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

Asian Long Horned Beetle Quarantine

I.D. No. AAM-31-03-00004-E
Filing No. 1229
Filing date: Nov. 4, 2003
Effective date: Nov. 4, 2003

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

Action taken: Amendment of Part 139 of Title 1 NYCRR.

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

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

Specific reasons underlying the finding of necessity: The Asian Long Horned Beetle, Anoplophora glabripennis, an insect species non-indigenous to the United States, was detected in the Greenpoint section of Brooklyn, New York in August of 1996. Subsequent survey activities delineated other locations in and about Amityville, Queens and Manhattan. As a result, 1 NYCRR Part 139 was adopted, establishing a quarantine of the areas in which the Asian Long Horned Beetle had been observed. The boundaries of those areas are described in 1 NYCRR section 139.2. Subsequent observations of the beetle have resulted in a need to modify the boundaries of the quarantine areas in Brooklyn and Queens described in 1 NYCRR section 139.2. This rule contains the needed modifications. This rule also amends 1 NYCRR section 139.3(b)(1) to add Celtis (Hackberry), Fraxinus (Ash), Platanus (Plane tree, Sycamore) and Sorbus (Mountain Ash) to the list of regulated host materials subject to regulation under the quarantine. These materials have been found to be subject to infestation by the Asian Long Horned Beetle. Finally, this rule deletes Hibicus Syriacus L. (Rose of Sharon), Malus (Apple), Melia (Chinaberry), Morus (Mulberry), Prunus (Cherry), Pyrus (Pear), Robinia (Locust) and citrus from the list of regulated host materials subject to regulation under the quarantine. The United States Department of Agriculture (USDA) has tested and determined that these species are not a host to the Asian Long Horned Beetle. The Asian Long Horned Beetle (ALB) is a destructive wood-boring insect native to China, Japan, Korea and the Isle of Hainan. It can cause serious damage to healthy trees by boring into their heartwood and eventually killing them. The adult Asian Long Horned Beetle has a large body (1 to 1¼ inches in length) with very long antenna (1.3-2.5 times their body length). Its body is black with white spots and its antenna are black and white. Adult beetles emerge during the spring and summer months from large (⅜ inch in diameter) round holes anywhere on infested trees, including branches, trunks and exposed roots, leaving large piles of course sawdust around the base of the trees or where the branches meet the main stem. They fly for two or three days, during which they feed and mate. To lay eggs, adult females make grooves on branches where new shoots arise (crotch). The larvae bore into and feed on the interior of the trees, where they over-winter. One generation is produced each year. Nursery stock, logs, green lumber, firewood, stumps, roots, branches and debris of a half inch or more in diameter are subject to infestation. Host hardwood materials at risk to attack and infestation include species of the following: Acer (Maple); Aesculus (Horse Chestnut), Albizzia (Silk Tree or Mimosa); Betula (Birch); Populus (Poplar); Salix (Willow); and Ulmus (Elm); Celtis (Hackberry), Fraxinus (Ash), Platanus (Plane tree, Sycamore) and Sorbus (Mountain Ash).

Since the Asian Long Horned Beetle is not considered established in the United States, the risk of moving infested nursery stock, logs, green lumber, firewood, stumps, roots, branches and debris of a half inch or more in diameter poses a serious threat to the hardwood forests and street, yard, park and fruit trees of the State. Approximately 858 million susceptible trees above 5 inches in diameter involving 62 percent (18.6 million acres) of the State's forested land are at risk. If the Asian Long Horned Beetle infestation were to expand beyond Manhattan, Brooklyn and Queens, the magnitude of the resulting damage could far exceed that of any previous insect infestation, including that involving the gypsy moth.

In 2001, approximately 25,000 trees were treated with Imidacloprid, a systemic insecticide. Control of the Asian Long Horned Beetle is accomplished by the removal of infested host trees and materials and then chipping or burning them. Survey and pesticides do not presently appear to be effective methods of controlling this pest. As a result, the quarantine imposed by this rule has been determined to be the most effective means of preventing the spread of the Asian Long Horned Beetle. It will help to ensure that as control measures are undertaken in the areas the Asian Long Horned Beetle currently infests, it does not spread beyond those areas via the movement of infested trees and materials.

The effective control of the Asian Long Horned Beetle within the limited areas of the State where this insect has been found is also important to protect New York's nursery and forest products industry. The failure of states to control insect pests within their borders can lead to federal

quarantines that affect all areas of those states, rather than just the infested portions. Such a widespread federal quarantine would adversely affect the nursery and forest products industry throughout New York State.

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 modify the quarantine area and restrict the movement of trees and materials from the areas of the State infested with Asian Long Horned Beetle could result in the spread of the pest beyond those areas and damage to the natural resources of the State and could result in a federal quarantine and quarantines by other states and foreign countries affecting the entire State. This would cause economic hardship to the nursery and forest products industries of the 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 Asian Long Horned Beetle beyond the areas currently infested and the detrimental consequences that would have, it appears that the rule modifying the quarantine area 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: Asian Long Horned Beetle quarantine.

Purpose: To modify the Asian Long Horned Beetle quarantine to prevent the spread of the beetle to other areas, to add four species (Celtis, Fraxinus, Platanus and Sorbus) to the list of regulated host materials subject to regulation under the quarantine and to delete eight species from that list.

