

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

Pine Shoot Beetle Quarantine

I.D. No. AAM-42-04-00008-E
Filing No. 1223
Filing date: Oct. 27, 2004
Effective date: Oct. 27, 2004

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

Action taken: Amendment of section 131.1 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: This rule amends the pine shoot beetle quarantine in section 131.1 of 1 NYCRR by extending that quarantine to the Counties of Albany, Broome, Cayuga, Chemung, Chenango, Clinton, Columbia, Cortland, Delaware, Essex, Franklin, Fulton, Greene, Hamilton, Herkimer, Jefferson, Lewis, Madison, Montgomery, Oneida, Onondaga, Otsego, Rensselaer, Saratoga, Schenectady, Schoharie, St. Lawrence, Schuyler, Seneca, Steuben, Sullivan, Tioga, Tompkins, Warren, Washington, Wayne and Yates. This rule also incorpo-

rates by reference, the most recent revisions to Federal regulations at 7 CFR sections 301.50 through 301.50-10, revised as of Jan. 1, 2004, which set forth requirements and restrictions for the movement of host materials. Finally, this rule deletes spruce, larch and fir from the list of regulated host materials subject to regulation under the quarantine, since the United States Department of Agriculture (USDA) has tested and determined that these materials are not a host to the pine shoot beetle.

The pine shoot beetle, *Tomicus piniperda*, an insect non-indigenous to the United States, is a destructive wood-boring insect native to Europe. The beetle attacks pine trees by nesting under the bark and feeding on new shoots. The resulting damage by the beetle causes shoot and branch mortality which affects the growth and appearance of the tree and may eventually lead to the death of the tree. Although it is a slow-moving pest, the pine shoot beetle is easily spread through the movement of Christmas trees, nursery stock and pine logs and lumber. The pine shoot beetle was first detected in a Christmas tree farm near Cleveland, Ohio in July of 1992 and subsequently spread to other parts of Ohio as well as to sections of Michigan, Indiana, Illinois, Pennsylvania and New York. On Nov. 19, 1992, the USDA adopted regulations establishing a pine shoot beetle quarantine to help prevent the spread of this pest. On Nov. 25, 1992, the Department, as an emergency measure, adopted section 131.1 of 1 NYCRR, which incorporated by reference that federal quarantine. This emergency measure was ultimately adopted as a permanent rule on March 17, 1993.

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. The specific reason for this finding is that the failure to immediately incorporate by reference the federal regulations which set forth requirements for the movement of host materials and to extend the quarantine could result in the spread of this pest. The beetle has already been detected in the Counties of Albany, Broome, Cayuga, Chemung, Chenango, Clinton, Cortland, Delaware, Essex, Franklin, Fulton, Greene, Hamilton, Herkimer, Jefferson, Lewis, Madison, Montgomery, Oneida, Onondaga, Otsego, Rensselaer, Saratoga, Schenectady, Schoharie, St. Lawrence, Schuyler, Seneca, Steuben, Sullivan, Tioga, Tompkins, Warren, Washington, Wayne and Yates. Failure to immediately extend the quarantine to these counties could result in the spread of the pest beyond those areas. Although the beetle has not as yet been detected in Columbia County, extension of the quarantine into Columbia County would establish a buffer between infested and uninfested counties, thereby helping to control the further spread of this pest. Columbia County is not the only county adjacent to counties in which the beetle has been detected, since the Counties of Ulster and Orange are also adjacent to the quarantined area. However, since Columbia County contains saw mills which process pine logs shipped from counties where the beetle has been detected, there is a greater likelihood that infested materials will be transported to Columbia County. Failure to establish such a buffer by immediately extending the quarantine into Columbia County could result in the spread of the pest through transportation of susceptible materials into Vermont and Massachusetts as well as those uninfested counties in New York which lie south of the Counties of Sullivan, Delaware, Greene and Columbia. The failure to immediately extend the quarantine will promote the spread of the beetle which can be easily transported on nursery stock, pine logs and lumber with bark attached from infested areas to uninfested areas. This would not only result in damage to the natural resources of the State, but could also result in a federal quarantine or quarantines by other

states which would cause economic hardship to the Christmas tree, nursery and forest products industries throughout New York State. The consequent loss of business would harm industries which are important to New York State's economy and as such, would harm the general welfare. Given the potential for the spread of the pine shoot beetle 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: Pine shoot beetle quarantine.

Purpose: To prevent the spread of the beetle in the Counties of Albany, Broome, Cayuga, Chemung, Chenango, Clinton, Columbia, Cortland, Delaware, Essex, Franklin, Fulton, Greene, Hamilton, Herkimer, Jefferson, Lewis, Madison, Montgomery, Oneida, Onondaga, Otsego, Rensselaer, Saratoga, Schenectady, Schoharie, St. Lawrence, Schuyler, Seneca, Steuben, Sullivan, Tioga, Tompkins, Warren, Washington, Wayne and Yates; incorporate by reference, Federal regulations at 7 CFR sections 301.50 through 301.50-10, revised as of Jan. 2004, which set forth requirements for the movement of host materials; and delete spruce, larch and fir from the list of regulated host materials subject to regulation under the pine shoot beetle quarantine.

Text of emergency rule: Section 131.1 of Title 1 of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended to read as follows: Pine Christmas trees, pine nursery stock and pine [spruce, larch and fir] logs and lumber, with bark attached, shall not be shipped, transported or otherwise moved from any point within Albany, Allegany, Broome, Cattaraugus, Cayuga, Chautauqua, Chemung, Chenango, Clinton, Columbia, Cortland, Delaware, Erie, Essex, Franklin, Fulton, Genesee, Greene, Hamilton, Herkimer, Jefferson, Lewis, Livingston, Madison, Monroe, Montgomery, Niagara, Oneida, Onondaga, Oswego, Ontario, Orleans, Otsego, Rensselaer, Saratoga, Schenectady, Schoharie, St. Lawrence, Schuyler, Seneca, Steuben, Sullivan, Tioga, Tompkins, Warren, Washington, Wayne, [and] Wyoming and Yates Counties to any point outside of said counties, except in accordance with 7 CFR sections 301.50 through 301.50-10 [(pages 27 - 34) (revised as of January 1, 1995)] (pages 33 - 41) (revised as of January 1, 2004) which is incorporated by reference herein. Copies of the Code of Federal Regulations may be obtained from the U.S. Government Printing Office, Washington, DC 20402 and the material incorporated by reference herein is available for public inspection and copying at the offices of the Department of Agriculture and Markets, Division of Plant Industry, [Capital Plaza, One Winners Circle] 10B Airline Drive, Albany, NY 12235.

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. AAM-42-04-00008-P, Issue of October 20, 2004. The emergency rule will expire December 25, 2004.

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

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 modification of the quarantine accords with the public policy objectives the Legislature sought to advance by enacting the statutory

authority in that it will help to prevent the spread within the State of an injurious insect, the pine shoot beetle.

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

The pine shoot beetle was first detected in a Christmas tree farm near Cleveland, Ohio in July of 1992 and subsequently spread to other parts of Ohio as well as to sections of Michigan, Indiana, Illinois, Pennsylvania and New York. On November 19, 1992, the United States Department of Agriculture (USDA) adopted regulations (7 CFR sections 301.50 through 301.50-10), establishing a pine shoot beetle quarantine as well as requirements and restrictions governing the movement of regulated materials from counties where this pest has been detected. On November 25, 1992, the Department, as an emergency measure, adopted section 131.1 of 1 NYCRR, which required that pine Christmas trees, pine nursery stock and pine, spruce, larch and fir logs and lumber, with bark attached, shall not be shipped, transported or otherwise moved from any point within Allegany, Cattaraugus, Erie, Genesee, Livingston, Monroe, Niagara, Oswego, Ontario and Wyoming Counties to any point outside said counties, except in accordance with federal regulations at 7 CFR sections 301.50 through 301.50-10. This emergency measure was ultimately adopted as a permanent rule on March 17, 1993.

However, subsequent observations of the pine shoot beetle in the Counties of Albany, Broome, Cayuga, Chemung, Chenango, Clinton, Cortland, Delaware, Essex, Franklin, Fulton, Greene, Hamilton, Herkimer, Jefferson, Lewis, Madison, Montgomery, Oneida, Onondaga, Otsego, Rensselaer, Saratoga, Schenectady, Schoharie, St. Lawrence, Schuyler, Seneca, Steuben, Sullivan, Tioga, Tompkins, Warren, Washington, Wayne and Yates, have resulted in the need to add these counties to the list of quarantined areas in section 131.1. The amendments contain the needed additions. Although the beetle has not as yet been detected in Columbia County, extension of the quarantine into that county will establish a buffer between infested and uninfested counties, thereby helping to control the further spread of this pest. Columbia County is not the only county adjacent to counties in which the beetle has been detected, since the Counties of Ulster and Orange are also adjacent to the quarantined area. However, since Columbia County contains saw mills which process pine logs shipped from counties where the beetle has been detected, there is a greater likelihood that infested materials will be transported to Columbia County. The need to establish such a buffer has resulted in the need to add Columbia County to the list of quarantined areas in section 131.1. The amendments contain the needed addition. The amendments also incorporate by reference, the most recent revision of the federal regulations at 7 CFR sections 301.50 through 301.50-10, revised as of January 1, 2004, which set forth requirements and restrictions governing the movement of regulated materials from counties where the pine shoot beetle has been detected. Finally, the amendments delete spruce, larch and fir from the list of regulated host materials subject to regulation under the quarantine, since the USDA has tested and determined that these materials are not a host to the pine shoot beetle.

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

4. Costs:

(a) Costs to the State government:

None.

(b) Costs to local government:

None.

(c) Costs to private regulated parties:

Under the amendments, regulated parties exporting host material from the quarantined area, other than pursuant to compliance agreement, will

require an inspection and the issuance of a federal or state phytosanitary certificate. This service is available at a rate of \$25 per hour. Most inspections will take one hour or less. It is anticipated that there would be 25 or fewer such inspections each year with a total annual cost of less than \$1,000.

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

(d) Costs to the regulatory agency:

(i) The initial expenses the agency will incur in order to implement and administer the regulation: None.

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

5. Local government mandate:

None.

6. Paperwork:

Under the amendments, regulated articles inspected and certified to be free of the pine shoot beetle moving from quarantined areas will have to be accompanied by a state or federal phytosanitary certificate of a limited permit or be undertaken pursuant to a compliance agreement.

7. Duplication:

None.

8. Alternatives:

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

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

10. Compliance schedule:

Immediate.

Regulatory Flexibility Analysis

1. Effect on small business:

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

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

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

2. Compliance requirements:

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

3. Professional services:

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

4. Compliance costs:

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

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

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

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

5. Minimizing adverse impact:

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

6. Small business and local government participation:

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

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

Rural Area Flexibility Analysis

1. Type and estimated numbers of rural areas:

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

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

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

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

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

3. Costs:

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

4. Minimizing adverse impact:

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

5. Rural area participation:

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

Job Impact Statement

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

EMERGENCY RULE MAKING

Golden Nematode Quarantine

I.D. No. AAM-46-04-00008-E

Filing No. 1234

Filing date: Nov. 2, 2004

Effective date: Nov. 2, 2004

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

Action taken: Addition of section 127.2 (l) and (m) to 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: This 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: Golden nematode quarantine.

Purpose: To prevent the further spread of this pest.

Text of emergency 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.*

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 30, 2005.

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

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:

This 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 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 immediately 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:

Farming and construction equipment located on the two farms affected by the extension of the quarantine will have to be cleaned and sanitized prior to leaving the quarantine zone. Depending upon the availability of resources and personnel, cleaning and sanitizing will 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 will 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 will incur, at most, annual costs for continued compliance with the rule of \$110.00 (\$10.00 per hour × 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.

Any potatoes planted at the two farm locations affected by the 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.

(d) Costs to the regulatory agency:

(i) The initial expenses the agency will incur in order to implement and administer the regulation: None.

(ii) It is anticipated that the Department will be able to use existing personnel to administer the extension of the quarantine and to perform the necessary cleaning and sanitizing of equipment in the extended quarantine area.

5. Local government mandate:

None.

6. Paperwork:

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

This 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 rule will 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 extension of the quarantine will have to be cleaned and sanitized prior to leaving the quarantine zone.

Any potatoes planted at the two farm locations affected by the 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.

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

3. Professional services:

In order to comply with the amendments, the two farms will 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 will be provided by the United States Department of Agriculture (USDA) and/or the Department. Otherwise, regulated parties will have to clean and sanitize their own equipment prior to leaving the quarantine zone.

It is anticipated that the rule will 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 will 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 extension of the quarantine will have to be cleaned and sanitized prior to leaving the quarantine zone. Depending upon the availability of

resources and personnel, cleaning and sanitizing will 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 will 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 will incur, at most, annual costs for continued compliance with the rule of \$110.00 (\$10.00 per hour × 11). Of course, this cost will 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 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.

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

5. Minimizing adverse impact:

The Department has designed the rule to minimize adverse economic impact on small businesses and local governments. The rule minimizes adverse economic impact by limiting the modified quarantined areas to only those areas where the golden nematode has been detected. The rule also minimizes 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. The approaches for minimizing adverse economic impact required by section 202-a(1) of the State Administrative Procedure Act and suggested by section 202-b(1) of the State Administrative Procedure Act were considered. Given all of the facts and circumstances, it is submitted that the rule minimizes adverse economic impact as much as is currently possible.

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

6. Small business and local government participation:

The Department has contacted the owners, operators and representatives of the two farms which are affected by the extension of the quarantine.

It is anticipated that the rule will 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 rule 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 extension of the quarantine will have to be cleaned and sanitized prior to leaving the quarantine zone. However, cleaning and sanitizing will 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 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.

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

Rural Area Flexibility Analysis

1. Type and estimated numbers of rural areas:

This 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 rule will affect these two farms, both of which are in rural areas.

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

The rule will not require any reporting or recordkeeping requirements for regulated parties.

With respect to compliance requirements, farming and construction equipment on the two farms affected by the 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 will 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 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 extension of the quarantine will have to be cleaned and sanitized prior to leaving the quarantine zone. However, cleaning and sanitizing is 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 will 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 will incur, at most, annual costs for continued compliance with the rule of \$110.00 (\$10.00 per hour × 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 amendments were drafted to minimize adverse impact on all regulated parties, including those in rural areas. The rule minimizes adverse economic impact by limiting the modified quarantined areas to only those areas where the golden nematode has been detected. The rule also minimizes 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 rule minimizes adverse economic impact as much as is currently possible.

5. Rural area participation:

The Department has contacted the owners, operators and representatives of the two farms which are affected by the extension of the quarantine. Both farms are located in rural areas of the State.

Job Impact Statement

The rule will not have a substantial adverse impact on jobs and employment opportunities. The modification of the quarantine area is designed to prevent the spread of the 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 rule 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.

PROPOSED RULE MAKING HEARING(S) SCHEDULED

Sanitation Requirements for Poultry Dealers and Poultry Transporters

I.D. No. AAM-46-04-00004-P

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

Proposed action: Amendment of Part 45 of Title 1 NYCRR.

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

Subject: Sanitation requirements for poultry dealers and poultry transporters.

Purpose: To prevent the spread of avian influenza through the live poultry markets.

