitor HIV are now a routine part of HIV health care but are not addressed by the current consent form. The revised consent form will provide a single and comprehensive way to obtain this consent. Finally, CDC recommends that state health departments conduct incidence testing on all persons newly diagnosed. Such testing does not provide accurate information about individual patients, but in aggregate the result allow estimation of HIV incidence in the populations. Consent for this test is also part of the revised consent form.

The current HIV release form must be revised to ensure compliance with the new federal Health Insurance Portability and Accountability Act ("HIPAA") privacy regulations at 45 C.F.R. Part 164. The revised release will permit HIPAA covered providers to disclose information, including HIV information, without violating federal law.

Both forms will be available on the NYSDOH web site. There is no requirement in statute that such forms be promulgated as regulations. Web-based forms can be more conveniently up-dated and made readily available to providers. Removal of the text of these forms from Section 63.11 and use of web-based forms that are current, clearly worded and simplified are urgent needs and provide a service to the regulated parties.

Costs:

Costs for the Implementation of, and Continuing Compliance with the Regulation to the Regulated Entity:

There will be no additional costs for the laboratories associated with the reporting of all HIV nucleic acid (RNA or DNA) detection test results and all CD4 lymphocyte test results, as this can easily be incorporated with

the existing reporting of positive HIV nucleic acid (RNA and DNA) detection tests. Approximately 25 laboratories conduct HIV drug resistance testing. Laboratories already reporting test results to the NYSDOH via the NYS Electronic Clinical Laboratory Reporting System (ECLRS) may require some one-time programming costs to set up the extraction of data from their testing systems and incorporating it with the ECLRS transfers. Laboratories not reporting through ECLRS will require a minimum commitment of additional staff time to establish an account on the NYS Department of Health's (NYSDOH) Health Provider Network (HPN) for highly secured transfer of data directly to the NYSDOH.

Updated and streamlined informed consent and release forms will be cost saving to regulated parties. They will save staff time in the informed consent process because the new form is a simplified and comprehensive, and is a more accurate reflection of existing testing protocols. The updated release form will facilitate a patient's right to authorize the exchange of HIV-related information. As persons with HIV/AIDS live longer, the authorized exchange of medical information is increasingly beneficial for coordination of medical care and other HIV-related services.

Costs to the Department of Health and other state and local governments:

The amendment to Section 63.4 will expand the current HIV reporting system requiring additional costs to the NYSDOH. Specifically, additional servers at a cost of approximately \$50,000 and 160 hours of contractual programming for a total cost of \$16,000 will be needed for implementation. The ECLRS modifications will require at least 80 hours of programming at \$8,000. Two additional staff persons will be required to 1) process the additional laboratory reports and 2) interpret, analyze and generate aggregate reports of the drug resistance data. These costs are based on the actual experience of the NYSDOH in developing the current ECLRS and the electronic HIV Surveillance systems.

There will be no costs to county health departments. The NYCDOHMH may require additional minor computer hardware and/or software to incorporate electronic drug resistance reporting into the NYC HIV Surveillance Program.

Agencies of state and local government that conduct HIV testing will incur no new costs as a result of these regulations deleting Section 63.11. As is the case with private regulated parties, costs associated with the time expended in obtaining informed consent for HIV testing and with release of HIV-related information should decrease as a result of these amendments.

Further, as of August 30, 2005, 62 of the 72 laboratories affected by this reporting requirement are reporting CD4 and viral loads as required. The resulting impact on the department's staff has been moderate and efficiencies are in place to minimize workload.

The above assessment of the cost benefits of deleting Section 63.11 is based upon actual experience on the part of the NYSDOH and providers in obtaining informed consent and securing authorization for the release of confidential HIV-related information.

Local Government Mandates:

There are no city or county laboratories conducting drug resistance testing. Therefore, the amendment of Section 63.4(a)(i) mandating the reporting of drug resistance testing does not impact any city or county government.

The proposed regulations concerning the repeal of Section 63.11 impose no new mandates on any county, city, town or village government, school district, fire district or other special district, unless a city, town or village government, school district, fire district or other special district offers HIV testing and is, therefore, subject to these regulations to the same extent as a private regulated party.

Paperwork:

There will be no additional paperwork required of the laboratories or NYCDOHMH. The majority of laboratories conducting HIV drug resistance testing for NYS residents are already reporting other required testing results through the NYSDOH's ECLRS system. These laboratories will be able to electronically report the results of their drug resistance testing through ECLRS as well. Laboratories not currently reporting through ECLRS will be required to report electronically to the NYSDOH via the file transfer utility over the highly secured Health Provider Network (HPN).

No new paperwork is required as a result of the deletion of Section 63.11. The proposed regulation deleting Section 63.11 would actually result in less paperwork since the release form is now inaccurate for use by HIPAA covered providers.

Duplication:

These rules, amendment of Section 63.4(a)(i) and repeal of Section 63.11 do not duplicate any other state law, rule or regulation. These regulations also do not duplicate any federal regulations, but rather the revised release form complies with recently enacted federal privacy regulations.

Alternatives:

The most effective and efficient way to monitor HIV drug resistance in a given population and to operate a system for enabling a clinical alert regarding the prevalence of drug resistance is to establish a comprehensive HIV Surveillance system that incorporates universal laboratory reporting of HIV drug resistance testing. Although research studies can provide valuable clinical information on HIV drug resistance, they are costly and only provide information specific to the study participants. The results of these studies cannot provide comprehensive information on the total NYS population of HIV infected people.

The Department of Health considered direct provider reporting in place of expanded laboratory electronic reporting. However, provider reporting on paper forms has been shown to be less reliable, less efficient and would prove to be more costly. Electronic clinical laboratory reporting for disease surveillance is universally promoted by public health authorities.