Text of emergency rule: Subdivision (a) of Section 139.2 of Title 1 of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended to read as follows:

(a) That area in the boroughs of Manhattan, Brooklyn and Queens in the City of New York and bounded by a line beginning at a point where the Brooklyn Battery Tunnel intersects the Manhattan shoreline of the East River, then west and north along the shoreline of the Hudson River to its intersection with Martin Luther King Jr. Boulevard, then east along Martin Luther King Jr. Boulevard and across the Triborough Bridge to its intersection with the west shoreline of Randall's and Ward's Island, then east and south along the shoreline of Randall's and Ward's Island to its intersection with the Triborough Bridge, then east along the Triborough Bridge to its intersection with the Queens shoreline, then north and east along the Queens shoreline to its intersection with the City of New York and Nassau County line, then southeast along the City of New York and Nassau County line to its intersection with the Grand Central Parkway, then west along the Grand Central Parkway to its intersection with the Jackie Robinson Parkway, then west along the Jackie Robinson Parkway to its intersection with [Woodhaven Boulevard, then south along Woodhaven Boulevard to its intersection with Atlantic Avenue, then west along Atlantic Avenue to its intersection with the Eastern Parkway Extension, then south, and west along the Eastern Parkway Extension and Eastern Parkway to its intersection with Grand Army Plaza, then west along the south side of Grand Army Plaza to its intersection with Union Street then west along Union Street to its intersection with Van Brunt Street, then south along Van Brunt Street to its intersection with Hamilton Avenue and the] *Park Lane, then south along Park Lane to its intersection with Park Lane South, then south and west along Park Lane South to its intersection with 112th Street, then south along 112th Street to its intersection with Atlantic Avenue, then west along Atlantic Avenue to its intersection with 106th Street, then south along 106th Street to its intersection with Liberty Avenue, then west along Liberty Avenue to its intersection with Euclid Avenue then south along Euclid Avenue to its intersection with Linden Boulevard, then west along Linden Boulevard to its intersection with Caton Avenue, then west on Caton Avenue to its intersection with Prospect Expressway, then north and west along Prospect Expressway to its intersection with the Gowanus Expressway, then north and west along the Gowanus Expressway to its intersection with the* Brooklyn Battery Tunnel, then north along Hamilton Avenue and the Brooklyn Battery Tunnel to its intersection with the East River, then north along the Brooklyn Battery Tunnel across the East River to the point of beginning.

Paragraph 1 of subdivision (b) of section 139.3 of Title 1 of the Official Codes, Rules and Regulations of the State of New York is amended to read as follows:

(1) Firewood (all hardwood species) and all host material living, dead, cut or fallen, inclusive of nursery stock, logs, green lumber, stumps, roots, branches and debris of a half inch or more in diameter of the following genera: Acer (Maple); Aesculus (Horse Chestnut); Albizzia (Silk Tree or Mimosa); Betula (Birch); [Hibicus syriacus L. (Rose of Sharon); Malus (Apple); Melia (Chinaberry); Morus (Mulberry);] Populus (Poplar); [Prunus (Cherry); Pyrus (Pear); Robinia (Locust);] Salix (Willow); Ulmus (Elm) [and citrus]*; Celtis (Hackberry); Fraxinus (Ash); Platanus (Plane Tree, Sycamore) and Sorbus (Mountain Ash)* are regulated articles.

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 2, 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, One Winners Circle, 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 proposed modification of the quarantine accords with the public policy objectives the Legislature sought to advance by enacting the statutory authority in that it will help to prevent the spread within the State of an injurious insect, the Asian Long Horned Beetle.

3. Needs and benefits:

The Asian Long Horned Beetle, Anoplophora glabripennis, an insect species non-indigenous to the United States was detected in the Greenpoint section of Brooklyn, New York in August of 1996. Subsequent survey activities delineated other locations in and about Amityville, Queens and Manhattan.

As a result, 1 NYCRR Part 139 was adopted, establishing a quarantine of the areas in which the Asian Long Horned Beetle had been observed. The boundaries of those areas are described in 1 NYCRR section 139.2. Subsequent observations of the beetle have resulted in a need to modify the boundaries of the quarantine areas in Brooklyn and Queens described in 1 NYCRR section 139.2. This rule contains the needed modifications. This rule also amends 1 NYCRR section 139.3(b)(1) to add Celtis (Hackberry), Fraxinus (Ash), Platanus (Plane tree, Sycamore) and Sorbus (Mountain Ash) to the list of regulated host materials subject to regulation under the quarantine. These materials have been found to be subject to infestation by the Asian Long Horned Beetle. Finally, this rule deletes Habicus Syriacus L. (Rose of Sharon), Malus (Apple), Melia (Chinaberry), Morus (Mulberry), Prunus (Cherry), Pyrus (Pear), Robinia (Locust) and cirtus from the list of regulated host materials subject to regulation under the quarantine. The United States Department of Agriculture (USDA) has tested and determined that these species are not a host to the Asian Long Horned Beetle.

4. Costs:

(a) Costs to the State government:

None.

(b) Costs to local government:

None.

(c) Costs to private regulated parties:

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

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

Tree removal services must chip host material or transport such material under a limited permit to a federal/state disposal site for processing.

Firewood from hardwood species within the quarantined area may not move outside that area due to the fact that it is not practical at this time to determine for certification purposes that the material is free from infestations.

The modification of the quarantine area in the borough of Brooklyn will affect one nursery located within the area.

The modification of the list of regulated host materials subject to infestation by the Asian Long Horned Beetle will affect fewer than 100 nurseries, arborists, tree removal services and firewood dealers located within all the quarantined areas.

(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:

Yard waste, storm clean-up and normal tree maintenance activities involving twigs and/or branches of ½" or more in diameter of host species will require proper handling and disposal, *i.e.,* chipping and/or incineration if such materials are to leave the area under quarantine. An effort is underway to identify centralized disposal sites that would accept such waste from cities, villages and other municipalities at no additional cost.