Public hearing(s) will be held at: 11:00 a.m., Jan. 6, 2005 at Department of Agriculture and Markets, 10B Airline Dr., Colonie, 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 45.1 of Title One of the Official Compilation of Codes, Rules and Regulations of the State of New York (1 NYCRR) is amended to read as follows:

(i) [Poultry] *Live poultry* market means any premises where live poultry are assembled and held for sale and slaughter. It does not include livestock auction buildings [regulated pursuant to] *as defined in Part 49 of this title or USDA inspected poultry slaughter plants located outside the City of New York and the counties of Nassau and Westchester.*

(m) [Poultry distributor means any person, firm or corporation which assembles live poultry for subsequent distribution to poultry markets.] *Poultry dealer and poultry transporter shall have the meaning accorded those terms in section 90-b of Article 5 of the Agriculture and Markets Law.*

Subdivisions (a), (b) and (c) of section 45.6 of Title 1 of 1 NYCRR are re-lettered subdivisions (b), (c) and (a), respectively, and amended to read as follows:

§ 45.6 [(c)] (a) No live poultry more than seven days old shall be moved into a live poultry market other than [directly from source flocks] *by a poultry dealer or poultry transporter holding a valid domestic animal health permit and from flocks which meet the requirements of subdivision [(a)] (b) of this section.*

§ 45.6 [(a)] (b) (1) No live poultry more than seven days old may be moved into a live poultry market unless [accompanied by] *the poultry dealer or poultry transporter possesses an approved certificate of veterinary inspection which states that either:*

[(1)] (i) the poultry identified thereon are moving [directly] *through a poultry dealer or poultry transporter from a source flock which is certified by the state or country of origin as an avian influenza monitored source; or*

[(2)] (ii) the poultry identified thereon are moving [directly] *through a poultry dealer or poultry transporter from a source flock in which a random sample of 10 birds were blood-tested negative for avian influenza within 10 days prior to the date of movement, using a test approved by the United States Department of Agriculture.*

(2) *The approved certificate of veterinary inspection required by this subdivision shall remain in the possession of the poultry dealer or poultry transporter moving the poultry directly to a live poultry market and further, the poultry shall be accompanied by an invoice setting forth:*

(i) *the name and address of the poultry dealer or poultry transporter that is moving the poultry;*

(ii) *the name and address of the live poultry market into which the poultry are being moved;*

(iii) *the number and type of poultry being moved;*

(iv) *the avian influenza status of the poultry; and*

(v) *the date of the movement of such poultry into the market.*

§ 45.6 [(b)] (c) No live poultry more than seven days old which [are] *is held on premises where within the previous 12 months there has been a positive avian influenza serology, [or] culture or a trace back to said premises of birds that tested positive for avian influenza [in] within the previous 12 months shall be moved into a live poultry market unless the State Animal Health Official of the state or country of origin certifies that:*

(1) all birds held on the premises at or after the time of the positive serology, [or] culture, *or trace back and prior to the cleaning and disinfection of the premises were removed to slaughter or slaughtered and the premises were thereafter cleaned and disinfected under official supervision and the replacement flock complies with (2) below, or*

(2) tracheal and cloacal swabs were obtained for virus isolation from 150 randomly selected birds in a flock held on such premises or from all of the birds in such flock, whichever is less, and such tests demonstrated that avian influenza was not present, and no bird in such flock exhibited clinical signs of avian influenza in the 45 days preceding the date of sampling. *If the birds so tested are waterfowl, then only cloacal swabs shall be required.* Such samples may be pooled in groups of up to five samples per culture.

§ 45.6 (f)(1) [A poultry distributor may apply for approved poultry wholesaler status by submitting to the commissioner a statement under oath or affirmation in which it agrees to:] *A poultry dealer or poultry transporter who buys or sells poultry to be sold or offered for sale in a live poultry market, or transports poultry to a live poultry market shall:*

(i) properly maintain, under supervision of the State Animal Health Official of the state in which it resides, the approved certificates of veterinary inspection required by this section, together with records of the poultry it receives and the poultry it ships; *and*

(ii) immediately make such records available for inspection and/or immediately provide copies thereof when requested to do so by representatives of the New York State Department of Agriculture and Markets, the United States Department of Agriculture and/or the appropriate State Animal Health Official, *and*

(iii) *accept only poultry meeting the requirements of this section* [.] *and*

(iv) *have a facility that can be routinely cleaned and disinfected on a year round basis to prevent survival of avian disease agents including avian influenza, and*

(v) *possess and utilize a working mechanical crate washer which cleans and disinfects crates between uses on a year round basis, provided such crate washer shall not be located or operated at a live poultry market, auction premises or poultry farming operation and provided further that crates which have been cleaned and disinfected shall not be exposed to or contaminated by crates which have not been cleaned and disinfected; and*

(vi) *use an all-season truck or vehicle wash facility to clean and disinfect trucks or vehicles between uses, provided such all-season truck or vehicle wash facility shall not be located or operated at a live poultry market, auction premises or poultry farming operation; and*

(vii) *compile, maintain and make available for inspection, for a period of two years, records of the dates and times such crates and trucks or vehicles were cleaned and disinfected.*

[Said statement shall be endorsed by the State Animal Health Official of the state in which the distributor resides. If satisfied of the ability and willingness of the poultry distributor to maintain and make such records available, accept only such poultry, and to otherwise comply with the requirements of this section, the commissioner may grant the distributor approved poultry wholesaler status.

(2) Live poultry from a distributor which has been granted approved poultry wholesaler status may move into a poultry market without being accompanied by the approved certificate of veterinary inspection required by subdivision (a) of this section, provided that such certificate has been issued and is in the possession of the distributor at the time of such movement, and further provided, that the poultry are accompanied by an invoice setting forth:

(i) the name and address of the distributor with approved wholesaler status that is moving the poultry;

(ii) the name and address of the market into which the poultry are being moved;

(iii) the type of poultry being moved;

(iv) the avian influenza status of the poultry; and

(v) the date of the movement of such poultry into the market.

(3) The approved wholesaler status of a poultry distributor may be withdrawn if the commissioner concludes there is reason to believe that the distributor has:

(i) moved or attempted to move into a live poultry market poultry infected with, or exposed to, avian influenza;

(ii) failed to comply with the written agreement it executed and submitted to the department; or

(iii) failed to comply with the requirements of this section.]

Text of proposed 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

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 16 of the Agriculture and Markets Law (Law) provides, in part, that the Commissioner shall have the power to execute and carry into effect the laws of the State and the rules of the Department, relative to the production, transportation, storage, marketing and distribution of food.

Section 18 of the 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.

Section 72 of the Law authorizes the Commissioner to adopt and enforce rules and regulations for the control, suppression or eradication of communicable diseases among domestic animals and to prevent the spread of infection and contagion.

Section 72 of the Law also provides that whenever a communicable disease affecting domestic animals shall exist or be brought into this State, the Commissioner shall take measures promptly to suppress the same and to prevent such disease from spreading.

2. Legislative objectives:

The statutory provisions pursuant to which these regulations are adopted are aimed at controlling, preventing and eradicating infectious and communicable diseases affecting domestic animals in the State.

The Department's proposed amendments to Part 45 will further these legislative goals by expanding the Department's avian influenza control program to require a poultry dealer or a poultry transporter holding a valid domestic animal health permit who buys or sells poultry to be sold or offered for sale in a live poultry market, or transports poultry to a live poultry market, to have facilities that can be cleaned and disinfected on a year round basis; to possess and utilize mechanical crate washers to clean and disinfect crates between uses on a year round basis; to use all-season truck or vehicle wash facilities to clean and disinfect trucks or vehicles between uses on a year round basis; and to compile and maintain records of the dates and times that the crates and the trucks or vehicles were cleaned and disinfected. The amendments will also clarify the requirement that the certificate of veterinary inspection shall remain with the DAHP holder (*i.e.* poultry dealer or poultry transporter) and the invoice shall accompany the poultry to the live poultry market.

3. Needs and benefits:

Avian influenza is caused by a virus that can strike susceptible poultry populations and may produce severe morbidity and mortality in a short period of time. It spreads rapidly, within and between flocks, through the movement of infected birds and contaminated fomites. The highly pathogenic virus produces the following signs: bloody nasal discharge, swelling and purple discoloration of the wattles and combs, diarrhea, pinpoint hemorrhages, loss of coordination and lack of energy and appetite.

In the past 20 years, avian influenza has posed a threat and has resulted in millions of dollars in damages to the poultry industry in New York State and other northeastern states. In 1983 and 1984, an avian influenza outbreak in the United States was responsible for the destruction of nearly 17 million birds in Pennsylvania, Maryland, New Jersey and Delaware. The eradication effort cost \$65 million dollars to complete and was responsible for an increase in poultry prices to the consumer of \$349 million dollars.

In December of 1992, avian influenza was diagnosed in a 30,000 bird turkey flock in Pennsylvania. By January of 1993, state officials throughout the northeastern United States were testing live poultry markets for avian influenza. The tests revealed that avian influenza was present in eight markets in New York, five markets in New Jersey and one market in Pennsylvania. The virus was also isolated on farms in Maryland, New Jersey and Pennsylvania as well as a poultry exhibition in Pennsylvania. Although the 1992-1993 avian influenza outbreak did not infect any large commercial flocks, the virus had managed to spread through five states in only two months.

In 1995 and 1996, avian influenza was isolated in flocks supplying poultry markets in the New York City metropolitan area. The costs of clean-up to the state and the owners of the flocks exceeded \$100,000 per flock. In 1997, Pennsylvania diagnosed avian influenza in a supply flock which provides birds to live poultry markets in New York City. Avian influenza was later detected in ten nearby commercial operations, the clean-up of which consisted of slaughtering over one million birds at a cost of \$5 million dollars.

In 1998, live poultry from all of the 78 live poultry markets in the New York City metropolitan area were tested for avian influenza. The virus was found in birds from 54, or 69%, of those markets. The prevalence of the virus in the live poultry markets prompted the adoption, on an emergency basis, of regulations which immediately prohibited the movement of poultry from infected flocks to the live poultry markets, by requiring that only birds from tested or monitored source flocks be allowed into the markets. Those regulations were subsequently adopted on a permanent basis. It was hoped that the new regulations would prevent the continued reintroduction of the virus. However, these control measures have not been entirely successful.

In June and July 2001, the United States Department of Agriculture (USDA) conducted a survey of live poultry markets. The survey revealed

that approximately 60 percent of the markets contained the avian influenza virus. In December 2001 and January 2002, an outbreak of avian influenza in six poultry flocks in Pennsylvania resulted in the destruction of 135,000 birds.

The continuing prevalence of avian influenza in the live poultry markets and the outbreak of the virus in the flocks in Pennsylvania prompted the Department, on January 24, 2002, to adopt, on an emergency basis, a regulation which provided that no live poultry shall be moved anywhere from a poultry market in the City of New York or in the Counties of Nassau and Westchester, unless specifically authorized by the Commissioner or his designee. This regulation was subsequently amended on an emergency basis to prohibit the movement of poultry from any poultry market, rather than just those markets in the City of New York and the Counties of Nassau and Westchester. This regulation, as amended, was ultimately adopted on a permanent basis in an effort to help limit the lateral transmission of avian influenza between the markets. However, this control measure has not been entirely successful, since as of December 2003, approximately 18 percent of the live poultry markets tested positive for the virus.

In the past two years, outbreaks of avian influenza in the United States have resulted in the destruction of approximately 5 million birds. In February 2004, outbreaks of avian influenza in Delaware, Maryland and a broiler flock in Texas resulted in the destruction of 436,600 birds on the farms as well as the depopulation, cleaning and disinfection of the nine live poultry markets in New York City which had received birds from those farms. In response to these latest outbreaks, 35 countries have placed embargoes on poultry and poultry products in the United States, 16 of which are nationwide embargoes that include New York State.

Adequate sanitation practices are key components in the control and eradication of avian influenza. This is evident based upon the results of a cooperative program, implemented in April 2002 by the Department and the USDA, whereby the 80 live poultry markets in the New York City metropolitan area were required to close their premises, depopulate their poultry stock and clean and disinfect their premises prior to reopening. At the same time, five poultry distributors in New York voluntarily closed, depopulated their poultry stock and cleaned and disinfected their premises. The closures took place between April 8 and April 10, 2002, during which time, environmental samples were taken from each market and distributor following the cleaning and disinfection process. These environmental samples were subsequently analyzed and found to be negative for avian influenza.

Part 45 of 1 NYCRR currently requires the cleaning and disinfection of any truck, coop, cage, crate or other conveyance for the purpose of removing, delivering or transporting live poultry prior to entering New York State and prior to entering any farm in New York State. Part 45 also requires all persons entering any premises containing live poultry within New York State with any poultry truck, feed delivery and/or service vehicle to take every sanitary precaution possible to prevent the introduction or spread of avian influenza, including the disinfection of all footwear before entering and after leaving any premises containing live poultry and the washing and disinfecting of the cabs, tires and bodies of all vehicles between each entry of a premises containing live poultry.

The Department's proposed amendments to Part 45 will expand and strengthen the Department's avian influenza control program by requiring a poultry dealer or a poultry transporter holding a valid domestic animal health permit who buys or sells poultry to be sold or offered for sale in a live poultry market, or transports poultry to a live poultry market, to have facilities that can be cleaned and disinfected on a year round basis; to possess and utilize mechanical crate washers to clean and disinfect crates between uses on a year round basis; to use all-season truck or vehicle wash facilities to clean and disinfect trucks or vehicles between uses on a year round basis; and to compile and maintain records of the dates and times that the crates and the trucks or vehicles were cleaned and disinfected. The amendments will also clarify the requirement that the certificate of veterinary inspection shall remain with the DAHP holder (*i.e.* poultry dealer or poultry transporter) and the invoice shall accompany the poultry to the live poultry market.

In conclusion, the Department believes that the amendments are essential disease control measures, since they will limit the transmission of avian influenza to live poultry markets from poultry dealers and poultry transporters.

4. Costs:

(a) Costs to regulated parties:

Under the proposed amendments, poultry dealers and poultry transporters holding a valid domestic animal health permit who buy or sell poultry

to be sold or offered for sale in a live poultry market, or transport poultry to a live poultry market, will have to purchase equipment to clean and disinfect crates between uses. Commercial devices capable of cleaning and disinfecting 400 crates per hour may be purchased new at a cost of \$50,000 or purchased used at auction for approximately \$12,000. Delivery and installation of either a new or used crate washer would cost between \$10,000 and \$12,000. However, based upon outreach with industry, the Department has determined that five (5) of the eight (8) poultry dealers and/or poultry transporters in New York State already have crate washers on their premises. Poultry dealers and poultry transporters would also have to use an all-season truck or vehicle wash facility in order to clean and disinfect trucks or vehicles between uses. Based upon outreach with industry, the Department has determined that three (3) of the eight (8) poultry dealers and/or poultry transporters in New York State already have on-site truck wash facilities. In lieu of establishing truck wash facilities, poultry dealers and poultry transporters would be able to comply with the amendments by using a commercial truck wash facility. Such facilities capable of cleaning and disinfecting trucks as large as 18-wheel rigs charge \$100 to \$400 per washing.

(b) Costs to the agency, state and local governments:

None.

(c) Source:

Costs are based upon observations of business practices in the industry as well as outreach with regulated parties.

5. Local government mandates:

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

6. Paperwork:

Under the proposed amendments, poultry dealers and poultry transporters holding a valid domestic animal health permit who buy or sell poultry to be sold or offered for sale in a live poultry market, or transport poultry to a live poultry market, will be required to compile, maintain and make available for inspection, for a period of two years, records of the dates and times that crates and trucks or vehicles were cleaned and disinfected. Such poultry dealers and poultry transporters would also be required to retain the certificate of veterinary inspection for the poultry they buy, sell or transport to a live poultry market.

7. Duplication:

None.

8. Alternatives:

The first alternative considered was not to amend the regulations. This alternative was rejected due to the fact that the present regulations do not adequately protect New York State's live poultry markets from avian influenza. The prevalence of the virus in approximately 18% of the live poultry markets in the New York City metropolitan area shows that current control measures are not sufficient. In light of the prevalence of virus in the markets and the recent outbreaks of avian influenza in Delaware and Texas, the Department believes that the proposed amendments are essential disease control measures, since they would limit the transmission of avian influenza from poultry dealers and poultry transporters to the live poultry markets.

The second alternative considered was to require poultry dealers and poultry transporters to establish and maintain a truck wash facility to clean and disinfect trucks and other vehicles used to carry poultry between uses. However, due to the availability of commercial truck wash facilities in New York State, this alternative was rejected as an excessive financial burden on regulated parties.

9. Federal standards:

The federal government has standards regarding the types and methods of testing poultry for the presence of avian influenza. The Department recognizes these as official tests for the detection of this virus. However, the federal government has no standards relative to sanitation requirements for a poultry dealer or a poultry transporter holding a valid domestic animal health permit who buys or sells poultry to be sold or offered for sale in a live poultry market, or transports poultry to a live poultry market.

10. Compliance schedule:

Immediate compliance by the industry is expected.

Regulatory Flexibility Analysis

1. Effect of rule:

There are eight (8) poultry dealers and/or poultry transporters in New York State, all of which are small businesses. There are also 38 poultry dealers and/or poultry transporters in other states and Canada.

The proposed amendments will have no impact upon local governments.

2. Compliance requirements:

Under the proposal, poultry dealers and poultry transporters holding a valid domestic animal health permit who buy or sell poultry to be sold or offered for sale in a live poultry market, or transport poultry to a live poultry market, will be required to compile, maintain and make available for inspection, for a period of two years, records of the dates and times that crates and trucks or vehicles were cleaned and disinfected. Such poultry dealers and poultry transporters will also be required to retain the certificate of veterinary inspection for the poultry they buy, sell or transport to a live poultry market.

The proposed amendments will have no impact upon local governments.

3. Professional services:

None.