The alternative of retaining the existing informed consent form and release form was determined to be unacceptable. The informed consent form does not reflect current HIV testing technology or benefits of testing. The retention of a release form in Section 63.11 that is not compliant with federal regulations is not an acceptable alternative.

The Department of Health is sensitive to the possibility of additional non-HIV infected persons being reported to the department due to the expanded reporting of all CD4 test results. We note that no report is placed on the registry without confirmation (*i.e.* matching with other HIV related tests or verifying status with a person's provider). These procedures have been in place for over ten years without incident or problem which negatively affect privacy. Nevertheless, the Department of Health considered the possibility of adding a provider check off to laboratory slips to indicate that the laboratory test was unrelated to HIV. After consideration of the unlikelihood of full provider compliance, confidentiality concerns, the necessity for laboratory software reprogramming based on this change and the costs involved as weighed against the problem free procedures long in existence, the Department decided to continue the present system.

Federal Standards:

The National Centers for Disease Control and Prevention (CDC) is currently in the process of updating the HIV Surveillance Guidelines. It is anticipated that the new guidelines will incorporate recommendations from the Council of State and Territorial Epidemiologists (CSTE) that all states require the laboratory reporting of both detectable and non-detectable viral load tests and all CD4 lymphocytes tests to state public health departments.

Monitoring the epidemic through broad reporting is promoted by the Centers for Disease Control and is widely accepted across the country. All but two states require reporting of some level of CD4 lymphocytes and/or viral loads and fourteen states have similarly undertaken to require the reporting of all CD4 lymphocytes and viral load testing (Arizona, Arkansas, Florida, Indiana, Iowa, Louisiana, Michigan, Mississippi, Missouri, New Hampshire, North Dakota, South Carolina, Utah and Wyoming). Comprehensive reporting enables the identification of previously unreported HIV cases. It also enables comparisons across geographic areas and across similar population groupings. Epidemiological prediction is facilitated and appropriate health planning can occur.

There are currently no federal regulations governing informed consent for HIV testing. The federal government has provided recommendations that state review their current requirements to remove unnecessary obstacles and barriers to HIV testing. Recent federal regulations, 45 C.F.R. Part 164, require that certain language appear on all release forms covered by the federal privacy act.

Compliance Schedule:

The emergency regulations be effective upon filing with the Secretary of State.

Regulatory Flexibility Analysis

Effect of Rule:

The proposed changes to the regulations will affect approximately 24 laboratories that conduct HIV drug resistance testing. Of these 24 laboratories, only two are classified as small businesses and both of those laboratories are located out of state. The only local government that will be impacted by these proposed changes is the NYCDOHMH, which is responsible for conducting HIV Surveillance in NYC, under a deputization agreement with the NYSDOH.

The deletion of Section 63.11 has no impact on small businesses.

Compliance Requirements:

Under the proposed changes, the laboratories that are small businesses will be required to electronically report the results and date of HIV drug resistance testing to the NYSDOH, along with the names and addresses of the patients and providers and other demographic data as required by the Commissioner. In addition, laboratories will be required to report all viral load and CD4 lymphocyte test results. The HIV drug resistance records for NYC residents will be transferred by the NYSDOH to the NYCDOHMH where they will be incorporated with the NYC HIV Surveillance System.

With respect to the use of new consent forms and release forms, providers confront no additional compliance requirements. The forms can be mailed on request and also downloaded and substituted for old forms as needed.

Professional Services:

Laboratories may require minimal computer programming to meet the requirements of these proposed laboratory changes. Technical assistance will be available from the NYSDOH.

NYCDOHMH may require an additional research scientist to analyze the HIV drug resistance data if they chose to do so under the authority of the state.

Use of new consent forms and release forms will not involve any additional professional services.

Compliance Costs:

Compliance costs for the laboratories that are classified as small businesses will likely be minimal due to the low volume of case reports expected from these entities. Technical assistance from the NYSDOH will be available.

Providers using release forms and consent forms now copy such forms for their own use. Therefore, no extra cost is anticipated.

Economic and Technological Feasibility:

Laboratories classified as small businesses will receive detailed instructions on how to report. In addition, technical assistance will be available from the NYSDOH.

Having forms available and updated on the internet, suitable for downloading, is both economically and technically feasible.

Minimizing Adverse Impact:

The adverse impact on the laboratories classified as small businesses will be minimized by utilizing ECLRS, which is the existing mode of electronic reporting for the majority of laboratories. For those not choosing to report via ECLRS, an alternative electronic reporting mechanism will be available. Technical assistance will be available from the NYSDOH.

There is no adverse impact regarding use of the new forms located on the NYSDOH web site.

Small Business and Local Government Participation:

The NYCDOHMH are supportive of the reporting of non-detectable viral loads, all CD4 lymphocyte test results and HIV drug resistance testing. Plans have been made to consult directly with all laboratories.

With respect to the new forms, the NYSDOH has shared the consent form with a few health and human service providers and has received comments from them for consideration. Plans have been made to contact other health and human service providers and stakeholders regarding the new consent form.

Rural Area Flexibility Analysis

None of the laboratories conducting HIV drug resistance testing are located in rural counties.

The repeal of Section 63.11 has no unique impact on rural area providers or patients.

Job Impact Statement

The emergency amendment of Section 63.4(a) will have no impact on jobs and employment opportunities.

The repeal of Section 63.11 does not impact on rural areas in any unique way. In fact, having updated forms available on the intranet will be a convenient service to rural providers and patients.

NOTICE OF CONTINUATION NO HEARING(S) SCHEDULED

Regulated Medical Waste

I.D. No. HLT-20-05-00024-C

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

The notice of proposed rule making, I.D. No. HLT-20-05-00024-P was published in the *State Register* on May 18, 2005.

Subject: Regulated medical waste.

Purpose: To update regulated medical waste regulations.