6. Paperwork:

Regulated articles inspected and certified to be free of Asian Long Horned Beetle moving from quarantined area must be accompanied by a state or federal phytosanitary certificate of a limited permit or be undertaken pursuant to a compliance agreement.

7. Duplication:

None.

8. Alternatives:

The failure of the State to modify the proposed quarantine to reflect the areas in which the Asian Long Horned 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. It could also place the State's own natural resources (forest, urban and agricultural) at risk from the spread of Asian Long Horned Beetle that could result from the unrestricted movement of regulated articles from the areas covered by the modified quarantine. In light of these factors there does not appear to be any viable alternative to the modification of quarantine proposed in this rulemaking.

9. Federal standards:

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

10. Compliance schedule:

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

Regulatory Flexibility Analysis

1. Effect on small business:

The small businesses affected by the changes in the quarantined area are the nurseries, arborists, tree removal services and firewood dealers located within that modified quarantined area. It is estimated that there is one such business within that area. The local governments involved in that modification of the boundaries of the quarantine areas are the City of New York and the boroughs of Brooklyn and Queens.

The small businesses affected by the changes to the list of regulated host materials subject to infestation by the Asian Long Horned Beetle are the nurseries, arborists, tree removal services and firewood dealers located within all the quarantined areas. It is estimated that there are fewer than 100 such businesses within these quarantined areas. The local governments involved are the City of New York, and the boroughs of Brooklyn, Queens and Manhattan.

Although it is not anticipated that local governments will be involved in the shipment of regulated articles from the quarantine area, in the event that they do, they would be subject to the same quarantine requirements as other regulated parties.

2. Compliance requirements:

All regulated parties in the modified quarantined areas will be required to obtain 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 proposed rule small businesses and local governments shipping regulated articles from the modified quarantined areas will require professional inspection services, which will be provided by the Department and the USDA.

4. Compliance costs:

(a) Initial capital costs that will be incurred by a regulated business or industry or local government in order to comply with the proposed rule:

None.

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

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

Tree removal services must chip host material or transport such material under a limited permit to a federal/state disposal site for processing.

Firewood from hardwood species within the quarantined area may not move outside that area due to the fact that it is not practical at this time to determine for certifications purposes that the material is free from infestation.

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

5. Minimizing adverse impact:

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

6. Small business and local government participation:

The Department has contacted various representatives of nurseries, arborists, the forestry industry, and local government to discuss the quarantine. It has also had extensive consultation with the United States Department of Agriculture.

The Department is involved in a continuing outreach program involving all of the parties affected by the rule. The quarantine has been discussed with the members of the Department's Plant Industry Advisory Committee, which includes representatives of the various types of regulated parties affected by the rule. In addition, a press release was issued at the time the original quarantine was imposed announcing the steps the State is taking to address the problem presented by the Asian Long Horned Beetle. Department representatives also attended a public meeting in Brooklyn, New York at which these issues were discussed and input was received. This outreach program will continue.

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

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

Rural Area Flexibility Analysis

The rule will not impose any adverse impact or reporting, recordkeeping or other compliance requirements on public or private entities in rural areas. This finding is based upon the fact that the modified quarantine area and the addition of species to the list of regulated host materials subject to regulation under the quarantine imposed by the rule, is limited to portions of the Boroughs of Manhattan, Brooklyn and Queens in the City of New

York, areas which do not fall within the definition of rural areas set forth in section 481(7) of the Executive Law.

Job Impact Statement

The rule will not have a substantial adverse impact on jobs and employment opportunities. The modification of the quarantine area and the addition of species to the list of regulated host materials subject to regulation under the quarantine, are designed to prevent the spread of the Asian Long Horned Beetle to other parts of the State. A spread of the infestation would have very adverse economic consequences to the nursery, forestry, fruit and maple product industries of the 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, other states and foreign countries. By helping to prevent the spread of the Asian Long Horned Beetle, the rule will help to prevent such adverse economic consequences and in so doing, protect the jobs and employment opportunities associated with the State's nursery, forestry, fruit and maple product industries.

Forest related activities in New York State provide employment for approximately 122,400 people. Of that number, 73,740 jobs are attributable to forest-based recreation and approximately 48,670 jobs are associated with the wood-based forest economy, including manufacturing. The forest-based economy generates payrolls of more than $1.789 billion with $1.133 billion attributable to forest-based manufacturing and $655.3 million for forest recreation. Forest-based economic activity accounts for 2% of New York's employment and 1% of the State's payroll. Wood energy also makes an important contribution to the State's economy. In 1985, wood energy accounted for 3,647 direct jobs and $78.4 million in direct income.

The nursery industry employed 6,011 persons in New York State in 1985. Approximately $40.1 million in wages were paid by the industry. As set forth in the regulatory impact statement, the cost of the rule to regulated parties is relatively small. The responses received during the Department's outreach to regulated parties indicate that the rule will not have a substantial adverse impact on jobs and employment opportunities.

Assessment of Public Comment

The agency received no public comment.

Department of Audit and Control

REVISED RULE MAKING NO HEARING(S) SCHEDULED

Budgets and Financial and Strategic Operation Plans of the Metropolitan Transportation Authority

I.D. No. AAC-36-03-00004-RP

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

Revised action: Addition of Part 202 to Title 2 NYCRR.

Statutory authority: New York State Constitution, art. X, section 5; Finance Law, section 8(14)

Subject: Budgets and financial plans, and strategic operation plans, of the Metropolitan Transportation Authority (MTA).