4. Compliance costs:

Under the proposed amendments, poultry dealers and poultry transporters holding a valid domestic animal health permit who buy or sell poultry to be sold or offered for sale in a live poultry market, or transport poultry to a live poultry market, will have to purchase equipment to clean and disinfect crates between uses. Commercial devices capable of cleaning and disinfecting 400 crates per hour may be purchased new at a cost of \$50,000 or purchased used at auction for approximately \$12,000. Delivery and installation of either a new or used crate washer would cost between \$10,000 and \$12,000. However, based upon outreach with industry, the Department has determined that five (5) of the eight (8) poultry dealers and/or poultry transporters in New York State already have crate washers on their premises. Poultry dealers and poultry transporters will also have to use an all-season truck or vehicle wash facility in order to clean and disinfect trucks or vehicles between uses. Based upon outreach with industry, the Department has determined that three (3) of the eight (8) poultry dealers and/or poultry transporters in New York State already have on-site truck wash facilities. In lieu of establishing truck wash facilities, poultry dealers and poultry transporters would be able to comply with the amendments by using a commercial truck wash facility. Such facilities capable of cleaning and disinfecting trucks as large as 18-wheel rigs charge \$100 to \$400 per washing.

5. Economic and technological feasibility:

The proposed economic and technological feasibility of complying with the amendments has been assessed.

The proposed amendments are economically and technologically feasible. The Department has determined that a number of poultry dealers and/or poultry transporters in New York State already have crate washers and on-site truck wash facilities. In lieu of establishing truck wash facilities, poultry dealers and poultry transporters will be able to comply with the proposed amendments by using a commercial truck wash facility.

The proposed amendments will have no impact upon local governments.

6. Minimizing adverse impact:

In conformance with State Administrative Procedure Act section 202-b(1), the amendments were drafted to minimize economic impact and reporting requirements for all regulated parties, including small businesses.

The Department has previously implemented less burdensome measures on regulated parties in an effort to help prevent the spread of avian influenza through the live poultry markets. Those measures include the requirement that only birds from tested or monitored source flocks be allowed into the markets and the prohibition against moving poultry between live poultry markets. Unfortunately, these measures have not been entirely successful, as evidenced by the prevalence of the virus in the markets.

The proposed amendments would expand and strengthen the Department's avian influenza control program by requiring poultry dealers and poultry transporters holding a valid domestic animal health permit who buy or sell poultry to be sold or offered for sale in a live poultry market, or transport poultry to a live poultry market, to have facilities that can be cleaned and disinfected on a year round basis; to possess and utilize crate washers to clean and disinfect crates between uses on a year round basis; to use all-season truck or vehicle wash facilities to clean and disinfect trucks or vehicles between uses on a year round basis; and to compile and maintain records of the dates and times that the crates and the trucks or vehicles were cleaned and disinfected. Although the amendments will result in a greater regulatory burden on regulated parties, the Department has nonetheless minimized adverse impact on them by allowing regulated parties to use commercial truck wash facilities rather than establishing and maintaining their own facilities.

The proposed amendments would have no impact upon local governments.

7. Small business and local government participation:

In light of the continued prevalence of avian influenza in the live poultry markets in New York and the recent outbreaks of the virus in poultry flocks in Delaware and Texas, the Department has been in contact with regulated parties, including small businesses, in an effort to determine how to strengthen the avian influenza control program. The need for adequate sanitation of crates housing poultry as well as of trucks or other vehicles transporting poultry was addressed.

Since the proposal will have no impact on local governments, there has been no outreach with local governments.

Rural Area Flexibility Analysis

1. Types and estimated number of rural areas:

There are eight (8) poultry dealers and/or poultry transporters in New York State, a number of which are located in rural areas.

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

Under the proposal, poultry dealers and poultry transporters holding a valid domestic animal health permit who buy or sell poultry to be sold or offered for sale in a live poultry market, or transport poultry to a live poultry market, will be required to compile, maintain and make available for inspection, for a period of two years, records of the dates and times that crates and trucks or vehicles were cleaned and disinfected. Such poultry dealers and poultry transporters will also be required to retain the certificate of veterinary inspection for the poultry they buy, sell or transport to a live poultry market.

3. Costs:

Under the proposed amendments, poultry dealers and poultry transporters holding a valid domestic animal health permit who buy or sell poultry to be sold or offered for sale in a live poultry market, or transport poultry to a live poultry market, including those located in rural areas, will have to purchase equipment to clean and disinfect crates between uses. Commercial devices capable of cleaning and disinfecting 400 crates per hour may be purchased new at a cost of \$50,000 or purchased used at auction for approximately \$12,000. Delivery and installation of either a new or used crate washer would cost between \$10,000 and \$12,000. However, based upon outreach with industry, the Department has determined that five (5) of the eight (8) poultry dealers and/or poultry transporters in New York State already have crate washers on their premises. Poultry dealers and poultry transporters, including those in rural areas, will also have to use an all-season truck or vehicle wash facility in order to clean and disinfect trucks or vehicles between uses. Based upon outreach with industry, the Department has determined that three (3) of the eight (8) poultry dealers and/or poultry transporters in New York State already have on-site truck wash facilities. In lieu of establishing truck wash facilities, poultry dealers and poultry transporters will be able to comply with the amendments by using a commercial truck wash facility. Such facilities capable of cleaning and disinfecting trucks as large as 18-wheel rigs charge \$100 to \$400 per washing.

4. Minimizing adverse impact:

In conformance with State Administrative Procedure Act section 202-bb(2), the amendments were drafted to minimize reporting and testing requirements for all regulated parties, including those in rural areas.

The Department has previously implemented less burdensome measures on regulated parties in an effort to help prevent the spread of avian influenza through the live poultry markets. Those measures include the requirement that only birds from tested or monitored source flocks be allowed into the markets and the prohibition against moving poultry between live poultry markets. Unfortunately, these measures have not been entirely successful, as evidenced by the prevalence of the virus in the markets.

The proposed amendments will expand and strengthen the Department's avian influenza control program by requiring poultry dealers and poultry transporters holding a valid domestic animal health permit who buy or sell poultry to be sold or offered for sale in a live poultry market, or transport poultry to a live poultry market, to have facilities that can be cleaned and disinfected on a year round basis; to possess and utilize crate washers to clean and disinfect crates between uses on a year round basis; to use all-season truck or vehicle wash facilities to clean and disinfect trucks or vehicles between uses on a year round basis; and to compile and maintain records of the dates and times that the crates and the trucks or vehicles were cleaned and disinfected. Although the amendments will result in a greater regulatory burden on regulated parties, the Department has nonetheless minimized adverse impact on them by allowing poultry

dealers and poultry transporters to use commercial truck wash facilities rather than establishing and maintaining their own facilities.

5. Rural area participation:

In light of the continued prevalence of avian influenza in the live poultry markets in New York and the recent outbreaks of the virus in poultry flocks in Delaware and Texas, the Department has been in contact with regulated parties, including those in rural areas, in an effort to determine how to strengthen the avian influenza control program. The need for adequate sanitation of crates housing poultry as well as of trucks or other vehicles transporting poultry was addressed.

Job Impact Statement

The proposed amendments will expand the Department's avian influenza control program by requiring poultry dealers and poultry transporters holding a valid domestic animal health permit who buy or sell poultry to be sold or offered for sale in a live poultry market, or transport poultry to a live poultry market, to have facilities that can be cleaned and disinfected on a year round basis; to possess and utilize crate washers to clean and disinfect crates between uses on a year round basis; to use all-season truck or vehicle wash facilities to clean and disinfect trucks or vehicles between uses on a year round basis; and to compile and maintain records of the dates and times that the crates and the trucks or vehicles were cleaned and disinfected. The amendments will also clarify the requirement that the certificate of veterinary inspection shall remain with the DAHP holder (*i.e.* poultry dealer or poultry transporter) and the invoice shall accompany the poultry to the live poultry market.

The proposed amendments will have no detrimental impact on jobs and employment opportunities in New York State but rather, are the most favorable alternative to retaining jobs in New York State. If nothing is done about controlling the spread of avian influenza to live poultry markets from poultry dealers and poultry transporters, it is possible that outbreaks of the disease will continue. The recent outbreak of avian influenza in poultry flocks in Delaware and Texas have prompted 35 countries to place embargoes on poultry and poultry products from those two states. However, of those 35 embargoes, 16 of them are nationwide in scope and as such, include poultry imports from New York as well as the rest of the United States. If this and other foreign embargoes of poultry products were to continue, it is possible that poultry markets would have to close to protect the poultry industry in the northeast United States. If this scenario were to occur, it is estimated that approximately 750-1,000 jobs in live poultry markets would be lost. It is also estimated that 750 to 1,000 jobs provided by poultry dealers and poultry transporters would be lost, since they would have no markets for their birds.

Banking Department

NOTICE OF ADOPTION

Change of Individual Designated to Receive Process

I.D. No. BNK-35-04-00003-A
Filing No. 1229
Filing date: Oct. 29, 2004
Effective date: Nov. 17, 2004

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

Action taken: Amendment of Supervisory Procedure FB 105 of Title 3 NYCRR.

Statutory authority: Banking Law, section 200

Subject: Procedure for a foreign banking corporation for a change of manager, representative or individual designated to receive process.

Purpose: To eliminate the current requirement that a litigation affidavit and resume must be submitted when a foreign banking corporation changes the individual designated to receive process, and add the position of deputy manager to the title of FB 105 to make it consistent with positions mentioned in the regulation itself.

Text or summary was published in the notice of proposed rule making, I.D. No. BNK-35-04-00003-P, Issue of September 1, 2004.

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., 6th Fl., New York, NY 10004-1417, (212) 709-1658, e-mail: sam.abram@banking.state.ny.us

Assessment of Public Comment

The agency received no public comment.

NOTICE OF ADOPTION

Public Access of Banking Department Records Under the Freedom of Information Law

I.D. No. BNK-35-04-00012-A
Filing No. 1228
Filing date: Oct. 29, 2004
Effective date: Nov. 17, 2004

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

Action taken: Repeal of Supervisory Procedure G 106 and adoption of new Supervisory Procedure G 106 to Title 3 NYCRR.

Statutory authority: Public Officers Law, section 87, *et seq.* (Freedom of Information Law)

Subject: Public access of Banking Department records under the Freedom of Information Law.

Purpose: To more closely follow the Freedom of Information Law and outline and provide clarity with respect to the department's FOIL procedures for public access to records.

Text or summary was published in the notice of proposed rule making, I.D. No. BNK-35-04-00012-P, Issue of September 1, 2004.

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., 6th Fl., New York, NY 10004-1417, (212) 709-1658, e-mail: sam.abram@banking.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-46-04-00005-E
Filing No. 1230
Filing date: Oct. 29, 2004
Effective date: Oct. 29, 2004

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's economy. The rule is necessary because section 7(c) of the chapter 60 of the Laws of 2004 mandate 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 applications and any other provisions deemed necessary and appropriate; and clarify necessary definitions pertinent 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 26, 2005.

Text of emergency rule and any required statements and analyses may be obtained from: Thomas P. Regan, Department of Economic Development, Counsels 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 emergency 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 emergency 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 emergency rule making. First, the emergency 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 emergency 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 emergency 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 emergency 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 emergency 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 emergency regulation as soon as it is implemented. In terms of compliance schedule, the statute (Chapter 60 of the laws of 12004) 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's 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.

Department of Health

EMERGENCY RULE MAKING

Serialized Official New York State Prescription Form

I.D. No. HLT-46-04-00002-E
Filing No. 1226
Filing date: Oct. 28, 2004
Effective date: Oct. 28, 2004

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

Action taken: Addition of Part 910; amendment of sections 85.21, 85.22, 85.23 and 85.25 of Title 10 NYCRR; 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 forge 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: Serialized official New York State prescription form.

Purpose: To combat and prevent prescription fraud.

Summary of emergency rule:

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 and the 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.

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 25, 2004.

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

Regulatory Impact Statement

Statutory Authority:

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 recordkeeping 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.

Minimize 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.

Minimize 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

Expansion of the New York State Newborn Screening Panel

I.D. No. HLT-46-04-00003-E

Filing No. 1227

Filing date: Oct. 28, 2004

Effective date: Oct. 28, 2004

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

Action taken: Amendment of sections 69-1.2 and 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 20 conditions — 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 rule making would be contrary to the public interest, and welfare.

Proposed addition of 20 new conditions would more than double 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 detecting infants with any one of 58 serious but treatable neonatal conditions. Immediate implementation of the proposed expanded panel, which may be accomplished with minimal to no additional costs, is both feasible and obligatory, since the necessary personnel and technology are already in place under the previous screening panel expansion, and a system for follow-up and assurance of access to necessary treatment for identified infants is fully established. This proposed expansion will allow the Department to take advantage of the multiplex capabilities of the tandem mass spectrometry (MS/MS) instrumentation already in operation in the Program and now used to screen for MCADD. 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. While it was not practicable to implement additional MS/MS testing prior to this time, now that the Program is technically proficient in MS/MS testing and experienced in spectrometric data collection and interpretation, failure to begin to do so immediately would mean infants would go untested, undetected, and may thus suffer irreversible medical harm and even death. Although individually each of the 20 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 20 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 Section 69-1.2 is hereby adopted by emergency promulgation.

Subject: Expansion of the New York State Newborn Screening Panel.

Purpose: To add 20 disorders to the panel.

Text of emergency rule: 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 shall include: phenylketonuria [,](*PKU*); branched-chain ketonuria, *also known as maple syrup urine disease (MSUD)*; homocystinuria[,]; galactosemia[,]; *hemoglobinopathies, including homozygous sickle cell disease*[,]; hypothyroidism[,]; biotinidase deficiency[,]; human immunodeficiency virus (HIV) exposure and

infection[,]; cystic fibrosis [,](*CF*); congenital adrenal hyperplasia [, and](*CAH*); medium-chain acyl-CoA dehydrogenase deficiency (MCADD); *argininosuccinic acidemia (ASA)*; *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)*; *glutaric acidemia type I (GA-I)*; *3-hydroxy-3-methylglutaryl-CoA lyase deficiency (HMG)*; *isovaleric acidemia (IVA)*; *long-chain 3-hydroxy acyl-CoA dehydrogenase deficiency (LCHADD)*; *3-methylcrotonyl-CoA carboxylase deficiency (3-MCC)*; *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)*; *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.

* * *

(b) [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] *biohazardous specimens shall be forwarded 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 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 25, 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: regsqa@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 or under of age 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 20 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 20 inherited metabolic disorders to the scope of newborn screening services already provided by the Department. They are: argininosuccinic acidemia (ASA); 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); glutaric acidemia type I (GA-I); 3-hydroxy-3-methylglutaryl-CoA

lyase deficiency (HMG); isovaleric acidemia (IVA); long-chain 3-hydroxyacyl-CoA dehydrogenase deficiency (LCHADD); 3-methylcrotonyl-CoA carboxylase deficiency (3-MCC); methylmalonyl CoA mutase deficiency (MUT); mitochondrial trifunctional protein deficiency (TFP); mitochondrial acetoacetyl-CoA thiolase deficiency (BKT); multiple acyl-CoA dehydrogenase deficiency (MADD, also known as GA-II); multiple carboxylase deficiency (MCD); propionic acidemia (PA); short-chain acyl-CoA dehydrogenase deficiency (SCADD); tyrosinemia (TYR); and very long-chain acyl-CoA dehydrogenase deficiency (VLCADD). 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.

The 20 conditions — all inborn errors of metabolism — can be grouped according to the resulting abnormality: organic acidemias; fatty acid oxidation disorders; and amino acid disorders. 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 it 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 a separate disorder, would translate into the Newborn Screening Program's detection of a total of more than 58 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 to each condition in existing regulation for which an acronym is commonly used (e.g., PKU for phenylketonuria). Such a linkage will facilitate recognition by primary care physicians and laypersons, most of whom are unfamiliar with the full, complex scientific names for 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 specimens with a protective flap that is preprinted with the universal biohazard symbol. Therefore, the existing requirement for enclosing the specimen in a transparent plastic bag and labeling the package by hand is no longer necessary.

Costs:

Costs to Private Regulated Parties:

Regulated parties (*i.e.*, 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, 1,500 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 numbers were developed from studies conducted by the Department on 4,200 residual newborn specimens stripped of all identifiers after completion of mandatory screening. The studies used a preliminary value for the cutoff point (marker level) for considering a specimen positive, a value that intentionally maximizes the number of presumptive positives. It is reasonable to expect that the cutoff point would be adjusted to capture a reduced number of false positives as the Program gains experience testing and verifies clinical outcomes.