Substance of rule: Existing Part 70 is rescinded and replaced with a new Part 70 containing five Subparts: 70-1 Applications and Definitions; 70-2 Management of Regulated Medical Waste (RMW); 70-3 Requirements for Autoclaves to Treat Regulated Medical Waste; 70-4 Approval of Alternative Regulated Medical Waste Treatment Systems; and 70-5 Approval Process for Alternative Technologies.

This amendment clarifies terminology; adds flexibility to existing regulatory requirements; and codifies advisories for RMW management previously promulgated in guidance documents, following 1993 statutory amendments. This proposal revises regulatory definitions for RMW, infectious agents and treatment in conformance with the Law; amends container-labeling requirements; and incorporates applicable requirements for transport and disposal of RMW, allowing for increased flexibility in financial management and planning.

Section 70-1.1 specifies that the requirements apply to hospitals, residential health care facilities, and diagnostic and treatment centers and clinical laboratories.

Section 70-1.2 includes new and revised definitions for terms used throughout the Subpart, including "alternative regulated medical waste treatment system," "autoclave," "biologicals," "certificate of treatment," "challenge testing," "clinical laboratory," "culture and stocks," "culture dishes and devices for transferring, inoculating and mixing cultures," "cycle," "decontamination," "destroyed waste," "efficacy testing," "hazardous waste," "household medical waste," "incinerator," "infectious agent," "monitoring," "operating parameters," "operation plan," "parametric control," "primary container," "residence time," "secondary container," "sharp," "solid waste," "sterilize," "universal warning sign," and "validation testing."

Section 70-2.1 stipulates the minimum requirements of a written plan for the management of RMW.

Section 70-2.2 contains requirements and standards for containment and storage of RMW; clarifies requirements for disposal and establishes time frames for storage of primary containers used to discard sharps; clarifies time frame for storage of RMW in patient care areas and clinical laboratories; sets requirements for rooms or areas used to store RMW; sets labeling requirements for secondary containers used to transport untreated RMW off-site for treatment; clarifies decontamination procedures and guidelines for reusing secondary containers; specifies disposal requirements for secondary containers intended for single use; clarifies on-site processing procedures for reusable sharps containers; and describes requirements for transport of RMW within a facility.

Section 70-2.3 specifies treatment methods for RMW; provides disposal requirements for hazardous, chemotherapeutic and radioactive waste; provides requirements for treatment of human tissue(s), or organs and animal body parts; stipulates transport, packaging and treatment requirements for cultures and stocks containing infectious agents; provides provision for sharps destruction and treatment; stipulates requirement for a response plan for handling untreated waste found commingled with solid waste; requires a radiation detection system for a facility to screen incoming waste for the presence of radioactive materials; requires a contingency plan for handling radioactive material found commingled with RMW delivered for treatment at a treatment facility; and clarifies treated RMW disposal options.

Section 70-2.4 describes requirements for transfer of untreated waste for off-site treatment; clarifies that generators of RMW must transfer custody of untreated waste only to an appropriately permitted (by DEC) hauler; provides exemption if monthly waste generation is under 50 pounds; establishes requirement for use of medical waste tracking forms; clarifies applicability of Federal Department of Transportation requirements to certain cultures and stocks; specifies treatment requirements for solid waste transported with untreated RMW.

Section 70-2.5 contains recordkeeping requirements and retention times for the quantity, types, on-site treatment and disposal of RMW.

Section 70-3.1 contains validation testing requirements for autoclaves used to treat RMW; and specifies required elements of protocols for validation testing.

Section 70-3.2 contains requirements for, and minimum elements of, an operational plan for facilities using autoclaves; specifies procedures that must be followed upon autoclave failure to meet operating parameters; contains requirements for monitoring autoclave performance; specifies standards for autoclave performance and for containment of RMW for treatment by autoclaving; and clarifies treatment of autoclaved sharps prior to disposal.

Section 70-3.3 clarifies the minimum operating parameters for treatment of RMW in a gravity-feed autoclave and in a vacuum-displacement autoclave; specifies approval requirements for use of an autoclave at alternative operating parameters.

Section 70-3.4 contains recordkeeping requirements and time frames for efficacy and validation testing, autoclave training, and documentation of corrective actions, modification of approved operating plans, residence time, pressure and temperature of treated loads.

Section 70-4.1 clarifies criteria for department approval of alternative treatment methods for RMW; and provides approval guidelines and time frames.

Section 70-4.2 establishes requirement for an operational plan approved by the department for each facility using an alternative RMW treatment system; stipulates required elements of the operation plan, including segregation of waste, safety and training plans for personnel handling RMW, emergency procedures, performance monitoring and routine maintenance; describes requirements for modification of the approved operation plan; stipulates the need for an approved plan prior to operation; describes procedures for system failure during operation; specifies monitoring requirements during operation; and stipulates operating personnel training requirements.

Section 70-4.3 clarifies the requirement for a protocol for validation testing; stipulates validation testing requirements to be met prior to placing system in operation.

Section 70-4.4 stipulates the additional recordkeeping requirements and retention times for efficacy and validation testing; for personnel records; for corrective actions; and for plan modifications.

Section 70-5 summarizes the approval process for Alternative Treatment Technologies in New York State.

Changes to rule: No substantive changes.

Expiration date: May 18, 2006.

Text of proposed rule and changes, if any, 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: regsna@health.state.ny.us

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

Power Authority of the State of New York

NOTICE OF ADOPTION

Rates for the Sale of Power and Energy

I.D. No. PAS-32-05-00014-A

Filing date: Oct. 25, 2005

Effective date: Nov. 1, 2005

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

Action taken: Adopt amendment of service tariffs for the Power Authority's Economic Development Power programs.

Statutory authority: Public Authorities Law, section 1005

Subject: Rates for the sale of power and energy.

Purpose: To recover cost of providing firm power and energy and implement L. 2005, ch. 313 regarding sale of power to various Economic Development Power Program customers.