Purpose: To prescribe specific requirements for the format of the MTA's budget, financial plan and certain financial information in its strategic operation plan, the documentation to be prepared with release of the budgets and financial plans and the periodic monitoring and reporting required during each fiscal year in connection with the budgets and financial plans.

Text of revised rule:

PART 202

Budget and Financial and Strategic Operation Plan Format, Supporting Documentation and Monitoring - Metropolitan Transportation Authority (Statutory Authority: Constitution, article X, section 5; State Finance Law section 8[14])

202.1 Purpose and Applicability of Part. This Part shall apply to the Metropolitan Transportation Authority, created pursuant to title 11 of article 5 of the Public Authorities Law (section 1260 et seq.). The purpose of this Part is to set forth specific requirements in connection with the format of, the preparation and maintenance of supporting documentation for, and the monitoring of, the annual budgets and financial plans, and the format of certain financial information in strategic operation plans, of the Metropolitan Transportation Authority. All requirements of this Part shall apply immediately upon the effective date of this Part, except as otherwise consented to by the Comptroller at the request of the Metropolitan Transportation Authority upon good cause shown.

202.2 Definitions. For purposes of the Part:

a. "MTA" shall mean the Metropolitan Transportation Authority, created by title 11 of article 5 of the Public Authorities Law (section 1260 et seq.), as amended.

b. "MTA Affiliates" shall mean the Triborough Bridge and Tunnel Authority, and the New York City Transit Authority and its subsidiary, the Manhattan and Bronx Surface Transit Operating Authority.

c. "MTA Subsidiaries" shall mean the Long Island Rail Road Company, the Metro-North Commuter Railroad Company, the Staten Island Rapid Transit Operating Authority, the Metropolitan Suburban Bus Authority, the MTA Capital Construction Company and the First Mutual Transportation Assurance Company, together with all other subsidiary corporations formed by the MTA in accordance with the provisions of section 1266(5) of the Public Authorities Law.

d. "MTA Headquarters" shall mean the budgetary component within the MTA that provides for certain centralized functions, such as budgeting, cash management, finance and legal services.

e. "MTA Agencies" shall mean MTA Headquarters, MTA Affiliates and MTA Subsidiaries.

f. "Budget" shall mean the preliminary, proposed final and final operating budgets of the MTA and each of the MTA Agencies.

g. "Plan" shall mean the financial plan for the MTA and each of the MTA Agencies, and any updates.

h. "Gap" shall mean the difference between projected revenues and expenses for any given fiscal year before a proposed fare increase or other proposed management actions that increase revenues or reduce costs.

i. "Gap-closing program" shall mean any combination of management actions that reduce costs or increase revenues that lower a gap in any given fiscal year.

j. "Utilization" shall mean subway, bus, railroad and paratransit ridership, and bridge and tunnel crossings.

k. "Reimbursable" shall mean costs and expenses that are funded by capital funds.

l. "Capital Program Review Board" shall mean the Metropolitan Transportation Authority Capital Program Review Board created by section 1269-a of the Public Authorities Law.

202.3 Budget and Plan Format. Each Budget and Plan shall: (a) be prepared so that information relating to the MTA and each of the MTA Agencies is presented in a consistent manner and format; (b) be prepared in accordance with generally accepted accounting principles, except as otherwise consented to by the Comptroller upon good cause shown; (c) be based on reasonable assumptions and methods of estimation; (d) include estimates of projected operating revenues and other operating funding sources (including but not limited to fares, tolls, taxes and governmental subsidies); (e) include estimates of projected reimbursable and non-reimbursable personal service operating expenses, including but not limited to salary and wage costs, overtime, health insurance and pension costs; (f) include estimates of projected reimbursable and non-reimbursable non-personal service operating expenses, including but not limited to power, fuel, public liability, insurance, materials and supplies, contract services and depreciation; (g) include estimates of projected debt service to finance the capital program approved by the Capital Program Review Board or any amendment proposed by the MTA to the approved capital program; (h) include estimates of projected debt service to finance capital needs that extend beyond the approved capital program or any amendment proposed by the MTA to the approved capital program; (i) include estimates of projected debt service for all other capital projects, such as projects for the Triborough Bridge and Tunnel Authority, to be funded during the Plan period in whole or in part by borrowings; (j) identify any planned transactions that would shift resources, from any source, from one year to another, and the amount of any reserves; (k) except in the case of the Triborough Bridge and Tunnel Authority, include a corresponding cash Budget and Plan, and identify all cash adjustments, in excess of $500,000, including but not limited to debt service, taxes and government subsidies; (l) be accompanied by a certification by the Executive Director of the MTA to the effect that, to the best of his or her knowledge and belief after

reasonable inquiry, the Budget or Plan, as the case may be, is based on reasonable assumptions and methods of estimation and that the requirements of sections 202.3 and 202.4 of this regulation have been satisfied.