Approximately 350 of the 1,500 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 1,150 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 expects that, on average, each of the seven metabolic centers would experience referral of an additional two 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 a repeat specimen and for ensuring referral of infants. Such costs would be limited to human resources costs of approximately 1.0 person-hour for communicating the need, and/or arranging for collection of a second specimen and its forwarding to the Department. On average, each birthing facility can expect to handle 3.5 additional infants in need of referral to a metabolic center per year as a result of screening tests that would be conducted pursuant to this proposal. This increase is expected to have little effect on the facility's workload since the current annual number of infants in need of referral at all facilities ranges from 350 to 500; therefore, no additional staff would be required at these institutions. 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 six screen-positive infants per 1,000 births; and a referral rate of two infants per 1,000 births.

Facilities and practitioners receiving referrals would incur human resources costs 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 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, using clinical assessment and laboratory tests.

Regulated parties will incur additional human resources costs, attributable to two to five person-hours and estimated at \$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 20 new metabolic conditions will require laboratory tests and comprehensive-level office visits at metabolic centers to determine final diagnosis. The cost of these services is estimated to be in the range of \$261,000 to \$754,000 annually, using the prevailing rate of \$300 for a comprehensive-level office visit, and, for the various laboratory tests that may be required, laboratory charges ranging from \$150 to \$1,000. The number and kind of laboratory tests, and therefore costs for testing, will vary greatly, depending on the type of metabolic disorder, the specific condition being investigated 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 was 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 healthcare 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 early 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 affected individuals 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. The Department will bolster staffing in the follow-up unit to handle the increased number of screen-positive results and interface with medical practitioners and facilities, by reprioritizing resources and redeploying and filling four positions with an annual value of \$169,000.

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 or under of age 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 newborns' specimens will sustain minimal to no increase 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 Department will continue to work with the Newborn Screening Task Force and affected parties toward optimal coordinated notification and implementation of the newborn test panel expansion. Program representatives and other senior Department staff met with the directors of affected metabolic centers on September 17, 2004; the agenda included ensuring that the centers have been properly identified and are appropriately certified. The Department anticipates that the Commissioner of Health will send a letter to all New York State-licensed physicians informing them of the newborn panel expansion. The letter will 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 20 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 or under of age, 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 will be referred to the facility physician already designated to receive positive screening results for MCADD and PKU.

Compliance Costs:

Birthing 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 follow-up of infants screening positive for one or more of the 20 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 results. 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, using 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 early 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:

This amendment is being proposed as an emergency rule, and ensuring notification of its provisions and requirements in accordance with the SAPA process to affected parties that are either small businesses or local governments would cause unnecessary and potentially detrimental delay in full implementation of the expanded screening profile proposed by this regulation. Notification will take place immediately preceding and concurrent with state-wide implementation of the expanded newborn screening panel, which is expected in November 2004.

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 persons or fewer 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 20 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 or under of age, 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 operate 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 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 20 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:

Birthing 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, using 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 avoided complications to offset treatment costs. Early diagnosis and early 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 the added 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 enhancements to present collection, reporting, follow-up and record-keeping practices.

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 20 conditions — 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.

NOTICE OF ADOPTION

Approval of Laboratories Performing Environmental Analysis

I.D. No. HLT-12-04-00015-A

Filing No. 1225

Filing date: Oct. 28, 2004

Effective date: Nov. 17, 2004

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

Action taken: Amendment of Subpart 55-2 of Title 10 NYCRR.

Statutory authority: Public Health Law, section 502

Subject: Approval of laboratories performing laboratory analysis.

Purpose: To standardize terminology, address new technology and practices; lessen the regulatory burden on environmental laboratories that conduct business in more than one state, codify criteria for method approval, clarify criteria for compliance and enforcement activities.

Text or summary was published in the notice of proposed rule making, I.D. No. HLT-12-04-00015-P, Issue of March 24, 2004.

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

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

Assessment of Public Comment

A Notice of Proposed Rule making for a comprehensive amendment to 10 NYCRR Subpart 55-2, including a summary of the proposed rule, was published in the *State Register* on March 24, 2004 for a 60-day comment period, with notice that the complete text was available from the Department's Office of Regulatory Reform. Prior to its publication in the *State Register*, more than 500 copies of the proposed Subpart 55-2 amendment were distributed to environmental laboratories holding New York State certificates of approval, as well as professional associations and trade

organizations representing the laboratory industry, and other affected parties. Two letters of formal comment were received in response. No substantive revisions to the published regulations are needed as a result of the comments.

One commentator suggested the proposed amendments should clarify ongoing issues regarding the applicability of Public Health Law section 502 (2) to environmental examinations conducted in other-than-traditional laboratory settings, *i.e.*, mobile or field testing. Public Health Law section 502 defines "environmental laboratory" as "any facility that examines or is available for the examination of samples or specimens including, but not limited to: air, stack emissions, wastewater, surface water, ground water, recreational waters, swimming pools, leachate, land runoff, solid waste, hazardous waste, soil, sediments and vegetation, as well as any substance that could contribute to the pollution of or that could be contaminated by material contained in such samples or specimens." The statute does not distinguish amongst fixed, mobile or portable field-testing laboratory facilities, and consequently, the Department has made no such distinction in its regulations. Additionally, it is unlikely the legislature would have intended to exempt some tests from regulatory oversight solely because a person or entity chose to perform the test in a non-fixed location. Furthermore, since Environmental Conservation Law section 3-0119 requires all testing performed pursuant to article seventeen, nineteen or twenty-seven of that chapter to be conducted in laboratories which have been issued a certificate of approval by the Commissioner of Health, the issuance of certificates of approval for mobile and field testing ensures that governmental and proprietary entities are not required to use fixed testing locations unnecessarily when tests may be performed properly in mobile or field testing facilities.

The commentator also sought clarification on how broadly a "certificate of approval" would be interpreted since laboratories are only required to obtain certificates of approval "for which the commissioner issues a certificate of approval for such examination." The proposed regulations address this issue in section 55-2.2(b). That section provides that certificate of approvals shall set forth the approved categories and analytes. Thus, if the commissioner issues a certificate of approval for an analyte such as "lead in potable water," laboratories testing for lead in potable water must have a certificate of approval to test for that analyte. As specified in section 55-2.2(c), testing performed in approved laboratories must also employ "approved methods." Pursuant to Public Health Law section 502, the Department may also impose conditions under which specific approvals are granted, which may include confirmatory testing when appropriate for the intended use(s) of the test results.

The commentator also questioned whether every sample collected must be tested via ELAP approved procedures. Public Health Law section 502 provides that examinations "shall be limited to the qualitative or quantitative determinations of the biological, chemical, radiochemical or physical characteristics of such samples or specimens for the purpose of public or personal health protection or the protection of the environment or natural resources." (emphasis supplied) Consequently, ELAP approved procedures must be used any time testing is being performed to protect the public health, the health of an individual, the environment, or natural resources. Testing for other purposes, such as for research or interim assessments during an environmental clean-up, are not required to be done in an approved facility via approved methods unless otherwise required by statute, regulation, contract or other applicable standards. The statute also exempts testing of residential water softeners and residential swimming pools.

The second commentator found the renumbering of the regulation's sections confusing when read in light of the recent emergency adoption of another regulation that added a new section 55-2.13 establishing critical agent testing standards. The emergency rule specifically reserved section 55-2.12 in anticipation of the amendments contained in this regulation which include renumbering existing section 52-2.11 as section 52-2.12. Hence, renumbered section 55-2.12 of this amendment will replace the section reserved earlier in the critical agent testing rule. Once both rules are adopted, they will be fully integrated and should eliminate any confusion caused by the simultaneous promulgation.

The same commentator felt that the incorporation by reference of the Department's Quality Systems Standards is incomplete because it states that the document is available only through the Department's Office of Regulatory Reform. The regulation sets forth one location where the incorporated document can be obtained, does not use the term "only," and is not intended to be exclusive. The Department plans to comply fully with the Executive Law requirements for publications referenced in regulation by also delivering copies to the Department of State, the State Legislative Library and designated State Supreme Court law libraries.

The commenter suggested that the comma following the word “chemical” in the section 55-2.1(g) definition of “analyte” is unnecessary and confusing. The Department agrees with this recommendation since “chemical” and “physical” are both intended to modify the term “property.” Consequently, the Department has made this non-substantive change in the regulation.

The commenter also recommended that the provision in section 55-2.2(b)(3) for listing a director on the certificate of approval be modified to read “technical director or lead technical director.” Although the Department agrees that designation of a lead technical director is required only when there are multiple directors, the suggested wording could be misconstrued as requiring all technical directors of a laboratory to be listed on the certificate, which is not the intent of the provision. Furthermore, whenever there is only one director, it is implicit that the sole director would be the lead technical director whose name should appear on the certificate of approval. Consequently, the Department has not incorporated the suggested change into the regulation.

The same commenter suggested section 55-2.2(c), which requires laboratories to employ only approved methods, be amended to clarify that the requirement only applies to tests “for which the commissioner issues a certificate of approval.” Since the statute itself makes it clear that the requirement for a certificate of approval only applies to tests “for which the commissioner issues a certificate of approval for such examination,” further clarification is unnecessary.

The commenter also expressed concern that the regulation’s provisions permitting the issuance of interim certificates of approval are at odds with the 1992 amendments to PHL section 502. Prior to the 1992 amendments, PHL section 502 obligated the Department to issue interim certificates within thirty days “to all laboratories which provide documentation in their application that they are capable of performing quality work in the category, procedure or specialty under review.” The 1992 amendments limited the Department’s obligation to issue certificates solely based upon a paper review to applications received from laboratories in existence prior to April first, nineteen ninety-three. The memoranda in support of the 1992 amendments reinforces this point by stating that the statute is being amended “to limit the required issuance of interim certificates, based upon evaluation of documentation only, to laboratories existing on or before April 1, 1993.” (emphasis supplied) Consequently, the statute does not prohibit the Department from making determinations concerning the issuance of interim certificates of approval based upon other criteria. The proposed regulation establishes such criteria, which include demonstration of satisfactory performance on proficiency testing in addition to submission of documentation that the owners and directors have the character and competence to provide high quality laboratory services and operate the laboratory in accordance with applicable statutory and regulatory requirements. The Department could also determine that an on-site inspection is necessary prior to the issuance of an interim certificate when the documentation submitted does not support a determination that the laboratory will provide high quality laboratory services and comply with applicable standards.

The commenter also suggested Section 55-2.6(f) be modified to require an on-site assessment of any laboratory that reapplies for certification after its certificate of approval is revoked. Although the Department anticipates that few laboratories would be considered for reapplication following revocation without an on-site inspection, when revocation has been based solely on administrative issues, such as the non-payment of the annual approval fee, an on-site inspection may not be necessary. Consequently, the Department prefers to retain the discretion permitted by the word “may” to enable it to consider whether an on-site assessment is warranted on a case-by-case basis.

NOTICE OF ADOPTION

Animals in Health Care Facilities

I.D. No. HLT-26-04-00003-A

Filing No. 1236

Filing date: Nov. 2, 2004

Effective date: Nov. 17, 2004

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

Action taken: Amendment of sections 405.24 and 415.29 of Title 10 NYCRR.

Statutory authority: Public Health Law, sections 2803 and 2803-h

Subject: Animals in health care facilities.

Purpose: To bring current standards for accessing service animals into compliance with the American with Disabilities Act and update additional standards for animals, consistent with law.

Text or summary was published in the notice of proposed rule making, I.D. No. HLT-26-04-00003-P, Issue of June 30, 2004.

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

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

Assessment of Public Comment

Comment

The Department received one comment. It came from the New York State Office of Advocate for Persons with Disabilities and was in enthusiastic support of the proposed changes. It noted that the amendments not only reflect changes necessitated by the Americans with Disabilities Act of 1990, but that it also strikes a reasonable balance concerning the health needs of patients and staff while protecting the rights of individuals who use service animals while in health care facilities.

NOTICE OF ADOPTION

DRGs, SIWs, Trimpoints and Arithmetic Mean LOS

I.D. No. HLT-31-04-00013-A

Filing No. 1235

Filing date: Nov. 2, 2004

Effective date: Nov. 17, 2004

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

Action taken: Amendment of sections 86-1.62 and 86-1.63 of Title 10 NYCRR.

Statutory authority: Public Health Law, section 2807-c(3)

Subject: DRGs, SIWs, trimpoints and arithmetic mean LOS used to determine case based payments.

Purpose: To modify the DRG listing, SIWs, trimpoints and arithmetic mean LOS.

Text or summary was published in the notice of proposed rule making, I.D. No. HLT-31-04-00013-P, Issue of August 4, 2004.

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

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

Assessment of Public Comment

The agency received no public comment.

NOTICE OF CONTINUATION NO HEARING(S) SCHEDULED

Perinatal Regionalization

I.D. No. HLT-21-04-00011-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-21-04-00011-P was published in the *State Register* on May 26, 2004.

Subject: Perinatal regionalization.

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

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

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

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

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

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

Changes to rule: No substantive changes.

Expiration date: May 26, 2005.

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.

Department of Labor

PROPOSED RULE MAKING NO HEARING(S) SCHEDULED

License, Registration, Inspection and Filing Fees of the Division of Safety and Health

I.D. No. LAB-46-04-00001-P

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

Proposed action: Amendment of Part 82 of Title 12 NYCRR.

Statutory authority: Labor Law, sections 21.11, 28.2b, 204-a, 458; and General Business Law, section 483

Subject: License, registration, inspection and filing fees of the Division of Safety and Health.

Purpose: To increase several fee categories to ensure efficient administration, on-site inspections and issuance of certificates and licenses and more accurately cover the current processing and inspection costs and expenses.

Text of proposed rule: TITLE 12 NYCRR, PART 82

"License, Registration, Inspection and Filing Fees of the Division of Safety and Health"

PART 82 - "License, Registration, Inspection and Filing Fees of the Division of Safety and Health"

82.1 Explosives.

(a) Certificate of competence as blaster. A non-refundable fee of [\$60] \$120 shall accompany each application to the Commissioner of Labor to take the exam for a certificate of competence as a blaster. Upon passing the exam, the application fee shall be applied towards the certificate of competence. Thereafter, a non-refundable fee of [\$60] \$120, payable to the Commissioner of Labor, shall accompany each triennial application for renewal of such certificate.

82.3 Crane operators.

A non-refundable fee of [\$60] \$120 shall accompany each application to the Commissioner of Labor to take the crane operator's exam. Such application and fee shall permit the applicant to take the exam on either of the next two available dates. Failure of the applicant to take the exam on those dates, or failure of the applicant to pass the exam, shall result in a forfeiture of the fee, and such applicant shall be required to submit a new application fee before being permitted to take the exam. Upon passing the exam, the application fee shall be applied towards the certificate of compe-

tence. A non-refundable fee of [\$60] \$120, payable to the Commissioner of Labor, shall accompany each triennial renewal of such certificate.

82.5 Ski tows and other Passenger Tramways

A non-refundable fee of [\$25] \$50 for a surface passenger tramway and [\$50] \$100 for an aerial passenger tramway shall be paid to the [Industrial] Commissioner of Labor for a certificate of registration of a passenger tramway, and for each annual review thereof, required by the rules implementing section 202-c of the Labor Law.

82.6 Boilers

(a) A non-refundable fee of [\$400] \$600, payable to the Commissioner of Labor, shall accompany an application for the review of a quality control system of a boiler manufacturer or repairer and each triennial renewal thereof.

(b) A non-refundable fee of [\$50] \$100, payable to the Commissioner of Labor, shall accompany each application to take the National Board of Boiler and pressure Vessel Inspectors quarterly exam, administered by the Department.

(c) A non-refundable fee of [\$20] \$50 shall be paid in advance to the Commissioner of Labor for a boiler inspector certificate of competence and shall accompany each annual renewal thereof.

82.7 Window cleaning scaffolds

A non-refundable fee of [\$250] \$1000, payable to the Commissioner of Labor, shall accompany each submission of a window cleaning scaffold plan for examination by the Department.