Text or summary was published in the notice of proposed rule making, I.D. No. PAS-32-05-00014-P, Issue of August 10, 2005.

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

Text of rule and any required statements and analyses may be obtained from: Angela D. Graves, Power Authority of the State of New York, 123 Main St., 15-M, White Plains, NY 10601, (914) 287-3092, e-mail: angela.graves@nypa.gov

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.

Division of Probation and Correctional Alternatives

EMERGENCY RULE MAKING

Case Record Management and Supervisor

I.D. No. PRO-45-05-00007-E

Filing No. 1269

Filing date: Oct. 25, 2005

Effective date: Oct. 25, 2005

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

Action taken: Amendment of section 348.4; repeal of section 351.7; and addition of new section 351.7 to Title 9 NYCRR.

Statutory authority: Executive Law, sections 243(1) and 257(4) and (5)

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

Specific reasons underlying the finding of necessity: To promote public/victim safety, increase offender accountability, facilitate appropriate communication and/or sharing by probation of certain case record information where deemed necessary.

Subject: Case record management and supervision of those under probation supervision.

Purpose: To clarify existing laws governing access and confidentiality of probation case records, provide greater flexibility in certain instances.

Text of emergency rule: Section 348.4, Accessibility of case records, is amended to read as follows:

(a) *General.* Case records shall be accessible, in whole or in part, only by those authorized by law, court order and/or the Division of Probation and Correctional Alternatives (DPCA). DPCA has access to all case records and probation departments shall provide copies of any case records to DPCA upon request.

(b) *Mandatory Sharing of Case Record Information.*

(1) A probation director, or his/her designee, must make available a copy of its pre-plea/pre-sentence report and any medical, psychiatric or social agency report submitted in connection with its pre-sentence investigation or its supervision of a defendant, to any court or to the probation department of any court within the state, that subsequently has jurisdiction over such defendant for the purpose of pronouncing or reviewing sentence and to any state agency to which the defendant is subsequently committed or certified or under whose care and custody or jurisdiction the defendant subsequently is placed upon the official written request of the court or agency. In any such case, the court or agency receiving such material must retain it under the same conditions of confidentiality as apply to the probation department that made it available.

(2) A probation director, or his/her designee, must provide a copy of a pre-plea/pre-sentence report prepared in the case of an individual, other than a youthful offender, who is known to be licensed pursuant to title 8 of the education law to the state department of health if the licensee is a physician, a specialist's assistant or a physician assistant and to the state education department with respect to all such other licensees. Such reports must be in writing and shall be accumulated and forwarded every 3 months. They shall contain the following information:

(i) the name of the licensee and the profession in which the license is held,

(ii) the date of the conviction and the nature thereof,

(iii) the index or other identifying file number.

In any such case, the state department receiving such material must retain it under the same conditions of confidentiality as apply to the probation department that made it available.

(3) Upon a determination by a probation director, or his/her designee, that probation records regarding an individual presently under the supervision of the department are relevant to an investigation of child abuse or maltreatment conducted by a child protective service pursuant to title 6 of article 6 of the social services law, he/she shall provide the records, or portions thereof, determined to be relevant to the child protective service conducting the investigation. Each probation director, or his/

her designee, shall make provisions for the transmission of those required records.

(4) A probation director, or his/her designee, must provide all requisite case record information with respect to interstate or intrastate transfer of any probationer or former conditional releasee and, upon official written request, forward any additional case record information to the agency to which supervision has been transferred. In any such case, the court or agency receiving such material must retain it under the same conditions of confidentiality as apply to the probation department that made it available.

(c) *Discretionary Sharing of Case Record Information.*

(1) Public agencies outside this state. A probation director, or his/her designee, may disclose any information in its file as to an adult probationer, including youthful offender information, to any probation, parole, or public institutional agency outside this state, upon official written request. Any release of information shall be conditioned upon the agreement of the receiving agency to retain it under the same conditions of confidentiality as apply to the probation department that made it available. "Public institutional agency" shall mean any governmental entity which has the legal authority to detain and/or obtain custody over an individual charged or previously convicted of a criminal offense or adjudicated a youthful offender, or which has the responsibility to make a legal determination with respect to sex offender registration and/or DNA compliance.

(2) A probation director, or his/her designee, may disclose relevant case record information, other than the pre-plea/pre-sentence/pre-dispositional report, not otherwise sealed or specifically restricted in terms of access by state or federal law, from its files concerning any adult offender (other than a youthful offender) or fingerprintable juvenile delinquent currently or previously under probation supervision or formerly under local conditional release supervision, to appropriate law enforcement authorities, school authorities, child protective services, public and/or treatment agencies, the judiciary, and victim(s)/victim(s) family member(s), for public safety and/or case management purposes, including, but not limited to the following:

(i) national and homeland security;

(ii) criminal investigations and/or execution of warrants;

(iii) sex offender registration and/or DNA compliance;

(iv) victim safety, including matters pertaining to domestic violence, child protection, and sexual offense;

(v) national instant criminal background check system (NICS)/weapons permits;

(vi) military eligibility;

(vii) professional licensing/certification;

(viii) monitoring of conditions of probation or conditional release;

(ix) risks and needs assessment;

(x) treatment or counseling services to a licensed or certified provider; and

(xi) probation or conditional release investigations;

In all such instances, those to whom access has been granted shall not secondarily redisclose such information without the express written permission of the probation director, or his/her designee, who authorized access.

(3) *Potential or Existing Employee/Volunteer.* A probation director or his/her designee may disclose to an existing or potential employer that an individual who is or may become an employee or a volunteer has been convicted of a crime or adjudicated a juvenile delinquent for a fingerprintable offense, the nature thereof, the terms and conditions of his/her release, and compliance under supervision, unless the records are otherwise sealed or restricted by federal or state law. In all such instances, those to whom access has been granted shall not secondarily redisclose such information without the express written permission of the probation director or his/her designee who authorized access.