202.4 Supporting Documentation. The MTA shall prepare working papers that detail the assumptions and methods of estimation used to calculate all operating and capital budget projections, consistent with prudent budgetary practices. The working papers shall be completed contemporaneously with the release of its Budgets and Plans and shall include a statement supporting the reasonableness of each estimate, and the underlying information on which the estimate is based, such as actual results from prior years, inflationary trends and economic data, assumptions regarding the cost of future collective bargaining agreements, utilization, demographic and other pertinent data. The MTA also shall prepare and make available for public inspection with the release of its Budgets and Plans: (a) a reconciliation that identifies all changes in estimates, in excess of $500,000, from the projections in the previous Budget or Plan (the reconciliation shall identify changes in operating revenues and receipts, expenses and disbursements, gap-closing programs, collective bargaining costs, staffing levels and other changes as may be necessary); (b) a projection of the number of employees to be employed by the MTA and each of the MTA Agencies covered in the Plan, including (1) whether the sources of funding such employees' salaries and benefits are reimbursable or non-reimbursable, (2) numbers of full-time and full-time equivalents, and (3) functional classification (e.g., operating, maintenance, administrative); (c) a statement of each revenue-enhancement and cost-reduction initiative that represents a component of any gap-closing program and the annual impact on each revenue and expense category, including the estimated impact on staffing, whether any positions to be eliminated are vacant or filled and whether the reduction will occur through attrition, layoff or other action; (d) a statement of the source and amount of any non-recurring receipt or savings in excess of $1,000,000 that is planned for use in any given fiscal year; (e) in the case of the Plan, a debt affordability statement showing the budgetary impact of planned borrowings for each year of the Plan consisting of the following: (1) an estimated debt service schedule for each year of the Plan, (2) the estimated principal amount of each year's borrowings and assumed interest rate(s), (3) projected debt service for each credit (other than borrowings secured solely by State service contract payments), as a percentage of total pledged revenues, and (4) cumulative debt service (other than borrowings secured solely by State service contract payments), as a percentage of each of the following: (i) operating revenues and government subsidies, (ii) fare and toll revenues, and (iii) non-reimbursable expenses; (f) in the case of the Plan, a statement of the annual projected capital costs by capital element (e.g., "rolling stock and buses") and sources of funding for each year of the Plan, and for each capital project, a statement projecting the annual commitment, total project cost, expected date of completion and an estimate of the annual cost for operating and maintaining those capital projects or capital elements that, when placed into service, are expected to have an impact of $1 million or more on the operating budget.

202.5 Monitoring the Budget and Plan. The MTA shall prepare and make available for public inspection one or more reports on the following: (a) within sixty days of the release of the adopted Budget and any updates to the Budget (except any updates released within 90 days of the close of the current fiscal year): (1) monthly projections for the current fiscal year of all revenues and expenses, in a format consistent with the Budget and Plan, (2) monthly projections for the current fiscal year of all receipts and disbursements, in a format consistent with the Budget and Plan, (3) monthly projections for the current fiscal year of staffing for the MTA and each of the MTA Agencies, in a format consistent with section 202.4 (b), and (4) monthly projections for the current fiscal year of utilization for each of the MTA Agencies that operate transportation systems, including bridges and tunnels; (b) within sixty days after the close of each month, in a format consistent with the Budget and Plan: (1) a comparison of actual revenues and expenses to planned levels for each of the MTA Agencies, explaining and quantifying variances that are due to timing or have a budgetary impact, (2) a comparison of actual receipts and disbursements to planned levels for each of the MTA Agencies, explaining and quantifying variances that are due to timing or have a budgetary impact, (3) a comparison of actual staffing to planned levels for the MTA and each of the MTA Agencies, explaining and quantifying variances that are due to timing or have a budgetary impact, and (4) a comparison of actual utilization to planned levels for each of the MTA Agencies that operate transportation systems, including bridges and tunnels, with an explanation of any variance and budgetary impact; (c) each quarter, until implemented or rescinded, the status of each gap-closing initiative with a projected value equal to or greater than $1,000,000 in any given fiscal year including milestones, impact on staffing, current implementation status, actual savings or revenues to date and projected annual savings or revenues in comparison to Budget and Plan projections. (The MTA, with the consent of the State Comptroller, may limit reporting to the largest initiatives that comprise 90 percent of the value of the agency gap-closing program); (d) each month, transfers to or from the corporate and stabilization accounts, interagency loans and other reserves or accounts; (e) each month, the status of capital projects by capital element, including but not limited to commitments, expenditures and completions, and an explanation of material variances from the Plan, cost overruns and delays.

202.6 Strategic Operation Plan. Financial information required to be submitted by the MTA pursuant to paragraphs (d) and (e) of subdivision (1) of section 1269-d of the Public Authorities Law for operating resources and costs shall be presented in a format consistent with the Budget and Plan.

Revised rule compared with proposed rule: Substantial revisions were made in sections 202.1, 202.2, 202.3, 202.4, 202.5 and 202.6.

Text of revised proposed rule and any required statements and analyses may be obtained from: Mitch Morris, Department of Audit and Control, 110 State St., 14th Fl., Albany, NY 12236, (518) 473-4138, e-mail: mmorris@osc.state.ny.us

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

Public comment will be received until: 30 days after publication of this notice.

Revised Regulatory Impact Statement

1. Statutory Authority: Article X, section 5 of the State Constitution provides that the accounts of certain public corporations created by special act of the Legislature (such as the Metropolitan Transportation Authority [the "MTA"]) shall be subject to the supervision of the State Comptroller. This constitutional grant has been interpreted by the Court of Appeals to be entirely discretionary to the Comptroller, who is to be guided by his personal responsibility and commitment to his oath of office. State Finance Law, section 8(14) authorizes the Comptroller to make, amend and repeal rules and regulations as he may deem necessary in the performance of the duties imposed upon him by law.

2. Legislative Objectives: The proposed rule will represent an exercise of the Comptroller's discretionary authority to supervise the accounts of the MTA by prescribing requirements for the clear and open presentation of its budgets and financial plans, and the format of certain financial information in its strategic operation plan, including the preparation of supporting documents underlying budget and financial plan assumptions and methods of estimation, and requiring an on-going review and oversight of financial condition by the monitoring of and reporting on the status of the budget and financial plans during the fiscal year.