82.8 Ionizing Radiation

(a) Radioactive material licenses — definitions. The Commissioner of Labor shall issue radioactive material licenses in any of the [three] five categories, defined as follows:

(1) Category #1

[Waste burial site operators
Waste disposal services
Manufacturers and/or distributors of generally licensed devices
Major processors, manufacturers or distributors of radioactive material products (possession limit greater than 0.1 Curie)
Sealed gamma radiographic sources
Sealed irradiation sources (1 kilo Curie or greater)
Commercial Nuclear Pharmacies
Broad Licenses (Z=3 to 83 with possession limit greater than 0.1 Curie)
Well Logging (Unsealed and Sealed Sources)]

Cyclotron Operations

Industrial Radiography - Fixed Facility Only

Industrial Radiography - Temporary job sites (may include fixed)

Licenses of Broad Scope NOS

Manufacturing NOS

Manufacturing of Radioactive Products - Broad Scope

Nuclear Laundry

Nuclear Pharmacy Operations

Open Irradiator (> IMCi)

Research & Development - Broad Scope

Waste Broker

Waste Disposal Facility (active)

Waste Services NOS

(2) Category #2

[Neutron generators
Static eliminator bars not requiring registration (specific licenses)
Radioactive material gauging devices not otherwise itemized and not requiring registration

Sealed irradiation sources (less than 1 kiloCurie)

Sealed specific nuclear material sources

Sealed radioactive material sources used in research and development

Sealed radioactive material sources not otherwise itemized

Unsealed radium and daughter products

Unsealed radioactive material used in research and development

Unsealed source material

Unsealed radioactive material not otherwise itemized

Unsealed special nuclear material

Therapy service

Radioactive material sales or service not otherwise itemized

Well Logging (Sealed Sources Only)]

Commercial Distribution of Radioactive Products

Decontamination & Decommissioning Service

Distribution of Radioactive Medical Products

Distribution of Radioactive Products NOS

Manufacturing of Radioactive Medical Products Limited Scope

Manufacturing of Radioactive Products Limited Scope

- Open Irradiator (>10,000 Ci <1M Ci)
- Research & Development Limited Scope (>1 Ci)
- Waste Disposal Facility (inactive)
- Waste Processing or Repackaging
- Well Logging and Tracer Studies
- (3) Category #3
- [Air ionizers
- Gas chromatographs
- Sealed calibration sources
- Sealed ionization or excitation sources
- Unsealed radioactive material on timepieces
- Leak Test services
- Humidity gauges
- Vacuum gauges not requiring registration
- Static meters not requiring registration
- Sealed light sources]
- Device Installation, Maintenance & Repair Service
- Full Health Physics Consulting Service
- Leak Test & Calibration Service
- Medical System Service
- Moisture/Density Gauge
- Open Irradiator (<= 10,000 Ci)
- Redistribution of Radioactive Products
- Research & Development Limited Scope (<1 Ci)
- Sealed or Unsealed Sources NOS
- Services NOS
- Well Logging (Sealed Sources Only)
- (4) Category #4
- Analytical Laboratory (radioactive sample analysis)
- Calibration service
- Fixed Gauges
- Gauges NOS
- Leak Test Service
- Portable X-ray Fluorescence Analyzer
- Possession Incident to Exempt Distribution (NRC E-License)
- Self-Shielded Irradiators
- (5) Category #5
- Analytical Instruments NOS
- Demonstration & Sales of Radioactive Products
- Gas Chromatograph
- Storage Only Pending Disposal

(b) Fees. (1) *Radioactive material licenses.* A non-refundable fee shall be submitted to the Commissioner of Labor with each application for a radioactive material license and each triennial renewal thereof, pursuant to the following schedule:

Category #1	[\$3,375]	\$7,500
Category #2	[\$1,695]	\$5,500
Category #3	[\$1,200]	\$4,000
Category #4		\$3,000
Category #5		\$1,500

(2) *Generally licensed devices.* A non-refundable fee in the amount of \$200, payable to the Commissioner of Labor, shall be submitted with each registration of a generally licensed device and each triennial renewal thereof.

(3) *Radiation equipment.* A non-refundable fee in the amount of \$100, payable to the Commissioner of Labor, shall be submitted with each registration of radiation equipment, and each triennial renewal thereof.

(c) *Additional fees.* A non-refundable fee shall be submitted to the Commissioner of Labor according to the following schedule:

Review of Decommissioning plan	\$2,500
Review of Sealed Source and Device Certificate application	\$1,500

Text of proposed rule and any required statements and analyses may be obtained from: Diane Wallace Wehner, Legal Assistant, Department of Labor, Counsel's Office, Rm. 509, State Campus, Bldg. 12, Albany, NY 12240, (518) 457-4380, e-mail: usbdww@labor.state.ny.us

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

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

Regulatory Impact Statement

1. Statutory Authority

Statutory authority exists in both the General Business Law and the Labor Law for the Commissioner to assure that adequate funding is available to carry out the public policy objectives of the Legislature relative to safety and health programs. Such authority includes proper funding for administration and program enforcement. Below are the reference cita-

tions, followed by the actual language for those fees where the Department has requested an increase:

- (General Language)
- Labor Law, Chapter 31
- Section 23.
- Section 27. 2. a. & b.
- Section 27. 3.
- (Specific Language)
- Certificate of Competence as a Blaster Fee
- Chapter 20, Section 483.
- Chapter 31, Section 458 & 462.
- Crane Operator Certificate Fee
- Chapter 20, Section 483.
- Surface Tramway/Aerial Tramway Fee
- Chapter 31, Section 202-c and Section 867.
- Boilers
- Chapter 31, Section 204.
- Window Cleaning Scaffold Approval Fee
- Chapter 31, Section 200 and Section 202.
- Ionizing Radiation Licenses Fee
- Chapter 20, Section 483.
- Labor Law, Chapter 31:

Section 23. Administrative regulations. The commissioner may make, amend and repeal regulations necessary for the internal administration of the department, and not in conflict with the rules adopted by the workmen's compensation board or the industrial board of appeals pursuant to this chapter for the enforcement of the labor law. Such regulations shall not be deemed rules within the meaning of this chapter unless the context otherwise requires.

Section 27.2 Safety and health standards. 1. Application. Notwithstanding any other provision in this chapter, a safety or health standard promulgated under this section shall apply only to employees not covered by a federal occupational safety or health standard promulgated under section six of the United States Occupational Safety and Health Act of 1970 (Public Law, 91-596). Provided, however, that no standard promulgated under this section shall apply to employees of the state, its political subdivisions and of any other governmental agency or instrumentality, to whom section twenty-seven-a of this chapter is applicable. 2. Standards. a. The commissioner shall by rule adopt, amend or repeal safety and health standards which provide reasonable and adequate protection to the lives, safety or health of employees and of persons lawfully frequenting a place of employment. b. The commissioner may require licenses as a condition of carrying on any industry, trade, occupation or process which the commissioner finds contains special elements of danger to the lives, safety or health of employees to whom this section is applicable or of persons lawfully frequenting the place of employment of such employees. The commissioner may establish a schedule of fees for such licenses, require medical inspection and supervision of persons so employed or applying for such employment, and may prescribe other appropriate requirements. 3. Regulations. The commissioner may promulgate such regulations as he shall consider necessary and proper to effectuate the purposes and provisions of this section.

Section 200. General duty to protect the health and safety of employees; enforcement. 1. All places to which this chapter applies shall be so constructed, equipped, arranged, operated and conducted as to provide reasonable and adequate protection to the lives, health and safety of all persons employed therein or lawfully frequenting such places. All machinery, equipment, and devices in such places shall be so placed, operated, guarded, and lighted as to provide reasonable and adequate protection to all such persons. The board may make rules to carry into effect the provisions of this section.

Section 202. Protection of the public and of persons engaged at window cleaning and cleaning of exterior surfaces of buildings. The owner, lessee, agent and manager of every public building and every contractor involved shall provide such safe means for the cleaning of the windows and of exterior surfaces of such building as may be required and approved by the board of standards and appeals. The owner, lessee, agent, manager or superintendent of any such public building and every contractor involved shall not require, permit, suffer or allow any window or exterior surface of such building to be cleaned unless such means are provided to enable such work to be done in a safe manner for the prevention of accidents and for the protection of the public and of persons engaged in such work in conformity with the requirements of this chapter and the rules of the board of standards and appeals. A person engaged at cleaning windows or exterior surfaces of a public building shall use the safety devices provided for his protection.

Every employer and contractor involved shall comply with this section and the rules of the board and shall require his employee, while engaged in cleaning any window or exterior surface of a public building, to use the equipment and safety devices required by this chapter and rules of the board of standards and appeals.

The provisions of this section shall not apply to (1) multiple dwellings six stories or less in height located anywhere in this state; nor to (2) any building three stories or less in height in cities, towns or villages having a population of less than forty thousand; nor to (3) the windows or exterior surfaces of any building which may be exempted under any rule adopted by the board of standards and appeals. The board of standards and appeals may grant variations pursuant to the provisions of section thirty of this chapter. All existing variations heretofore made by the board relating to the cleaning of windows are hereby validated and continued in full force and effect until amended or terminated by the board. The board of standards and appeals may make rules to effectuate the purposes of this section. Notwithstanding any other law or regulation, local or general, the provisions of this section and the rules issued thereunder shall be applicable exclusively throughout the state and the commissioner shall have exclusive authority to enforce this section and the rules issued thereunder.

Section 202-c. Prevention of personal injuries in the use of ski tows, other passenger tramways and downhill ski areas. The commissioner may make rules, consistent with article eighteen of the general obligations law, guarding against personal injuries to employees and the public in the use and operation of ski tows, other passenger tramways and downhill ski areas.

Section 204. Inspection of boilers; enforcement; fees; identification; exceptions.

1. Inspection. The commissioner shall cause to be inspected at least once every two years all boilers as defined in this section, except for high pressure power boilers, antique boilers and miniature boilers, which the commissioner shall cause to be inspected at least once each year, and except for boilers inspected and insured by a duly authorized insurance company in accordance with the provisions of subdivision eight of this section and with the rules of the commissioner. 2. Enforcement. If upon inspection of a boiler the commissioner finds a violation of the provisions of this section or of the rules of the board or if the commissioner receives notice from a duly authorized insurance company that the owner or lessee of a boiler has failed, after notice from the insurance company, to comply with the provisions of this section and rules of the board, the commissioner shall issue an order to the owner or lessee directing compliance therewith. If in the judgment of the commissioner the boiler is in an unsafe or dangerous condition the commissioner shall order the use of the boiler discontinued until such dangerous and unsafe condition has been remedied. Such order shall be served upon the owner or lessee of the boiler, personally or by mail. 3. Fees. A fee of one hundred dollars shall be charged the owner or lessee of each boiler internally inspected and sixty dollars for each boiler externally inspected by the commissioner, provided however, that the external inspection of multiple boilers connected to a common header or of separate systems owned or leased by the same party and located in the same building, with a combined input which is 300,000 BTU/hour or less, shall be charged a single inspection fee, and further provided that, not more than one hundred sixty dollars shall be charged for the inspection of any one boiler for any year; except that in the case of an antique steam engine maintained as a hobby and displayed at agricultural fairs and other gatherings, a fee of fourteen dollars only shall be charged the owner or lessee thereof for each boiler internally inspected by the commissioner and a fee of six dollars only shall be charged for each boiler externally inspected by the commissioner, but not more than twenty dollars shall be charged for the inspection of any one such boiler for any year, and except that in the case of a miniature boiler a fee of forty dollars only shall be charged for the inspection of any one such boiler for any year. Such fee shall be payable within thirty days after inspection.

Section 458. Licenses and certificates. 1. No person shall purchase, own, possess, transport or use explosives unless a license therefor shall have been issued as provided in this article. Application for such a license shall be made to the commissioner on forms provided and shall contain such information as the commissioner may require. Where the commissioner finds that the applicant has complied with the requirements of this article and the rules promulgated hereunder, the commissioner shall issue a license or renewal thereof which shall be valid for one year from the date of issuance. Such application and each renewal thereof shall be accompanied by a fee of fifty dollars non-refundable to be payable to the commissioner. 2. No person shall manufacture, deal in, sell, give or dispose of explosives unless a license therefor shall have been issued to such person

for that purpose by the commissioner as provided in this article, nor shall any person sell, give or dispose of explosives to, or manufacture explosives for any person who does not hold a license as provided by subdivision one of this section. Application for such a license, which shall be renewed annually, shall be made to the commissioner on forms provided and shall contain such information as the commissioner may require. The commissioner, after investigation of the application, shall issue a license or renewal thereof, which shall be valid for one year from the date of issuance, where the commissioner finds that the applicant has complied with the requirements of this article and the rules promulgated hereunder. Each application for such a license, or for its renewal, shall be accompanied by a fee of one hundred dollars non-refundable to be payable to the commissioner. 3. No person shall keep or store explosives unless a certificate therefor shall have been issued by the commissioner as herein provided, but this requirement shall not apply to the storage at any one time by farmers of two hundred pounds or less of blasting explosives for agricultural purposes. Application for such a certificate shall be made to the commissioner on forms provided and shall contain such information as the commissioner may require. The commissioner, where it is found that the applicant has complied with the requirements of this article and the rules promulgated hereunder, shall issue a certificate or a renewal thereof, which shall be valid for one year from the date of issuance. In addition to any other causes for revocation of a certificate hereinafter provided, the commissioner may revoke or modify such certificate because of any change in the conditions under which it was granted, or for failure to pay the annual fee hereinafter provided. The owner or user of a magazine shall annually pay to the commissioner in advance a fee, not exceeding one hundred dollars, which shall be proportioned according to the quantity of explosives authorized by the certificate to be stored in the magazine.

Section 462. Rules and regulations. The commissioner may make rules supplemental to this article as he shall deem necessary or desirable to assure the public safety as well as to provide reasonable and adequate protection of the lives, health and safety of persons employed in the manufacture, storage, handling and use of explosives. The commissioner may prescribe such regulations as he may deem necessary and proper for the administration of this article.

Section 867. Safety in skiing code. 1. The commissioner, on the advice of the passenger tramway advisory council as created pursuant to section twelve-c of this chapter, shall promulgate rules and regulations, consistent with article eighteen of the general obligations law, intended to guard against personal injuries to downhill skiers which will, in view of such intent, define the duties and responsibilities of downhill skiers and the duties and responsibilities of ski area operators.

General Business Law, Chapter 20

Section 483. Administration. 1. The commissioner is hereby authorized and directed to prescribe such rules and regulations as may be necessary and proper for the administration and enforcement of this article. 2. Such regulations may provide for examinations, categories of certificates, licenses, or registrations, age and experience requirements, payment of fees, and may also provide for such limitations and exemptions as the commissioner finds necessary and proper. In the case of blasters, such regulations may require fingerprinting, and in the case of users of radioactive material, such regulations may require the posting of a bond or other security. 3. Any member of a blaster examining board, crane operating examining board, laser operating examining board, or other board created pursuant to rules and regulations of the commissioner to implement this article shall serve without salary or other compensation.

2. Legislative Objectives

All of the items covered by these fees (detonation of explosives, crane operator competency and certification, ski tow and tramway operation, pressure vessel or boiler operation, window cleaning scaffold operation and the use of ionizing radiation) involve elements of potential danger to the lives, health and safety of the citizens of the state and to their property. Special rules, regulations and enforcement power are necessary to insure that only proper methods, means and experienced persons are utilized and are authorized to engage in such uses and operations. The revenue collected from the fees currently charged within these programs is utilized by the Department to ensure that periodic on-site inspections, plan reviews and competency examinations are conducted for each of these operations.

3. Needs and Benefits

A recent Program review by the Department disclosed the need for reasonable increases in several fee categories to maintain administrative efficiency, to continue with the conduct of necessary on-site inspections and to enhance the issuance of certificates and licenses, all of which are directly proportional to insuring a safer workplace. These proposed fee

increases will also be utilized by the Department to implement and improve technological processing techniques that will benefit those customers we serve. For example, a more efficient and timely customer electronic application processing system will be implemented. This system will not only enhance first time applications, but will also result in even more expediency with customer renewal applications received and processed by the Department. Finally, these fee structures have remained unchanged for the past 12 years or more and, unfortunately, do not adequately cover the Department's current processing and inspection costs and expenses. Keeping the fees at the current rate will not promote the Department preference for electronic filling and processing.

The following is a brief explanation of needs and benefits for each increase proposed:

82.1, 82.3

The fee for blaster and crane operator certificates has been in place for the last 12 years or more. Over this period of time, Department costs have increased significantly for administering and issuing certificates and for the conduct of associated on-site inspections. Additionally, required staff time for blaster and explosives activities has recently increased again due to the expanded coordination and inquiries from local, federal, and state enforcement agencies and the heightened concerns associated with terrorism and homeland security.

82.5

The fee for surface and aerial tramways has not changed for the past 12 years. However, over this period of time, the complexity of these tramways, many now costing \$1 million or more to purchase and operate, has increased. Additional resources for proper staff training and on-site inspections are required by the program to meet these new levels of industry sophistication. Department administrative costs associated with training and inspections (inspector salaries, travel costs, technical research) have increased substantially. All of these factors warrant the requested increase to ensure that the Department is able to continue to dedicate the inspection resources necessary to conduct a full safety review of the tramways before they are put into service and to have sufficient and capable resources available to respond to potential incidents, accidents or complaints.

82.6

The fee associated with the review of quality control system of a boiler, National Board of Boiler and Pressure Vessel Inspection Exam, and boiler inspector certificate of competency has not been changed for 12 years. Over this period of time, the administrative costs and technological complexity (high efficiency boilers, control circuitry, temperature and flow controls) of boilers have increased substantially. Increased staff review, inspections, administration and training time are required to ensure the safe operation of boilers. The Department's fixed costs of salary, benefits and travel have increased substantially during this time.