(4) *Public Information.* A probation director, or his/her designee, may disclose relevant case record information (not including the Division of Criminal Justice Services criminal history record or any portion thereof) relative to an adult probationer (other than a youthful offender) or former conditional releasee, not otherwise sealed or restricted by state or federal law, for the purpose of apprehending a wanted person in connection with a crime, a violation of probation or conditional release, a probation or conditional release warrant, a violation of an order of protection, or in response to an incident wherein the department's, or any individual under probation supervision actions, are the subject of a media or news story. A probation director or his/her designee may disclose the name, gender, race, date of birth/age, height, weight, eye color, hair color,

conviction offense, probation term, warrant/absconder status, and photograph of an adult probationer (other than a youthful offender).

(5) *Research.* Case records may be accessible, in whole or in part, for bona fide research conducted by a governmental entity or educational institution, where the probation director, or his/her designee, has made a bona fide research determination and approved of the research project. In such instance, the probation director, or his/her designee, shall enter into a written agreement as to terms and conditions of the research, and keep a log of any research project, its purpose, and dates of research conducted and/or completed. The following confidentiality safeguards shall be observed:

(i) coding is required to ensure that any youth or adult receiving, or previously having received, probation services are not identified by name;

(ii) access is restricted to only those involved in the research whose responsibilities cannot be accomplished without such access and to secure written confidentiality agreements from any research project staff to adhere to all terms and conditions of the research, including confidentiality provisions herein stated;

(iii) researchers are not permitted to copy any case records in any manner with identifying information and each probation director shall take such precautionary departmental security measures to guarantee compliance;

(iv) that any project records copied shall be maintained in secure locked files;

(v) to retain any data received or copied only so long as necessary to effectuate the purposes of the research project and to return or destroy the data in such a way as to prevent their unauthorized use;

(vi) to guarantee that research performed or information accessed will not result in adverse action against the subject of the research;

(vii) the probation department has advance access to any preliminary findings and/or draft report prior to finalization, publication, or distribution and to furnish the probation director with any final project report or findings in a timely manner; and

(viii) no assignment of research shall occur without the written consent of the probation director or his/her designee.

The probation director, or his/her designee, shall promptly provide the State Director of Probation and Correctional Alternatives with a copy of the final project report from any bona fide research project for which a written agreement is entered into.

(6) *Data sharing.* A probation director, or his/her designee, may voluntarily submit data in its files to the Division of Criminal Justice Services (DCJS).

(7) *Freedom of Information Law.* A probation director, or his/her designee, may deny access to case records or portions thereof sought pursuant to article 6 of the public officers law (the freedom of information law) which meet the enumerated criteria established by subdivision two of section 87 of the public officers law. Criteria includes (a) records or portions that are specifically exempted by state or federal statute, (b) if disclosed would constitute an unwarranted invasion of personal privacy, (c) are compiled for law enforcement purposes and which if disclosed would (i) interfere with law enforcement investigations or judicial proceedings, (ii) deprive a person of a right to a fair trial or impartial adjudication, (iii) identify a confidential source or disclose confidential information relating to a criminal investigation, or (iv) reveal criminal investigative techniques or procedures, (d) are inter-agency or intra-agency materials (i) which are not statistical or factual tabulations or data, (ii) instructions to staff that affect the public, or (iii) final agency policy or determinations. Case records or portions thereof which are exempt from disclosure and not accessible include, but are not limited to pre-plea/pre-sentence/pre-dispositional reports, medical records, confidential HIV-related information, victim's name and address, youthful offender records, juvenile delinquency adjustment records, sex offender registration information, and DCJS criminal history records.

(d) *Policies and Procedures.* A local probation director shall establish written policies and procedures governing release of case records consistent with laws governing access and confidentiality and disseminate such policies and procedures to their agency staff.

Section 351.7 of 9 NYCRR is repealed. A new Section 351.7 is added to read as follows:

351.7 *Supervisory Directives/Instructions.* Courts are required to impose specific conditions relating to supervision and other conditions required by law, and may impose other conditions of probation relative to conduct, rehabilitation, movement, and controls, so as to ensure that the individual being supervised will lead a law abiding life or assist him/her in

doing so, or to ameliorate the conduct which gave rise to the offense/petition or prevent incarceration/ placement. Every probation director may establish written policies providing that additional supervisory directives and/or instructions required for the individual to follow as part of his/her respective supervision plan. Any directives and/or instructions shall be reviewed and approved by a supervisor within the department. Such directives or instructions shall relate to and clarify any general or specific conditions of probation imposed by the court relative to conduct, rehabilitation, movement, controls, assessment, needs, or classification relevant to the supervision plan of the individual. He/she shall be given written documentation of any such directives or instructions and the probation officer shall review its content with the individual being supervised to ensure that he/she is aware of and understands these supervisory requirements. The individual being supervised shall sign an acknowledgement that it has been provided and explained.

This notice is intended to serve only as a notice of emergency adoption. This agency intends to adopt this emergency rule as a permanent rule and will publish a notice of proposed rule making in the *State Register* at some future date. The emergency rule will expire January 22, 2006.

Text of emergency rule and any required statements and analyses may be obtained from: Linda J. Valenti, Counsel, Division of Probation and Correctional Alternatives, 80 Wolf Rd., Suite 501, Albany, NY 12205, (518) 485-2394

Regulatory Impact Statement

1. Statutory authority:

Executive Law Section 243(1) empowers the State Director of Probation and Correctional Alternatives to promulgate rules "which shall regulate methods and procedure in the administration of probation services," including but not limited to "supervision, case work, recordkeeping . . . and research so as to secure the most effective application of the probation system and the most efficient enforcement of the probation laws throughout the state."