3. Needs and Benefits: A report issued by the State Comptroller in April 2003 concerning the MTA's finances noted the need for improved presentation, documentation and monitoring of MTA budget and financial plan information to ensure an open and clear process for the benefit of taxpayers, the riding public and other stakeholders. The proposed rule implements recommendations made in the report. The improved format, documentation, monitoring and reporting requirements in this proposed regulation will benefit the taxpayers, riding public and other MTA stakeholders by ensuring that appropriate financial information is provided to facilitate an open budget and plan process.

4. Costs: None. Information that would be required by the proposed regulation is already prepared internally by the MTA. Moreover, the MTA is currently implementing changes to its budgetary processes that would facilitate compliance with this rule.

5. Local Government Mandates: None.

6. Paperwork: The proposed rule would require reporting on budget and plan progress during each fiscal year by the MTA. It would also require the preparation of supporting documentation with the MTA's budget and financial plan. Both paperwork requirements are needed to ensure full, open and clear disclosure of the MTA's budget and plan information for the benefit of taxpayers, the riding public and other MTA stakeholders.

7. Duplication: None.

8. Alternatives: None.

9. Federal Standards: None.

10. Compliance Schedule: This regulation is effective upon adoption and filing. All requirements will apply to the MTA immediately upon the effective date, except as otherwise consented to by the Comptroller at the request of the MTA upon good cause shown. It is expected that most of the budget and plan monitoring provisions of the regulation can be complied

with beginning immediately upon the effective date. Provisions with respect to the preparation of budgets and plans will be applicable beginning with the MTA's next budget and plan after the effective date of the regulation.

Regulatory Flexibility Analysis and Rural Area Flexibility Analysis

Changes made to the original published proposed rule do not necessitate revision to the previously published Regulatory Flexibility Analysis or Rural Area Flexibility Analysis.

Summary of Assessment of Public Comment

The Office of the State Comptroller ("OSC") received two written comments concerning the proposed rule within the comment period, after the Notice of Proposed Rule Making was published on September 10, 2003.

One comment was favorable, indicating support for the proposed rule. No response was made to this comment in the Assessment of Public Comment ("Assessment"). A second comment was received from the Metropolitan Transportation Authority ("MTA"). The MTA expressed a number of concerns and offered some suggested changes to the proposed rule.

The MTA raised concerns with respect to the timing of the implementation of certain aspects of the proposed rule. The proposed rule was revised to provide that all its requirements will apply immediately, except as otherwise consented to by the Comptroller at the request of the MTA upon good cause shown. The MTA also suggested several definitional changes. Revisions were made to address several of the suggested changes. OSC believes the suggested changes not made are adequately covered in the proposed rule as revised.

The MTA suggested eliminating the requirement that its Budgets and Plans be prepared in accordance with generally accepted accounting principles ("GAAP"). The proposed rule was revised to require preparation in accordance with GAAP except as otherwise consented to by the Comptroller upon good cause shown. The Assessment notes that OSC believes that MTA Budgets and Plans should be prepared on a GAAP basis, consistent with its audited financial statements.

The MTA also expressed concern with respect to identifying the planned use of certain specific reserves. The proposed rule was revised to provide that only the amounts of reserves be identified in the Budget and Plan, but that working papers detail the planned uses. Access by the public to the working papers would be provided in accordance with applicable laws. The Comptroller would have access to all working papers pursuant to his constitutional and statutory authority. In response to MTA comments, the proposed rule was also revised, in connection with debt service projections, to include certain agencies not covered by the capital program approved by the Capital Program Review Board and to allow the MTA to base projections on a proposed amendment to the capital program.

In the case of several requirements in the proposed rule, the MTA suggested that materiality thresholds be added. The proposed rule has been revised to add such thresholds in a number of instances. Certain suggested clarifications in connection with the debt affordability statement were also made. In connection with the requirement to identify gap-closing initiatives, however, the Assessment notes that OSC believes the MTA should identify all such initiatives. In addition, OSC believes that it is not appropriate to provide a threshold for the preparation of working papers. The proposed rule was revised to permit quarterly reporting of gap-closing initiatives and, with the consent of the Comptroller, limit reporting to those initiatives that comprise 90% of the gap-closing program for the MTA Agencies.

The MTA suggested changes to the required certification of the Budget and Plan, noting that both were "forward-looking" documents. The proposed rule was revised to require the Executive Director of the MTA to certify, to the best of his or her knowledge and belief after reasonable inquiry, that the Budgets and Plans are based on reasonable assumptions and methods of estimation and the requirements of section 202.3 and 202.4 of the proposed rule have been satisfied.

The MTA suggested that working papers be prepared contemporaneously with, or within a reasonable time after, the release of the Budget or Plan. The Assessment notes that OSC believes working papers need to be available with the release of the Budget and Plan.

Concerns were expressed by the MTA as to the timeframe for certain reports. The proposed rule was revised to allow the MTA additional time to prepare the required monthly projections and to exclude budget updates released within 90 days of the close of the current fiscal year. Revisions were also made to reflect MTA's proposal that monthly reports that compare actual performance against planned levels be prepared 60 days, instead of 30 days, after the close of the month.

The MTA suggested that it use current reporting and record keeping required under the Public Authorities Law as a basis for monitoring the capital program. No revision to the proposed rule was made since the monthly reports currently produced by the MTA would appear to fulfill most of the requirements under the proposed rule.