82.7

The \$250 fee for window cleaning scaffold approvals was established in 1989. Since that time, building design and architecture have become much more elaborate and ornate (*i.e.* overhangs, atriums, domes, spires, sloped curtain walls, skylights, etc.). As a result, window cleaning technology has undergone significant changes, becoming a much more sophisticated and complicated operation. The required staff time that now must be devoted to the review and approval of window cleaning scaffold applications has at least doubled (two to three site visits are now required as compared to one visit, several rounds of reviews of applications as compared to one, pre-application meetings and phone calls with contractors, architects, etc.). This fee charged by the Department for approval is a "one-time" charge to the owner or operator of the scaffold. Department costs associated with these reviews (engineer salaries, travel expenses for site visits, research, etc.) have increased substantially. At the same time, the cost of window cleaning equipment has increased by approximately 40% since 1989. Today's more sophisticated window cleaning technology may cost upwards of \$1,000,000. All of these factors warrant the requested increase to ensure that the Department is able to dedicate the engineering resources necessary to conduct a full safety review of the window cleaning devices before they are put into service.

82.8

The new fee categories proposed were created to better reflect the variety of material use programs licensed by the Department. Doing so facilitates assigning fees based upon the amount of Department resources required to license and inspect facilities. Under the existing scheme, programs of widely disparate complexity and relative hazard are forced within the same fee categories. License category changes are also necessitated to better reflect the existing types of radioactive materials use programs licensed by the Department. In many cases such changes are a result of

technology updates. For example, the use of cyclotrons for the commercial production of positron emission tomography (PET) agents is a new technology which we have been asked to license for the first time within just the past few years. Also, portable x-ray fluorescence (XRF) analysis instruments have become widely used for identifying lead paint in older residential buildings. These are currently assigned to the same fee category as portable moisture/density gauges, which are significantly more hazardous and require more careful oversight, increased time, resources and cost by the Department. The proposed fee categories would assign XRF units to a lower fee category. Each fee category encompasses several license categories that have been grouped together because they present a comparable level of hazard and/or complexity and therefore requires a comparable expenditure of Department resources to regulate. As the fee categories decrease, the license categories grouped into each also decrease in hazard and/or complexity.

4. Costs:

- a. Costs are limited to the fee increases for regulated parties.
- b. Costs are limited to the fee increases for those state and local governments that are covered.
- c. Costs are based solely on fee increases to cover the current processing and inspection expenses.

5. Local Government Mandates:

The following summarizes the limited application to local government:

82.1 Blaster: The fee increase is applicable to individuals that may work for local government. NYC is fee exempt.

82.5 Tramway: The application to local government is extremely limited due to the cost of acquiring and maintaining a tramway. Very few local governments can afford or require a tramway.

82.7 Window Cleaning scaffolds: This fee increase will have very limited impact on local government, since review and approval is only applicable to buildings over 75 feet (*i.e.* approximately five stories). For larger buildings where the approval fee is applicable, the fee is a very small percentage of the overall cost of construction and therefore will not have any negative impact.

82.8 Ionizing Radiation: Application is limited to NYC and Buffalo City.

6. Paperwork:

Paperwork related impacts will be limited to revising those portions of the application forms related only to the amount of fees to be paid. There are no new requirements for any additional information or data from the applicant or customer. The Department is also committed to expanding the availability and use of e-filing and providing access to rules, regulations and forms on its Internet site. Such access will help to keep costs down for those customers, will control Department operational and administrative costs and will result in more efficiency.

7. Duplication:

There is no duplication of services or fees or pre-emption by other state or federal agency.

8. Alternatives:

All reasonable alternatives were given careful consideration by the Department as prescribed in SAPA Section 202b(1). However, none of the suggested alternatives were able to adequately address the revenue shortfall and the need to maintain services. Alternatives considered include:

a. The establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small businesses and local governments.

Since the proposed fee increases do not impose additional reporting requirements and preclude the establishment of differing compliance, this alternative was not applicable. Overall, this proposal will have little or no direct impact on local government and minimal indirect impact in some limited areas of small business.

b. The use of performance, rather than design, standards.

The proposal precludes use of this alternative. Flexibility is already provided to allow reasonable timeframes for customer compliance. The revenue process is prescribed by internal controls that correctly preclude the use of performance standards.

c. An exemption from coverage by the rule, or by any part thereof, for small businesses and local governments so long as the public health, safety, or general welfare is not endangered.

The proposal does not expand coverage to include any additional small businesses or local governments other than those currently covered. Likewise, this proposal does not place any additional mandates (other than a fee increase) on those small businesses or local governments who must currently comply with the occupation safety and health requirements of the

labor Law. The projected revenue increase will allow the Department to adequately cover those costs to provide public and occupational safety and health services that are essential to protecting lives, health, and safety of all New York citizens to these existing customers.

Other alternatives beyond those described above were also considered by the Department. They include:

- No action alternative: One alternative considered was to select no action. Program cost cutting and downsizing has already been implemented to the extent practical. This alternative would not provide the needed solution to protect safety and health for those program operations.

- Fee increases lower than what is proposed were also considered by the Department and discarded because they would not allow for the Program to deliver the required service to protect public health and safety.

The Department contacted several customers to discuss the nature of the proposed fee increases. A brief synopsis of the comments of those contacted follows:

Boiler Fee Increases:

- One respected representative within the industry had no major concerns with the proposed increase.

- Another respected representative within the industry requested details on the rationale for the increases. When this detail was provided he indicated that other than a fee increase there may not be any options available.

Power Scaffold Plan Review Fee Increases:

- One respected representative within the industry is not opposed, but thought that \$500 fee would be better than \$1,000.

- Another respected representative within the industry is not opposed, but also suggested \$500 fee rather than \$1,000.

Radioactive Materials Licensing Fee Increases:

- One respected representative within the industry opposed to large fee category increases. Prefers a smaller incremental increase in each fee category.

- Another respected representative within the industry opposes fee increase. Suggests that fee increase be proportional to the dollar sales of a company, whereby those whose general sales are over \$1 million annually be charged a higher licensing fee.

- Still another respected representative within the industry states that since his company is a radioactive isotope user, he really cannot argue against a fee increase. He objects to the percentage amount of the proposed fee increase and suggest that perhaps a "step" increase be considered instead of a large all at once increase.

9. Federal Standards:

There are no federal standards that either duplicate or pre-empt the state standards.

10. Compliance Schedule:

Compliance for the proposed fee increases will require no more than one month once customers are properly notified of the new fees. These are nominal fee increases that vary in timeframes from 1 year to 3 years, depending on the category. Fee increases will not be due for as many as 3 years, or as little as 1 month from customer notification of the changes.

Regulatory Flexibility Analysis

1. Effect of Rule

Proposed fee increases for Blaster, Crane Operator, Surface Tramways, Aerial Tramways and Scaffolds will have no impact on New York City. New York City issues their own Blaster and Crane Operator Certificates. New York City and Buffalo conduct their own boiler inspections. The City of White Plains has mandated that boilers within their jurisdiction be inspected by a certified Insurance Company employee.

The Department issues certificates to employees, whereas licenses are issued to employers or businesses. It is not customary for employers to pay for employee certificates. Therefore business will not be impacted by proposed fee increases for these categories.

There are approximately 100 small business operations that are licensed by the Department for the use of radiological XRF device to analyze lead paint. However, the 3-year licensing fee increase of \$1,305 (or \$435/year) is considered nominal for this type business application. New York City and Buffalo are licensed users of such type devices, but will be minimally impacted by the nominal fee increases. All others licensed by the Department for the use of radiological materials are medium to large sized businesses.

2. Compliance Requirements

There are no additional customer compliance requirements associated with the proposed increase in fees.

3. Professional Services

There are no additional professional services required with the proposed fee increases. All procedures for licenses and certificates, etc. will

remain the same. The Department's movement toward electronic filing will in fact enhance the application and approval process.

4. Compliance Costs

There are no additional compliance costs for local governments or employers. Fee increases will not vary depending on the type and/or size of the small business or local government. Business or employer compliance costs are limited to the fee increases which are nominal considering the revenue that is generated from such licensed or certificate operations. For example: a tramway operator will pay an additional \$25 or \$50 per year (or a total of \$50 or \$100 per year) for a Department inspection; a blaster or crane operator would pay an additional \$60 for a 3-year certification (or a total of \$120 for 3 years); a one time engineering plan review fee for scaffolds would increase from \$250 to \$1000; and the one time fee to take a boiler competency exam would increase by \$50. Local government or small businesses are not likely to purchase more than a few radiological devices that will require a license due to the initial cost of purchase. Such devices cost \$30,000 or more. Similarly, expensive power operated scaffolds or tramways are not likely to be purchased by small business or local government for the same rationale.

5. Economic and Technological Feasibility

There is minimal impact on technological feasibility to small business or local government. Such feasibility is a function of the fee increases and the size of the business. Affected small business and local governments will be minimally affected due to the limited number of licenses or inspections that will be required.

6. Minimizing Adverse Impact

There will be no adverse economic impact on small business or local government. Proposed fee increases were limited to the costs associated with administering and issuing the licenses or certificates. Other approaches as specified in SAPA § 202-b(1) were considered.

7. Small Business and Local Government Participation

Participation will be provided pursuant to SAPA requirements.

Rural Area Flexibility Analysis

1. Types and Estimated Numbers of Rural Areas

The fee increase will not affect any particular rural area. Certified blasters, crane operators, boiler activities and ionizing radiation activities are located throughout the state. Although many tramways are located at ski areas that are in rural areas, there will be little or no effect on rural areas due to the nominal fee increase as compared to the overall costs of operations. Window cleaning scaffolds are primarily utilized on multi-story buildings in urban areas; and, therefore, the associated fee increase will not impact rural areas.

2. Reporting, Recordkeeping, and Other Compliance Requirements; and Professional Services

There is no additional reporting, recordkeeping, nor other compliance requirements or professional services. All forms will be updated to reflect the fee increase.

3. Costs

Additional costs are limited to the fee increases. There is no likely variation in costs for different types of public or private entities in rural areas.

4. Minimizing Adverse Impact

No impact on rural areas. Fee increases were limited to cover the costs of administration.

5. Rural Area Participation

The lack of rural area impact precludes the need for additional rural area participation.

Job Impact Statement

1. Nature of Impact

The proposed fee increases will have no adverse impact on either jobs or employment opportunities for those customers subject to such increases. There are no increased mandates associated with this proposal.

Monetarily, the proposed fee increases are a very small percentage of the overall costs required to purchase, operate or use the materials covered within these Programs. For example, a single tramway can cost upwards of several million dollars to purchase and operate. The proposed fee increase of either \$25 or \$50 for this program will be insignificant compared to annual operational costs of a tramway. The Departments proposed fee of \$1000 for a "one-time" plan review fee for power scaffolds, which as a device can cost upwards of \$1 million, is also relatively small considering the use and operation of such devices. Radiological Licenses are issued primarily to mid to large service and manufacturing firms and large public agencies. The license-related activities of these entities represent a very small portion of their overall business operation. Additionally, local governments, including New York City, are not subject to blaster, crane

operator certification and boiler fees and are exempt from ski tow, power scaffold and passenger tramway fees.

Finally, possession of blaster, crane operator and boiler certificates actually enhances employment opportunities for the holders of such. The proposed fee increases for these certificates, when compared to the income potential that will be earned in these professions, are relatively small.

The following chart shows the details of the proposed increases:

Program	Current Fee	Proposed Fee	# Customers Affected	Local Gov't	NYC
Blaster	\$60/3 yrs	\$120/3 yrs	650	NA	NA
Crane Operator	\$60/3 yrs	\$120/3 yrs	4,000	NA	NA
Surface Tramway	\$25/yr	\$50/yr	433*	Exempt	Exempt
Aerial Tramway	\$50/yr	\$100/yr	*See Above	Exempt	Exempt
Boilers					
-Quality Control	\$400/3 yrs	\$600/3 yrs	39	NA	NA
-Exam	\$50/yr	\$100/yr	15	NA	NA
-Certificate	\$30/Report	\$50/Report	350	NA	NA
Scaffolds	\$250/Once	\$1000/Once	29	NA	NA
Radiological					
Category 1	\$3375/3 yrs	\$7500/3 yrs	51	Covered	Covered
Category 2	\$1695/3 yrs	\$5500/3 yrs	45	Covered	Covered
Category 3	\$1200/3 yrs	\$4000/3 yrs	168	Covered	Covered
Category 4*	\$1200/3 yrs	\$3000/3 yrs	229	Covered	Covered
Category 5*	\$1200/3yrs	\$1500/3 yrs	3	Covered	Covered

NOTE * = New Fee Category

2. Categories and Numbers Affected

The proposed fees are either one-time payment, paid annually, paid per report or certificate or paid every three years. Many of these fees will apply to medium and large business operations. The fee increases are a small percentage of overall costs for these entities and will have no effect on any category or impact on the number of jobs.

3. Regions of Adverse Impact

The fees apply to employment, jobs and businesses that are not concentrated in any specific region of the state. Therefore, there is no impact.

4. Minimizing Adverse Impact

The Department has minimized any adverse impact by limiting all fee increases to the costs of program administration. There are no other customer mandates required in this proposal.

5. Self-Employment Opportunities

There will be little or no impact on self-employment opportunities, since the fees are a small percentage of overall business costs.

be billed 25 cents per page. Please use tracking number found on last line of notice in requests.

Assessment of Public Comment

An assessment of public comment is not submitted with this notice because the rule is within the definition contained in section 102(2)(a)(ii) of the State Administrative Procedure Act. (03-E-0932SA1)

NOTICE OF ADOPTION

Lightened Regulation by Northrop Grumman Corporation and Northrop Grumman Systems Corporation

I.D. No. PSC-33-04-00027-A

Filing date: Oct. 27, 2004

Effective date: Oct. 27, 2004

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

Action taken: The commission, on Oct. 20, 2004, adopted an order in Case 04-W-0886 approving Northrop Grumman Corporation (NGC) and Northrop Grumman Systems Corporation's (NGSC) request to be lightly regulated as water-works corporations.

Statutory authority: Public Service Law, sections 2(26), (27), 89-a, 89-b, 89-c, 89-d, 89-e, 89-f, 89-g, 89-h, 89-i, 105, 106, 107, 108, 109, 110, 111, 112, 113, 114, 114-a, 115, 116, 117, 118, 119-b and 119-c

Subject: Joint petition for a declaratory ruling

Purpose: To exempt NGC and NGSC from regulatory requirements as water-works corporations.

Substance of final rule: The Commission granted Northrop Grumman Corporation and Northrop Grumman Systems Corporation lightened regulation as the owners and operators of a water distribution system located in Long Island, New York, 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-0886SA1)

Public Service Commission

NOTICE OF ADOPTION

Recovery of Cost Energy Conservation Programs by the New York Municipal Power Agency

I.D. No. PSC-30-03-00008-A

Filing date: Oct. 27, 2004

Effective date: Oct. 27, 2004

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

Action taken: The commission, on Oct. 20, 2004, adopted an order in Case 03-E-0932 approving New York Municipal Power Agency's (NYMPA) request to recover the costs of the Municipal Alternative-Vehicle Program (MAP).

Statutory authority: Public Service Law, sections 65, 66 and 66-c

Subject: Recover costs of loans through the purchased power adjustment clauses (PPAC).

Purpose: To recover the costs of the Municipal Alternative-Vehicle Program through the PPAC.

Substance of final rule: The Commission authorized certain municipal electric systems to recover the costs of a program to purchase electric and hybrid vehicles through their Purchased Power Adjustment Clauses.

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

NOTICE OF ADOPTION

Gas Cost Adjustment by the Brooklyn Union Gas Company d/b/a KeySpan Energy Delivery New York

I.D. No. PSC-34-04-00022-A

Filing date: Oct. 27, 2004

Effective date: Oct. 27, 2004

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

Action taken: The commission, on Oct. 20, 2004, adopted an order in Case 04-G-0642 allowing The Brooklyn Union Gas Company d/b/a KeySpan Energy Delivery New York (KEDNY) to implement a new process for estimating and prorating gas consumption for calculating bills and granted KEDNY a waiver of the regulations governing calculation of the gas cost adjustment.

Statutory authority: Public Service Law, sections 65 and 66

Subject: Petition by KEDNY to change its methods of calculating bills.

Purpose: To improve billing accuracy for the ratepayers.