Executive Law Section 257(4) establishes that it is "the duty of every probation officer to furnish to each of his probationers a statement of the conditions of probation, and to instruct him with regard thereto; to keep informed concerning his conduct habits, associates, employment, recreation and whereabouts;... to aid and encourage him by friendly advice and admonition; and by such other measures as may seem most suitable to bring about improvement in his conduct, condition and general attitude toward society." Further, Executive Law Section 257(5) recognizes that "[P]robation officers may require such reports by probationers as are reasonable or necessary."

2. Legislative objectives:

These regulatory amendments are consistent with legislative intent that the State Director adopt regulations in areas relating to critical probation functions. It is in keeping with legislative intent to promote professional standards governing the administration and delivery of probation services in the area of case records management and enhance supervisory controls with respect to probationer's conduct, as well as enhance numerous legislative measures which have been enacted into law to promote greater offender accountability and safeguard the public and victims.

There exists various state and federal laws governing confidentiality, access and release of information which are typically contained in probation case records. Additionally there exists specific state laws and existing rules and regulations, having the force and effect of law, relative to conditions of release and delivery of supervision services. These emergency regulatory amendments in this area conform with existing laws governing confidentiality of certain case record information and conditions of release, and provide probation departments with the necessary means and flexibility to communicate more effectively and better manage those under their supervision. Public safety and the general welfare of the public are served by emergency adoption of these regulatory amendments.

3. Needs and benefits:

These regulatory amendments clarify rule language governing mandatory sharing of probation case record information in an effort to assist practitioners in fulfilling their responsibilities under law. Further, additional rule language clarify discretionary sharing of probation case record information authorized in existing law and also expands upon probation's ability to share and/or otherwise disclose certain case record information to particular individuals or entities for public safety and/or case management purposes. Specific parameters are established as to disclosure regarding a potential or existing employee/volunteer, as well as with respect to public information and research. Lastly, reinforced are the limitations which prevent disclosure of records sealed or otherwise restricted in terms of access by state and/or federal law.

More comprehensive provisions in the area of case record management, including establishment and dissemination to staff as to local policies and procedures will prove beneficial in terms of compliance with existing laws, improving professional communication for public safety and/or case management purposes, facilitating probation research, and addressing other areas of public concern.

Additionally, the regulatory language recognizing the ability of probation to require any individual under supervision to follow supervisory directives/instructions which relate to and clarify any general or specific conditions of probation imposed by the court relative to conduct, rehabilitation, movement, controls, assessment, needs or classification relevant to the supervision plan of the individual, reinforces laws governing conditions of release, and provides probation with a mechanism to better ensure those under supervision will lead a law abiding life and adhere to court conditions imposed. Requiring interested probation departments to establish written policies in this area, ensure supervisor approval, and require review of any such directives/instructions with the probationer coupled with their signature and receipt of such material strikes a fair balance to guard against arbitrary and indiscriminate application and foster better understanding by the individual under supervision.

Moreover, these regulatory amendments address a need to strengthen community corrections by affording greater flexibility in handling certain functions consistent with good professional practice. It is in the best interests of the state and local government that these regulatory amendments be adopted. These amendments will better address and optimize public and victim safety, promote greater offender accountability, facilitate better communication by probation departments, clarify certain constraints in law and establish appropriate safeguards to guarantee more uniform application.

4. Costs:

These changes are procedural in nature and may require some additional training. However, we do not foresee these regulatory reforms leading to significant additional costs to probation departments. Clearly, any minimal costs are significantly outweighed by increased public safety interests and offender accountability provided by these new provisions.

5. Local government mandates:

These emergency regulatory amendments establishes that every local probation director must establish written policies and procedures governing release of case records consistent with laws governing access and confidentiality and disseminate such policies and procedures to their agency staff. Additional regulatory language provides that interested probation departments enter into a research agreement as to any bona fide research which they approve, and establish written policies if requiring any additional supervisory directives/instructions as part of an individual's supervision plan. While not expressly required before, it is consistent with routine business operations that state and local government agencies have established procedures governing key activities to ensure consistency in application and foster better understanding among staff. Accordingly, we do not anticipate these new requirements will be burdensome or costly.

The Division circulated two earlier drafts of these regulatory amendments to the Council of Probation Administrators, (the statewide professional association of probation administrators) who assigned it to a specific committee for review and the State Probation Commission, the state advisory body to the Division. All probation directors received the most recent prior draft language. We incorporated in these amendments certain verbal and written suggestions earlier raised by probation professionals to address problems which they previously experienced and to clarify certain provisions in law.

Overall, the Division has received favorable support from probation agencies that these new regulatory amendments are manageable and consistent with good professional practice.

6. Paperwork:

The proposed rule will potentially lead to additional paperwork, although minimal in content with respect to establishing or expanding local procedures to address new regulatory language.

7. Duplication:

This proposed rule does not duplicate any State or Federal law or regulation. It clarifies and reinforces certain laws with respect to confidentiality and access to probation case record and terms and conditions of release and supervision and helps achieve greater flexibility where necessitated.

8. Alternatives:

In view of the need to establish stronger minimum standards relative to case records and strengthen probation management of those under supervision in order to achieve greater offender accountability, protect public and

victim safety, and facilitate better case management, regulatory amendments in these two areas are critical and no other alternatives were determined appropriate.

9. Federal standards:

There are certain federal standards governing confidentiality and access of certain documents contained in case records and these regulatory amendments are consistent with these requirements.

10. Compliance schedule:

Through prompt dissemination and because amendments are not unduly burdensome, local departments should be able to promptly implement these amendments.

Regulatory Flexibility Analysis

A regulatory flexibility analysis for small businesses is not required by Section 202-a of the State Administrative Procedure Act, no small business recordkeeping requirements, needed professional services, or compliance requirements will be imposed on small businesses.