Citing Patterson v Carey, the MTA expressed the view that the imposition of the requirements in the proposed rule in connection with the preparation of certain portions of the Strategic Operation Plan was not within the scope of the Comptroller's constitutional authority to supervise the "accounts" of public corporations. OSC does not concur with the MTA's reading of Patterson v Carey, and firmly is of the view that the proposed rule falls squarely within the Comptroller's constitutional discretionary authority to supervise the "accounts" of certain public corporations. Although not in response to the MTA's comment, the proposed rule independently was revised to provide that financial information for operating resources and costs in the Strategic Operation Plan, required by paragraphs d and e of subdivision 1 of the Public Authorities Law, must be presented in a format consistent with the Budget and Plan.

Office of Children and Family Services

NOTICE OF CONTINUATION
NO HEARING(S) SCHEDULED

Subsidized Child Care Services

I.D. No. CFS-21-03-00011-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. CFS-21-03-00011-P was published in the *State Register* on May 28, 2003.

Subject: Subsidized child care services.

Purpose: To establish standards for the provision of subsidized child care services by social services districts.

Substance of rule: The regulations revise Part 415 of Title 18 NYCRR to implement title 5-C of the Social Services Law (SSL), which created the New York State Child Care Block Grant (NYSCCBG). The regulations also implement the Federal statutory and regulatory requirements that govern the Federal funds included in the NYSCCBG. In addition, the regulations set forth the requirements for the provision of child care services under the Title XX Social Services Block Grant Program as well as child care services provided as preventive or as child protective services under certain circumstances.

Changes to rule: No substantive changes.

Expiration date: May 27, 2004.

Text of proposed rule and changes, if any, may be obtained from: Public Information Office, Office of Children and Family Services, 52 Washington St., Rensselaer, NY 12144, (518) 473-7793

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

Department of Civil Service

PROPOSED RULE MAKING
NO HEARING(S) SCHEDULED

Jurisdictional Classification

I.D. No. CVS-46-03-00005-P

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

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

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

Subject: Jurisdictional classification.

Purpose: To classify a position in the non-competitive class in the New York State Thruway Authority.

Text of proposed rule: Amend Appendix(es) 2 of the Rules for the Classified Service, listing positions in the non-competitive class, in the New York State Thruway Authority, by increasing the number of positions of Assistant Counsel from 2 to 3.

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

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

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

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

The proposed rule is subject to consolidated statements and analyses printed in the issue of February 12, 2003 under the notice of proposed rule making, I.D. No. CVS-06-03-00005-P.

New York State Energy Research and Development Authority

NOTICE OF EXPIRATION

The following notice has expired and can not be reconsidered unless the Energy Research and Development Authority publishes a new notice of proposed rule making in the NYS *Register*.

Minimum Energy Efficiency Standards

I.D. No.	Proposed	Expiration Date
ERD-17-03-00004-P	April 30, 2003	October 27, 2003

Department of Health

EMERGENCY RULE MAKING

Newborn Screening

I.D. No. HLT-36-03-00008-E
Filing No. 1224
Filing date: Oct. 29, 2003
Effective date: Oct. 29, 2003

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

Action taken: Amendment of section 69-1.2 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: The Department of Health finds that immediate adoption of this rule is necessary to preserve the public health, safety and general welfare, and that compliance with State Administrative Procedure Act (SAPA) Section 202(1) for this rulemaking would be contrary to the public interest. This regulatory amendment adds three conditions to the current eight that comprise New York State's newborn screening test panel, pursuant to existing Subpart 69-1.2. Funding to expand the current newborn screening program to include testing for cystic fibrosis (CF), congenital adrenal hyperplasia (CAH), and medium-chain acyl-CoA dehydrogenase deficiency (MCADD) was approved in the 2000-2001 New York State budget. During the intervening period since August of 2000, the necessary personnel and technology have been procured to implement the new testing, and develop a system for follow-up and assurance of access to necessary treatment for identified infants.

New York Public Health Law Section 2500-a lists six conditions to be tested for and authorizes the Commissioner of Health to designate additional diseases or conditions for inclusion in the screening program by regulation. In October 2000, the Commissioner issued a letter to all physicians in New York State informing them of the intended program expansion to include CF, CAH and MCADD. No negative comments were received from the medical community in response. The Newborn Screening Program also has engaged in ongoing discussions with immediately affected providers and consumers, directors of specialty treatment centers and parents of affected children. The specialty treatment centers conduct follow-up care of presumptive-positive infants identified by screening. Specialty centers have raised only one concern: about access to genetic counseling for families of infants identified as unaffected by CF, but who are carriers of related genetic variants. The program has responded that such counseling services are available to all State residents through contract facilities under the New York State Genetic Services Program.

Within the last six weeks, the program has resolved methodological issues and testing algorithms, so that implementation of the new testing can now proceed. While it was not practicable to implement testing prior to this time, now that the program is technically equipped to perform the testing, failure to begin to do so immediately would mean infants will go untested, undetected, and may therefore suffer irreversible medical harm and even death. Therefore, mandatory inclusion of the three additional conditions under the implementing regulations is time-constrained. To avoid unnecessary 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: Newborn screening.

Purpose: To add three conditions to the current eight that comprise New York State's newborn screening panel.

Text of emergency rule: Pursuant to the authority vested in the Commissioner of Health by Section 2500-a of the Public Health Law, existing Section 69-1.2 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York (NYCRR) is amended, to be effective upon filing with the Secretary of State, 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 sections 2500-a and 2500-f of the Public Health Law shall be done by the testing laboratory according to recognized clinical laboratory procedures.

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

This notice is intended to serve only as a notice of emergency adoption. This agency intends to adopt the provisions of this emergency rule as a permanent rule, having previously published a notice of proposed rule making, I.D. No. HLT-36-03-00008-P, Issue of September 10, 2003. The emergency rule will expire December 27, 2003.