Substance of final rule: The Commission authorized The Brooklyn Union Gas Company d/b/a KeySpan Energy Delivery New York (KEDNY) to use new procedures for estimating and prorating gas consumption based on degree day occurrence in calculating bills and granted KEDNY a waiver of 16 NYCRR Section 720-6.5(c), 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-G-0642SA1)

NOTICE OF ADOPTION

Contract Consultant and Associated Expenditures by ICF Associates, LLC

I.D. No. PSC-35-04-00015-A

Filing date: Oct. 29, 2004

Effective date: Oct. 29, 2004

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

Action taken: The commission, on Oct. 20, 2004, adopted an order in Case 00-G-0996 approving an expenditure of \$245,413 for ICF Associates, LLC to conduct a study of the oil industry infrastructure.

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

Subject: Assessment of the oil industry infrastructure.

Purpose: To evaluate the domestic heating oil industry's infrastructure and provide services to meet specific objectives.

Substance of final rule: The Commission authorized an expenditure of \$245,413 for a consultant, ICF Associated, LLC, to conduct a study of the oil industry infrastructure and approved the final scope of study (statement of work) agreed to by the consultant, subject to the terms and conditions of 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. (00-G-0996SA8)

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

Rules and Guidelines Governing Installation of Metering Equipment

I.D. No. PSC-46-04-00009-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 issuing new guidelines on and revising existing policies and procedures governing the metering of a customer's electric and/or gas consumption by meter service providers (MSPs) or meter data service providers (MDSPs).

Statutory authority: Public Service Law, art. 2, sections 44, 66, 72, 80 and 85

Subject: Rules and guidelines governing installation of metering equipment and access to and exchange of metering data between MSPs, MDSPs, utilities and customers.

Purpose: To establish uniform statewide business practices governing interactions between utilities, MSPs, MDSPs and customers regarding the measurement of customer's energy consumption and the exchange of measurement data between interested parties.

Substance of proposed rule: The Commission concluded in Opinion No. 97-13 issued in Case 94-E-0952 that "the move towards the provision of competitive metering can begin." At that time, the Commission believed that the availability of competitive electric metering services could contribute to the development of a robust retail energy market in New York. The Commission subsequently adopted revisions to Parts 92 and 93 of its

regulations to allow non-utility entities to submit new meters for Commission approval and to recognize Meter Service Providers as entities authorized to install and maintain meters on the customer's premises.

The Commission now seeks comments from interested parties regarding the current state of competitive metering in New York and what policies could be adopted that would be most effective in stimulating the continued development of competitive metering services.

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

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

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

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

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

(00-E-0165SA4)

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

Order Regarding Retail Renewable Portfolio Standard by New York State Energy Research and Development Authority, et al.

I.D. No. PSC-46-04-00010-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 whether to approve or reject, in whole or in part, petitions for clarification and/or reconsideration of its order regarding retail renewable portfolio standard issued Sept. 24, 2004 in Case 03-E-0188, filed by New York State Energy Research and Development Authority, the Small Hydro Group, and Ridgewood Renewable Power, L.L.C.

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

Subject: Order regarding retail renewable portfolio standard issued on Sept. 24, 2004.

Purpose: To clarify and/or reconsider the order.

Substance of proposed rule: New York State Energy Research and Development Authority (NYSERDA), the Small Hydro Group (SHG) and Ridgewood Renewable Power L.L.C. (Ridgewood) filed petitions seeking clarification and/or reconsideration of the Public Service Commission's Order Regarding Retail Renewable Portfolio Standard issued September 24, 2004 in Case 03-E-0188. Specifically, NYSEDA requests clarification that the contracts or agreements to be entered into by NYSEDA and delivery utilities shall provide for transfer payments beyond 2013 for program and administrative costs and shall expressly require the delivery utilities to continue making such transfer payments beyond 2013 as may be necessary to fulfill long-term RPS program contracts. SHG requests clarification and/or reconsideration of several portions of the September 24, 2004 Order, including but not limited to, the following: exemptions from the non-bypassable wires charge; deferral of "too much" for subsequent proceedings (e.g., the development of the criteria for proving financial need); adoption of an externalities credit; and guidance on how long renewable power producers will be paid under the RPS program and what will happen when the 25% goal is achieved. Ridgewood seeks reconsideration of the decision to require monthly matching of energy deliveries and asks instead for hourly matching.

The Commission may approve or reject such petitions, in whole or in part. In addition, the Commission may decide to offer different or additional clarification of its September 24, 2004 Order.

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

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

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

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

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

(03-E-0188SA4)

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

Minor Rate Increase by Iliion Board of Light Commissioners

I.D. No. PSC-46-04-00011-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 or reject, in whole or in part, a proposal filed by Iliion Board of Light Commissioners to make various changes in the rates, charges, rules and regulations contained in its tariff schedule, P.S.C. No. 2—Electricity to become effective March 1, 2005.

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

Subject: Minor rate increase.

Purpose: To increase annual electric revenues by about \$296,135 or 13 percent and convert the tariff schedule into electronic format.

Substance of proposed rule: On October 28, 2004, the Iliion Board of Light Commissioners (Iliion) filed proposed tariff revisions to increase its annual electric revenues by about \$296,135 or 13%. The revisions include a proposal to increase its reconnection charges to better represent the cost to perform reconnection services. Iliion also proposes to establish a new reformatted electronic tariff schedule, P.S.C. No. 2, consistent with the new electronic tariff system. The new electronic tariff system became operational April 2003. The Commission may approve, reject or modify, in whole or in part, Iliion's proposed tariff revisions.

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

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

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

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

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

(04-E-1336SA1)

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

Service Application Form by Consolidated Edison Company of New York, Inc.

I.D. No. PSC-46-04-00012-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 approve, modify, or reject, in whole or in part, a proposal filed by Consolidated Edison Company of New York, Inc. to make various changes in the rates, charges, rules and regulations contained in its tariff schedule, P.S.C. No. 9—Electricity to become effective Jan. 24, 2005.

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

Subject: Service application form.

Purpose: To revise the service application form and make housekeeping changes.

Substance of proposed rule: On October 25, 2004, Consolidated Edison Company of New York, Inc. (Con Edison) filed proposed tariff revisions to modify its service application form to conform to the application in the

schedule for gas service, P.S.C. No. 9—Gas, and to make other housekeeping changes. The revised application form reflects the changes in gas rate options available to religious organizations, community residences, and veterans' organizations. The Commission may approve, reject or modify, in whole or in part, Con Edison's proposed tariff revisions.

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

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

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

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

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

(04-E-1337SA1)

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

Rules and Guidelines Governing Installation of Metering Equipment

I.D. No. PSC-46-04-00013-P

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

Proposed action: The Public Service Commission is considering issuing new guidelines on and revising existing policies and procedures governing the metering of a customer's electric and/or gas consumption by meter service providers (MSPs) or meter data service providers (MDSPs).

Statutory authority: Public Service Law, art. 2, sections 44, 66, 72, 80 and 85

Subject: Rules and guidelines governing installation of metering equipment and access to and exchange of metering data between MSPs, MDSPs, utilities and customers.

Purpose: To establish uniform statewide business practices governing interactions between utilities MSPs, MDSPs and customers regarding the measurement of customer's energy consumption and the exchange of measurement data between interested parties.

Substance of proposed rule: The Commission concluded in Opinion No. 97-13 issued in Case 94-E-0952 that "the move towards the provision of competitive metering can begin." At that time, the Commission believed that the availability of competitive electric metering services could contribute to the development of a robust retail energy market in New York. The Commission subsequently adopted revisions to Parts 92 and 93 of its regulations to allow non-utility entities to submit new meters for Commission approval and to recognize Meter Service Providers as entities authorized to install and maintain meters on the customer's premises.

The Commission now seeks comments from interested parties regarding the current state of competitive metering in New York and what policies could be adopted that would be most effective in stimulating the continued development of competitive metering services.

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

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

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

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

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

(02-M-0514SA2)

Racing and Wagering Board

EMERGENCY RULE MAKING

Drug Testing in Horses

I.D. No. RWB-46-04-00007-E

Filing No. 1233

Filing date: Nov. 1, 2004

Effective date: Nov. 1, 2004

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

Action taken: Amendment of sections 4043.6, 4043.7, 4038.18, 4120.10, 4120.11, 4109.7 and 4113.3 of Title 9 NYCRR.

Statutory authority: Racing, Pari-Mutuel Wagering and Breeding Law, sections 101, 301 and 902

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

Specific reasons underlying the finding of necessity: These rule amendments will provide an effective mechanism to deter the use in the racing horse of the potent tranquilizers reserpine and fluphenazine. Both drugs are being abused in an effort to gain an improper advantage in pari-mutuel racing; however the existing time-based structure of the equine drug rule does not provide effectively for the sanction of abusers and deterrence. These rule amendments will provide an effective mechanism to deter the use of erythropoietin and darbepoietin in the racing horse. These substances are being abused in an effort to gain an improper advantage in pari-mutuel racing; however the existing equine drug rule does not provide an effective means for the sanction of abusers and deterrence. The continued abuse of these drugs and substances, which have no legitimate use in pari-mutuel racing, undermines public confidence in the integrity of racing with resultant loss of willing participants and bettors. This would result in the loss of significant revenues to the State, municipalities, breeders and the industry. In addition, the continued undeterred use of these drugs and substances poses a threat to the safety of both the equine and human racing participants. An emergency rule making is necessary because the Board has determined that emergency adoption is necessary for the preservation of the general welfare and public safety and that standard rule making procedures would be contrary to the public interest.

Subject: Testing of horses for the drugs reserpine and fluphenazine and for the antibodies of erythropoietin and darbepoietin, as well as the consequences of positive tests.

Purpose: To provide for effective testing for the drugs reserpine and fluphenazine and for the antibodies of erythropoietin and darbepoietin and the consequences of positive tests, in order to defer their use in horses that complete in pari-mutuel racing; and provide for the exclusion from racing of those horses that are the subject of a positive test until there is a subsequent negative test. Claimants of horses will have the option of voiding any claim based upon the report of a positive test.

Text of emergency rule: THOROUGHBRED

AMEND Part 4043 (Drugs Prohibited and Other Prohibitions) to add a new Rule 4043.6:

4043.6 Erythropoietin and Darbepoietin

(a) A finding by the laboratory that the antibody of erythropoietin or darbepoietin was present in the sample taken from a horse shall establish that the horse is unfit to race in any subsequent race, subject to the provisions of paragraph b.

(b) Any horse that has been the subject of a finding by the laboratory that the antibody of erythropoietin or darbepoietin was present in the sample taken from that horse shall not be entered or allowed to race in any subsequent race until the horse has tested negative for the antibodies of erythropoietin or darbepoietin in a test conducted by the laboratory.

(c) Notwithstanding any inconsistent provision of this Part, a horse shall not be subject to disqualification from the race and from any share of the purse in the race, and the trainer of the horse shall not be subject to application of trainer's responsibility based upon the finding by the laboratory that the antibody of erythropoietin or darbepoietin was present in the sample taken from that horse.

AMEND Rule 4038.18 (Certain Voidable Claims) to add new paragraphs (b) and (c) and reletter existing paragraphs (b) and (c) to be (d) and (e) respectively:

(a) Post-race positive. Should the analysis of a post-race blood or urine sample taken from a claimed horse result in a post-race positive test, the claimant's trainer shall be promptly notified in writing by the stewards and the claimant shall have the option to void said claim within five days of receipt of such notice by his trainer. An election to void a claim shall be submitted in writing to the stewards by the claimant or his trainer.

(b) Erythropoietin and darbepoietin. Should the analysis of a post-race blood or urine sample taken from a claimed horse result in a finding by the laboratory that the antibody of erythropoietin or darbepoietin was present in the sample taken from that horse, the claimant's trainer shall be promptly notified in writing by the stewards and the claimant shall have the option to void said claim within five days of receipt of such notice by his trainer. An election to void a claim shall be submitted in writing to the stewards by the claimant or his trainer.

(c) Reserpine and fluphenazine. Notwithstanding any inconsistent provision of Part 4043, should the analysis of a post-race blood or urine sample taken from a claimed horse result in a finding by the laboratory that the drug reserpine or the drug fluphenazine was present in the sample taken from that horse, the claimant's trainer shall be promptly notified in writing by the stewards and the claimant shall have the option to void said claim within five days of receipt of such notice by his trainer. An election to void a claim shall be submitted in writing to the stewards by the claimant or his trainer.

[(b)] (d) Upper neurectomy or unreported lower neurectomy. Where an upper neurectomy as defined in subdivision (a) of section 4025.31 of this Subchapter or a lower neurectomy which has not been reported as required in subdivision (b) of section 4025.31 has been performed on a horse prior to the race in which it is claimed, the claimant shall have the option to void said claim upon written notice to the stewards from the claimant or his trainer given within 10 days following the date of the claim.

[(c)] (e) Undeclared pregnant mare. Where a pregnant mare has been claimed which pregnancy has not been disclosed as required in section 4038.17 of this Part, the claimant shall have the option to void the claim upon written notice to the stewards from the claimant or his trainer within 10 days following the date of the claim.

HARNESS

AMEND Part 4120 (Drugs Prohibited and Other Prohibitions) by adding a new Rule 4120.10:

4120.10 Erythropoietin and Darbepoietin

(a) A finding by the laboratory that the antibody of erythropoietin or darbepoietin was present in the sample taken from a horse shall establish that the horse is unfit to race in any subsequent race, subject to the provisions of paragraph b. Such horse shall be placed on the stewards's list.

(b) Any horse that has been the subject of a finding by the laboratory that the antibody of erythropoietin or darbepoietin was present in the sample taken from that horse shall not be entered or allowed to race in any subsequent race until the horse has tested negative for the antibodies of erythropoietin or darbepoietin in a test conducted by the laboratory.

(c) Notwithstanding any inconsistent provision of this Part, a horse shall not be subject to disqualification from the race and from any share of the purse in the race and the trainer of the horse shall not be subject to application of trainer's responsibility based upon the finding by the laboratory that the antibody of erythropoietin or darbepoietin was present in the sample taken from that horse.

AMEND Rule 4109.7 (Certain Voidable Claims) to add new paragraphs b and c and reletter paragraphs b and c to be d and e respectively:

(a) Post-race positive. Should the analysis of a post-race blood or urine sample taken from a claimed horse result in a post-race positive test, the claimant's trainer shall be promptly notified in writing by the judges and the claimant shall have the option to void said claim within five days of receipt of such notice by his trainer. An election to void a claim shall be submitted in writing to the judges by the claimant or his trainer.

(b) Erythropoietin and darbepoietin. Should the analysis of a post-race blood or urine sample taken from a claimed horse result in a finding by the laboratory that the antibody of erythropoietin or darbepoietin was present in the sample taken from that horse, the claimant's trainer shall be promptly notified in writing by the judges and the claimant shall have the option to void said claim within five days of receipt of such notice by his trainer. An election to void a claim shall be submitted in writing to the judges by the claimant or his trainer.

(c) *Reserpine and fluphenazine. Notwithstanding any inconsistent provision of Part 4120, should the analysis of a post-race blood or urine sample taken from a claimed horse result in a finding by the laboratory that the drug reserpine or the drug fluphenazine was present in the sample taken from that horse, the claimant's trainer shall be promptly notified in writing by the judges and the claimant shall have the option to void said claim within five days of receipt of such notice by his trainer. An election to void a claim shall be submitted in writing to the judges by the claimant or his trainer.*

[(b)] (d) Upper neurectomy or unreported lower neurectomy. Where an upper neurectomy as defined in subdivision (a) of section 4025.31 of this Subchapter or a lower neurectomy which has not been reported as required in subdivision (b) of section 4025.31 has been performed on a horse prior to the race in which it is claimed, the claimant shall have the option to void said claim upon written notice to the judges from the claimant or his trainer given within 10 days following the date of the claim.

[(c)] (e) Undeclared pregnant mare. Where a pregnant mare has been claimed which pregnancy has not been disclosed as required in section 4038.17 of this Part, the claimant shall have the option to void the claim upon written notice to the judges from the claimant or his trainer within 10 days following the date of the claim.