Any impact a local government is addressed in both the Regulatory Impact Statement and the Rural Area Flexibility Analysis.

Rural Area Flexibility Analysis

1. Types and estimated number of rural areas:

Forty-four local probation departments are located in rural areas and will be affected by the emergency rule amendments.

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

These regulatory amendments strengthen procedural requirements and improves probation practice, yet should not impose significant additional local probation costs. There are no professional services likely to be needed in any rural area to comply with these regulatory changes. These regulatory amendments only refer to one reporting requirement with respect to a probation department approving a bona fide research project. Where this occurs, which we anticipate as infrequent, a copy of the final research project must be submitted to the Division. This requirement is not onerous. Specific written policies and procedures governing release of case records and a written policy as to any supervisory directives/instruction which a probation department may require are normal business activities and in keeping with good professional practice. While the former is mandatory and the latter conditioned only where a policy is instituted, the Division does not anticipate these requirements as costly or burdensome.

Moreover case record and supervision rule amendments will improve compliance with state laws governing access to records and conditions of release, enhance probation communications, achieve greater offender accountability, and enhance public and victim safety.

3. Costs:

There are no significant additional costs or new annual costs required to comply with these emergency regulatory changes. Clearly, any minimal costs, are significantly outweighed by increased public and victim safety interests and offender accountability provided by these new provisions.

4. Minimizing adverse impact:

These regulatory amendments will have no adverse impact on rural areas.

5. Rural area participation:

DPCA has discussed earlier proposed regulatory changes with the Executive Committee of the Council of Probation Administrators, which include a cross-section of urban, rural, and suburban jurisdictions, and we have circulated and submitted comments on a prior draft of this regulatory reform to all probation directors and the State Probation Commission. The current emergency regulatory amendments incorporate many verbal and written suggestions from probation professionals, including rural entities, across the state to address problems which probation departments experience in the area of case records and supervision and to clarify certain procedural provisions and existing laws governing confidentiality and access to probation case records. More flexibility in disclosing certain case record information was sought and clearer explanation as to under what circumstances case record information must and in other instances can be disclosed. Brief details of some of these changes are highlighted in the regulatory impact statement. Moreover, DPCA did not find significant differences between urban, rural, and suburban jurisdictions as to issues raised or suggestions for change.

Job Impact Statement

A job impact statement is not being submitted with these emergency regulations because it will have no adverse effect on private or public jobs or employment opportunities. The revisions are procedural in nature and clarify laws governing confidentiality and case records and provide for establishment of supervisory directives. These changes are not onerous in

nature and can be implemented through correspondence and training of probation staff.

Public Service Commission

NOTICE OF ADOPTION

Transfer of Hard Copies of Accounts, Books and Records by Long Island Water Corporation

I.D. No. PSC-23-04-00008-A

Filing date: Oct. 24, 2005

Effective date: Oct. 24, 2005

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

Action taken: The commission, on Aug. 24, 2005, adopted an order in Case 04-W-0595 approving a petition by Long Island Water Corporation (LIWC) to transfer the hard copies of its accounts, books and records from its principal office in Lynbrook, New York to Mt. Laurel, New Jersey.

Statutory authority: Public Service Law, sections 543 and 561.2

Subject: Transfer of LIWC's accounts, books and records out-of-state.

Purpose: To approve LIWC's transfer of accounts, books and records out-of-state.

Substance of final rule: The Commission approved a petition by Long Island Water Corporation to transfer the hard copies of its accounts, books and records from its principal office in Lynbrook, New York to Mt. Laurel, New Jersey, 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-W-0595SA1)

PROPOSED RULE MAKING NO HEARING(S) SCHEDULED

Renewable Portfolio Standard Program Funding by Boralex New York, Inc.

I.D. No. PSC-45-05-00010-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 matters related to the application of Boralex New York Inc., on behalf of its Chateaugay, NY biomass facility for Renewable Portfolio Standard (RPS) Program funding as a maintenance resource pursuant to the commission's order approving implementation plan, adopting clarifications, and modifying Environmental Disclosure Program that was issued on April 14, 2005.

Statutory authority: Public Service Law, sections 4(1), 5(2), 66(1) and (2)

Subject: Application for RPS Program funding as a maintenance resource.

Purpose: To consider an implementation plan that addresses matters pertinent to implementing the retail renewable portfolio standard.

Substance of proposed rule: Pursuant to the Commission's Order Approving Implementation Plan, Adopting Clarifications, And Modifying Environmental Disclosure Program that was issued on April 14, 2005 (Implementation Plan Order), Boralex New York Inc. submitted on July 13, 2005 an application for a determination on RPS Program eligibility and funding for its Chateaugay, New York biomass facility. Commencing commercial operation in 1993, the facility is an 18 megawatt (net) wood-

fired electrical generating plant consisting of a wood storage structure, boiler building, ash storage area, turbine generator building, water-cooled condenser, electrostatic precipitator and stack. The major subsystems include a fuel receiving and handling system, boiler, condensing turbine, air and water quality control systems, and combustion monitoring and control systems. The fuel is comprised of whole tree chips and mill wood residue. The plant produces approximately 120,000 megawatt-hours of electricity and consumes approximately 205,000 tons of waste wood annually.

The application asserts that the facility has not been able to operate profitably over the most recent four years because of the high cost of fuel and low energy prices. The application states that RPS Program funds are necessary to stabilize operations and provide funds for necessary capital improvements.

Based on a review of the application and supporting documentation, the Director of the Commission's Office of Electricity and Environment has determined, pursuant to the delegation afforded him by the Implementation Plan Order, that the facility is eligible to participate in the RPS Program as a maintenance resource. The Commission will render a decision on Boralex's RPS Program funding request. Options under consideration may include offering Boralex performance payments based on renewable energy produced over a period of years at a level the Commission deems appropriate to assist the facility to maintain financial viability during the term of its participation in the RPS Program. Other appropriate actions may be considered as well. The Commission may also decide to impose conditions on any such award to ensure protection of the public interest and achievement of its renewable energy policy goals.