AMEND Rule 4113.3 to add a new paragraph i:

4113.3. Reasons for placing a horse on the steward's list.

A horse shall be placed on the steward's list at each track for the following reasons:

- (a) it has a tube in its throat;
- (b) it is dangerous or unmanageable. Such horse must work out before the judges on the main track, secure permission of the judges to qualify and then qualify in two consecutive qualifying races before release from the steward's list;
- (c) it is sick, lame or unfit to race. Such horse must perform before the State veterinarian and be certified fit to race by the State veterinarian before release from the steward's list;
- (d) it is unable to start satisfactorily behind the starting gate. Such horse must work out behind the starting gate, be approved by the starter and then qualify once before release from the steward's list;
- (e) it has been high nerved;
- (f) it has performed poorly. Such horse shall qualify once before release from the steward's list.
- (g) it has tested positively for a drug. Such horse shall qualify in a workout and thereafter test negative for drugs before release from the steward's list.
- (i) *it has been the subject of a finding by the laboratory that the antibody of erythropoietin or darbepoietin was present in the sample taken from the horse. Such horse shall test negative for the antibodies of erythropoietin or darbepoietin in a test conducted by the laboratory before release from the steward's list.*

THOROUGHBRED:

4043.7 *Reserpine and Fluphenazine*

(a) *Notwithstanding any inconsistent provision of this Part, a finding by the laboratory that the drug reserpine or the drug fluphenazine was present in the sample taken from a horse shall result in the disqualification of the horse from the race and from any share of the purse in the race.*

(b) *The trainer of a horse which has been the subject of a finding by the laboratory that the drug reserpine or the drug fluphenazine was present in the sample taken from that horse shall not be subject to application of trainer's responsibility based solely upon the finding by the laboratory that the drug reserpine or the drug fluphenazine was present in the sample.*

HARNESS:

4120.11 *Reserpine and Fluphenazine*

(a) *Notwithstanding any inconsistent provision of this Part, a finding by the laboratory that the drug reserpine or the drug fluphenazine was present in the sample taken from a horse shall result in the disqualification of the horse from the race and from any share of the purse in the race.*

(b) *The trainer of a horse which has been the subject of a finding by the laboratory that the drug reserpine or the drug fluphenazine was present in the sample taken from that horse shall not be subject to application of trainer's responsibility based solely upon the finding by the laboratory that the drug reserpine or the drug fluphenazine was present in the sample.*

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 29, 2005.

Text of emergency rule and any required statements and analyses may be obtained from: Jennifer A. Whalen, One Watervliet Ave. Ext., Suite

2, Albany, NY 12206-1668, (518) 453-8460, e-mail: info@ racing.state.ny.us

Regulatory Impact Statement

Statutory authority: The Board is authorized to promulgate these rules pursuant to Racing, Pari-Mutuel Wagering and Breeding Law Section 101, 301, and 902. The Board has general jurisdiction over all horse racing and all pari-mutuel wagering activities in New York State. The Board is authorized to promulgate rules necessary to prevent the administration of drugs or other improper acts to racehorses prior to a race. The Legislature has directed that the Board promulgate any rules necessary to implement equine drug testing so that the public's confidence and the high degree of integrity in racing are assured.

Legislative objectives: To enable the New York State Racing and Wagering Board to preserve the integrity of pari-mutuel racing.

Needs and benefits: These rule amendments are necessary to provide an effective mechanism to address and deter the use in the racing horse of the tranquilizers reserpine and fluphenazine, as well as the substances erythropoietin and darbepoietin. Both drugs are being abused in an effort to gain an improper advantage in pari-mutuel racing. The substances erythropoietin and darbepoietin, which stimulate red cell production, are similarly being abused. This information is derived from tests on samples from horses in competition and research conducted by the Board's Equine Drug Testing and Research Program at Cornell University. The Board's existing time-based equine drug rules do not provide effectively for the determination of use or sanctions. The continued and undeterred use of these drugs and substances undermines public confidence in the integrity of racing with corresponding loss of wagering handle. Wagering handle generates significant revenues for the State, municipalities, breeders and tracks. In addition, the continued abuse of the regulated drugs and substances poses a threat to the health of the horse and the safety of both the equine and human participants.

Costs: These rules will impose no new costs for state or local governments. The rule will not impose any new costs on the Racing and Wagering Board for the implementation and continued administration of the rule. The costs of manpower, testing and incidental expenses will be accomplished within existing budget limitations.

These rules will impose no costs upon regulated parties in order to comply with limitations concerning the use of the regulated drugs and substances. The only costs are those associated with the sanctions in the event of non-compliance.

Paperwork: There is no additional paperwork required by or associated with these rule amendments.

Local government mandates: This rule would impose no local government mandates.

Duplication: There are no other state or federal requirements similar to the provisions contained in the rule amendment.

Alternative approaches: There are no other significant alternatives to this rule, which was drafted to accomplish the stated benefits with the least negative impact upon the pari-mutuel racing industry. No action would fail to address the existing problems associated with continued abuse of the drugs and substances that are the subject of these rules.

Federal standards: The rule does not exceed any minimum standards of the federal government because there are no applicable federal rules.

Compliance schedule: Compliance can be accomplished immediately.

Regulatory Flexibility Analysis

1. Effect of Rule: The rules do not apply to and thus will not adversely affect local government. The rules will impact all licensed owners and trainers of racehorses that seek to compete in pari-mutuel racing. There are thousands of such licensed owners and/or trainers. The number of horses owned or trained by such licensees may range from one to hundreds. These individuals operate businesses that generally employ less than one hundred persons.

2. Compliance Requirements: There are no required reporting or recordkeeping requirements for small businesses. There are no professional services that are likely to be needed to comply with these rules. The rules do not impose any technological requirements on the industry. The compliance component of the rules, *i.e.* the exclusion of a horse from pari-mutuel racing competition, is a consequence of the report of a positive test. In that situation, the horse may not participate again until the horse has been retested without a positive result.

3. Professional Services: There are no professional services required to comply with the proposed rules.

4. Compliance Costs: There are few anticipated compliance costs. The licensees should already be monitoring use of drugs and other substances to assure conformity with Board rules. There will be a potential loss of

purse monies associated with the exclusion of horses until a clearance test. This cost cannot be estimated due to the competitive nature of horse racing. During this time there might be lower costs associated with the care of the horse if the horse is not maintained in active training status. The cost of the necessary retest will be borne by the Board.

5. Economic and Technological Feasibility: There are no technological requirements associated with compliance. There should be no costs associated with compliance. Erythropoietin and darbepoietin have no legitimate use in the racing horse and therefore no affirmative compliance requirement exists. The drugs reserpine and fluphenazine are tranquilizers for which alternatives exist. Horsemen may comply with the prohibitions of the rule by use of alternative drugs at an equal or lesser cost.

6. Minimizing Adverse Impact: The Board attempted to minimize adverse impact, consistent with the need to assure public safety and general welfare, by excluding a horse from competition only for the limited period necessary for a negative retest and by providing for limitation of disciplinary sanctions from the otherwise general application of the trainer's responsibility rule.

7. Small Business and Local Government Participation: The Board provided notice of the concepts and general requirements of these rules to various segments of the regulated racing industry. Among those segments were the representative horsemen's associations. These associations (one per track) include most if not all of the small business industry participants (owners and trainers) as members.

Rural Area Flexibility Analysis

1. Types and estimated numbers of rural areas:

The rules will impact all licensed owners and trainers of racehorses that seek to compete in pari-mutuel racing. Many of the licensees affected by these rules are located within "rural areas" as that term is defined in New York State Executive Law Section 481(7). The impact of compliance of those entities located in rural areas should be substantially the same as, if not identical to that in other than rural areas.

2. Reporting, recordkeeping and other compliance requirements:

There are no required reporting or recordkeeping requirements for small businesses. There are no professional services that are likely to be needed to comply with these rules. The rules do not impose any technological requirements. The compliance component of the rules, *i.e.* the exclusion of a horse from pari-mutuel racing competition, is a consequence of the report of a positive test. In that situation, the horse may not participate again until the horse has been retested without a positive result.

3. Costs:

There are few anticipated compliance costs. The licensees should already be monitoring use of drugs and other substances to assure conformity with Board rules. There will be a potential loss of purse monies associated with the exclusion of horses until a clearance test. This cost cannot be estimated due to the competitive nature of horse racing. During this time there might be lower costs associated with the care of the horse if the horse is not maintained in active training status. The cost of the necessary retest will be borne by the Board.

4. Minimizing adverse impact:

As a consequence of the location of horsemen in rural areas, these rules have similar impact on rural areas as on non-rural areas of the State. The geographic location of the horses and horsemen is incidental to the substance of the rule. Consequently, there is no way to design the rule to minimize impact on rural areas.

5. Rural area participation:

The Board provided notice of the concepts and general requirements of these rules to various segments of the regulated racing industry. Among those segments were the representative horsemen's associations. These associations (one per track) include most if not all of the rural area small business industry participants (owners and trainers) as members.

Job Impact Statement

A job impact statement is not submitted with this notice because the New York State Racing & Wagering Board has determined that these rules will not have a substantial adverse impact on jobs and employment opportunities. The area of potential impact is that which will result from the exclusion of a horse from pari-mutuel competition until such time as the horse tests negative for the drug or substance that resulted in the ineligibility to participate. For the drugs reserpine and fluphenazine, it is estimated that the period of exclusion following the reported result of a positive test would be very short. Based upon the facts that these drugs may not be lawfully administered to the horse within one week before the start of the racing program and the typical ten-day period between the collection of a sample and report of a positive test, there should be a relatively short period of exclusion provided the horse is subject to a prompt retest.

Although reserpine and fluphenazine are detectable beyond the one-week period, this situation differs little from the existing situations involving other drugs. Based upon experience, there will be relatively few positive tests and no substantial adverse impact on jobs for industry participants such as trainers and grooms.

For the substances erythropoietin and darbepoietin, it is estimated that the period of exclusion following the reported result of a positive test would range from several weeks to a period in excess of 120 days. However, based upon the results of preliminary testing, which involved approximately 37,000 horses, it is estimated that less than one percent of horses actually tested will test positive. All horses are not subject to post-race testing. Although a single horse may be excluded potentially for a period of several months, most owners and trainers do not race only one horse. Thus there should be no likelihood of substantial adverse impact on jobs due to the temporary exclusion of these horses from racing. Furthermore, these horses will still require care even if not actively training or racing.

The New York State Racing and Wagering Board has made this determination based upon the above information and its knowledge and familiarity with the conduct of pari-mutuel wagering throughout New York State.

Office of Temporary and Disability Assistance

PROPOSED RULE MAKING NO HEARING(S) SCHEDULED

Income Standards for Eligibility for Emergency Assistance for Needy Families with Children

I.D. No. TDA-46-04-00006-P

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

Proposed action: Amendment of section 372.2(a)(2) of Title 18 NYCRR.

Statutory authority: Social Services Law, sections 20(3)(d), 34(3)(f), 131(1), 350-j and 355(3)

Subject: Income standards for eligibility for emergency assistance for needy families with children (EAF).

Purpose: To establish an objective income standard that will be used by social services districts when determining eligibility for EAF.

Text of proposed rule: Paragraph (2) of subdivision (a) of section 372.2 is amended to read as follows:

(2) the child is without *available income* or resources immediately accessible to meet his or her needs and those needs cannot be met under Part 352 of this Title by an advance allowance *and the household's available income on the date of application is at or below 200 percent of the current federal poverty level for that household size (the Federal Office of Management and Budget defines and annually revises federal income official poverty lines in accordance with section 673(2) of the Omnibus Budget Reconciliation Act of 1981 [P.L. 97-35]), or the household is financially eligible to receive public assistance in accordance with Part 352 of this Title or, for households in receipt of child protective, child preventive or other child welfare services, at least one member of the household is in receipt of public assistance or Supplemental Security Income;*

Text of proposed rule and any required statements and analyses may be obtained from: Ronald Speier, Office of Temporary and Disability Assistance, 40 N. Pearl St., Albany, NY 12243, (518) 474-6573

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

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

Regulatory Impact Statement

1. Statutory Authority:

Section 20(3)(d) of the Social Services Law (SSL) authorizes the Department of Social Services to promulgate regulations to carry out its powers and duties. Section 122 of Part B of Chapter 436 of the Laws of 1997 reorganized the Department of Social Services into the Department of Family Assistance with two distinct offices, the Office of Children and

Family Services and the Office of Temporary and Disability Assistance (OTDA). The functions of the former Department of Social Services concerning public assistance programs were transferred by Chapter 436 to OTDA.

Section 34(3)(f) of the SSL requires the Commissioner of the Department of Social Services to establish regulations for the administration of public assistance within the State. Section 122 of Part B of Chapter 436 of the Laws of 1997 provides that the Commissioner of the Department of Social Services will serve as the Commissioner of OTDA.

Section 131(1) of the SSL requires social services officials, insofar as funds are available therefore, to provide adequately for those unable to maintain themselves, in accordance with the requirements of the SSL.

Section 350-j of the SSL provides that social services districts, insofar as federal funds are available therefore, must provide emergency assistance to needy families with children (EAF).

Section 355(3) of the SSL requires OTDA to promulgate regulations necessary for the carrying out of the provisions of the EAF program.

2. Legislative Objectives:

It was the intent of the Legislature in enacting the above statutes that OTDA establish rules, regulations and policies to ensure that public assistance is provided to eligible persons who are unable to provide for themselves so that, whenever possible, such persons can be restored to a condition of self-support and self-care.

3. Needs and Benefits:

The proposed amendment would require social services districts to use an objective income standard when determining eligibility for EAF. This requirement is consistent with the terms of the acknowledged as complete State Plan submitted to the Department of Health and Human Services for the Temporary Assistance for Needy Families Program (TANF). Families who lose eligibility for TANF-funded assistance due to the State's 60-month time limit remain eligible for EAF because the federal government defines payments made under EAF as non-assistance. The 200 percent standard is a rational number to use since these same families are eligible for TANF-funded services under the TANF block grant if their incomes are at or below 200 percent of the federal poverty level and the 200 percent level is used by social services districts to determine eligibility for other public assistance programs.

The federal government has accepted the 200 percent standard since it acknowledged as complete the EAF State plan that contained that standard. In addition, the social services districts have been using the 200 percent standard since November 2002. The standard would be the basis for auditing the State's EAF cases. The federal government stated that without an objective income standard, our EAF State plan would not be accepted. The 200 percent standard selected does not significantly alter the delivery of EAF and satisfies the federal audit requirement.

4. Costs:

Social services districts throughout the State have been informed of the income standard contained in the proposed amendment; the districts are currently using that standard when determining eligibility for EAF. Therefore, the amendment is expected to have no fiscal impact.

5. Local Government Mandates:

The proposed amendment will not impose any new mandates on social services districts.

6. Paperwork:

There will be no new forms or new reporting requirements due to this change.

7. Duplication:

The proposed amendment does not duplicate, overlap or conflict with any existing State or federal regulations.

8. Alternatives:

The only alternative would be not to make the proposed change to the eligibility standards for the EAF Program. This alternative was rejected since to do so would make the Office's regulations inconsistent with its TANF State Plan.

9. Federal Standards:

The proposed amendment does not exceed federal minimum standards for the same subject.

10. Compliance Schedule:

Social services districts have already implemented the proposed amendment.

Regulatory Flexibility Analysis

1. Effect of rule:

The proposed amendment would not have any impact on small businesses in the State. The amendment would need to be implemented by the 58 social services districts in the State.

2. Compliance requirements:

The proposed amendment would require social services districts in the State to apply an objective income standard when determining eligibility for Emergency Assistance to Needy Families with Children. This requirement is consistent with the terms of the acknowledged as complete State Plan submitted to the Department of Health and Human Services for the Temporary Assistance for Needy Families Program.

3. Professional services:

No new professional services will be needed by the social services districts in order for them to comply with the proposed amendment.

4. Compliance costs:

The proposed amendment will not require the social services districts to incur any initial capital costs. The districts will not be required to incur any costs for continuing compliance with the proposed amendment.

5. Economic and technological feasibility:

Social services districts have the economic and technological feasibility to implement the proposed amendment.

6. Minimizing adverse impact:

The proposed amendment will not have an adverse economic impact on social services districts in the State.

7. Small business and local government participation:

Every social services district in the State has been informed of the proposed amendment and no objections have been expressed.

Rural Area Flexibility Analysis

1. Type and estimated numbers of rural areas:

The proposed amendment will affect the 44 rural social services districts in the State.

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

The proposed amendment would require social services districts in rural areas to apply an objective income standard when determining eligibility for Emergency Assistance to Needy Families with Children. This requirement is consistent with the terms of the acknowledged as complete State Plan submitted to the Department of Health and Human Services for the Temporary Assistance for Needy Families Program.

No new professional services, reporting or recordkeeping requirements will be imposed on the social services districts in rural areas in order for those districts to comply with the proposed amendment.

3. Costs:

The proposed amendment will not require the social services districts to incur any initial capital costs. The districts will not be required to incur any costs for continuing compliance with the proposed amendment.

4. Minimizing adverse impact:

The proposed amendment will not have an adverse economic impact on social services districts in rural areas.

5. Rural area participation:

Every social services district in the State has been informed of the proposed amendment and no objections have been expressed.

Job Impact Statement

A job impact statement has not been prepared for the proposed regulations. It is evident from the subject matter of the regulations that the job of the worker making the decision in the local social services district will not be affected in any real way. Thus, these changes will not have any impact on jobs and employment opportunities in the State.