Text of proposed rule and any required statements and analyses may be obtained by filing a Document Request Form (F-96) located on our website <http://www.dps.state.ny.us/f96dir.htm>. For questions, contact: Central Operations, Public Service Commission, Bldg. 3, Empire State Plaza, Albany, NY 12223-1350, (518) 474-2500

Data, views or arguments may be submitted to: Jaclyn A. Brillig, 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-E-0188SA13)

PROPOSED RULE MAKING NO HEARING(S) SCHEDULED

Treatment of Lost and Unaccounted Gas Costs by Corning Natural Gas Corporation

I.D. No. PSC-45-05-00011-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, modify, or reject, in whole or in part, the filing made by Corning Natural Gas Corporation for an extension of time to review its lost and unaccounted for gas during the 12 months ended Aug. 31, 2005 and for authorization to defer certain associated costs.

Statutory authority: Public Service Law, sections 65 (1), 66 (4) and (9)

Subject: Treatment of lost and unaccounted for gas costs.

Purpose: To consider if the commission should allow the company to defer certain costs pertaining to the lost and unaccounted for gas during the 12 months ended Aug. 31, 2005.

Substance of proposed rule: The Commission is considering whether to approve, reject, or modify the filing made by Corning Natural Gas Corporation (Corning). On October 17, 2005, Corning filed its annual gas cost reconciliation for the 12 months ended August 31, 2005, which included the reconciliation of actual lost and unaccounted for gas (LAUF) with the target LAUF set in Case 02-G-0003. Corning has calculated that its actual LAUF is greater than the target LAUF. Corning believes that the calculated figure is abnormal and requests additional time to carry out further analysis before being required to include this amount to be refunded to customers. Corning has petitioned the Commission for the authority to defer the finally determined costs associated with the LAUF, in full, in Account No. 186, Miscellaneous Deferred Debits, and further requests that

the related income tax effects be recorded in the appropriate deferred income tax account.

Text of proposed rule and any required statements and analyses may be obtained by filing a Document Request Form (F-96) located on our website <http://www.dps.state.ny.us/f96dir.htm>. For questions, contact: Central Operations, Public Service Commission, Bldg. 3, Empire State Plaza, Albany, NY 12223-1350, (518) 474-2500

Data, views or arguments may be submitted to: Jaclyn A. Brillling, 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.

(05-G-1155SA2)

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

Submetering of Electricity by Andrews Building Corporation

I.D. No. PSC-45-05-00012-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 grant, deny or modify, in whole or in part, the petition filed by Andrews Building Corporation to submeter electricity at 25 W. Houston St., New York, NY.

Statutory authority: Public Service Law, sections 2, 4(1), 65(1), 66(1), (2), (3), (4), (12) and (14)

Subject: Submetering of electricity.

Purpose: To consider the request of Andrews Building Corporation to submeter electricity at 25 W. Houston St., New York, NY.

Substance of proposed rule: The Public Service Commission is considering whether to grant, deny, or modify, in whole or part, the petition filed by Andrews Building Corporation to submeter electricity at 25 West Houston Street, New York, New York.

Text of proposed rule and any required statements and analyses may be obtained by filing a Document Request Form (F-96) located on our website <http://www.dps.state.ny.us/f96dir.htm>. For questions, contact: Central Operations, Public Service Commission, Bldg. 3, Empire State Plaza, Albany, NY 12223-1350, (518) 474-2500

Data, views or arguments may be submitted to: Jaclyn A. Brillling, 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.

(05-E-1290SA1)

Proposed action: This is a consensus rule making to repeal Part 8300 to Title 9 NYCRR.

Statutory authority: L. 1995, ch. 83, sections 3-9

Subject: Rules of the former Office of Rural Affairs relating to public access to records.

Purpose: To repeal rules of the former Office of Rural Affairs relating to public access to records. Functions of the Office of Rural Affairs were transferred to the Department of State by Chapter 83 of the Laws of 1995. The rules of the Office of Rural Affairs found in Part 8300 of Title 9 NYCRR should be repealed because they duplicate Department of State regulations found in Chapter 11 of Title 19 NYCRR.

Text of proposed rule: Part 8300 of Title 9 NYCRR is REPEALED.

Text of proposed rule and any required statements and analyses may be obtained from: Nathan A. Hamm, Department of State, 41 State St., Albany, NY 12231, (518) 474-6740

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

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

This action was not under consideration at the time this agency's regulatory agenda was submitted.

Consensus Rule Making Determination

The purpose of the rule is to repeal rules of the former New York State Office of Rural Affairs relating to "Public Access to Records." All functions of the Office of Rural Affairs were transferred to the Department of State by Chapter 83 of the Laws of 1995. The rules of the Office of Rural Affairs found in Part 8300 of Title 9 NYCRR should be repealed because they duplicate Department of State regulations found in Chapter II of Title 19 NYCRR.

No person is likely to objection to the adoption of the proposed rule because it repeals obsolete regulatory provisions and is otherwise non-controversial.

Job Impact Statement

The purpose of the rule is to repeal rules of the former New York State Office of Rural Affairs relating to "Public Access to Records." All functions of the Office of Rural Affairs were transferred to the Department of State by Chapter 83 of the Laws of 1995. The rules of the Office of Rural Affairs found in Part 8300 of Title 9 NYCRR should be repealed because they duplicate Department of State regulations found in Chapter II of Title 19 NYCRR.

It is therefore apparent from the nature and purpose of the rule that it will not have a substantial adverse impact on jobs and employment opportunities.

Department of State

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

Public Access to Records

I.D. No. DOS-45-05-00004-P

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