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

Regulatory Impact Statement

Statutory Authority:

Public Health Law (PHL) Section 2500-a requires institutions caring for infants 28 days or under of age, as well as persons required to register the birth of a child, to cause newborns to be tested for phenylketonuria, branched-chain ketonuria, homocystinuria, galactosemia, homozygous sickle cell disease, hypothyroidism, and other diseases and 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 that would require newborn testing in accordance to the Department's mandate to prevent infant and child mortality, morbidity, and diseases and defects of childhood. Pursuant to this authority, biotinidase deficiency and human immunodeficiency virus (HIV) have been added to the newborn testing panel by regulatory amendment since the enactment of Section 2500-a.

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 three disorders to the list of seven 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. The Legislature recently affirmed its objective for a healthy young citizenry by enacting a State budget with dedicated funding for expansion of the State's Newborn Screening Program's testing panel, applying new technologies for the most accurate and timely identification of affected infants. The Department anticipates this express commitment to maintaining a premier program to continue in the form of annual appropriations to ensure funding for staffing and non-personal services.

Needs and Benefits:

Following legislative enactment of PHL Section 2500-a, the New York State Newborn Screening Program began as a statewide mandatory initiative to detect infants with serious but treatable neonatal conditions, and refer those infants for immediate medical intervention and follow-up. Regulations promulgated by the Commissioner of Health in 10 NYCRR Subpart 69-1 set forth requirements for specimen collection, testing, result reporting and case follow-up. Data compiled from New York State's Newborn Screening Program and other states' programs have shown that timely intervention and treatment can drastically improve affected infants' survival chances and quality of life. Advancing technology, emerging novel 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 amendment of Subpart 69-1.2.

This amendment would add three disorders — cystic fibrosis (CF), congenital adrenal hyperplasia (CAH) and medium-chain acyl-CoA dehydrogenase deficiency (MCADD) — to the scope of newborn screening services already provided by the Department. The three new disorders meet established criteria applied worldwide for newborn screening program test panels. These criteria are: the conditions must be medically significant; their incidence and prevalence must represent a matter of public health concern, or they must affect a substantial number of newborns, so that the resulting cost to society for health care and lost productivity is significant; reliable assays for diagnosis of the conditions, suitable for large-scale population screening, must be available; and early detection of the disorders during the neonatal period must allow for medical intervention effective in amelioration, or prevention of medical complications and other consequences.

An American Academy of Pediatrics task force reviewing newborn screening has suggested that state newborn screening programs consider testing for CF — one of the most common serious inherited disorders. Chronic illness and even death can result from alterations in the viscosity (thickness) of body secretions, especially in the lungs, pancreas and gastrointestinal tract, caused by CF. Such alterations lead to impaired absorption of nutrients in the gastrointestinal tract, and eventual malnutrition and failure to thrive; as well as impaired lung function resulting in increased chronic bacterial bronchitis and abundant inflammation in the airways, respiratory failure, and even death. Early detection and intervention ensures improved infant nutritional status and linear growth, as well as more stable lung function. In New York State's birth population, CF has a combined incidence of one in 3,700 births, resulting in an expected annual incidence of 86 CF cases.

CAH is the third most common condition that can be detected by newborn screening and the most immediately lethal. This inherited endocrine disorder may cause sexual misassignment of female infants as male at birth, with eventual accelerated skeletal maturation and short stature in both sexes. Treatment with supplements slows precocious maturation, and surgery can correct genital malformations. CAH affects one in 5,000 newborns in the State, yielding an expected annual incidence of 50 cases. Testing for CAH is now a part of many states' screening profiles, including the neighboring states of Massachusetts, Rhode Island, Pennsylvania and New Jersey. In 1999, the Department received 25 unsolicited letters from physicians, endocrinology experts and families of affected infants, urging addition of CAH testing for New York's newborns.

MCADD is one of several abnormalities in the body's ability to metabolize fats, resulting in toxic build-up of fatty acids. Although the disorder's presentation is variable, it may cause hypoglycemia, lethargy, vomiting, seizures and coma. One-third of infants die during the first clinical episode, and MCADD is thought to be the cause of one to two percent of sudden infant deaths. Survivors of severe clinical episodes may experience muscle weakness, failure to thrive and cerebral palsy, as well as learning difficulties. However, the disorder is effectively treated when detected early, primarily through avoidance of fasting. MCADD has an estimated incidence of one in 18,000 births in the State, an expected annual incidence of 14 cases of the condition.

Costs:

Costs to private regulated parties:

Regulated parties include the approximately 170 hospitals, and diagnostic and treatment centers providing birthing services in the State, their chief executive officers, and birth attendants who assist with at-home births (*i.e.,* licensed midwives). These entities 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, birthing facilities and, to a lesser extent, at-home birth attendants would likely incur minimal additional costs related to fulfilling their responsibilities for ensuring referral of infants who screen positive for CF, CAH or MCADD, specifically, human resources costs of approximately 1.0 person/hour (for nursing and counseling staff with clerical support) for communicating the need of and/or arranging referral for medical evaluation of the additional identified infants. Overall, for 95 percent of the State's birthing facilities (*i.e.,* 156 of 163), the number of infants requiring referral would increase from seven or fewer to no more than ten per week; therefore, no additional staff would be required at these institutions.

Facilities and practitioners receiving referrals, including: hospitals; specialized care centers; clinical specialists (*i.e.,* medical geneticists); and primary and ancillary care providers (*i.e.,* pediatricians, nutritionists and physical therapists), would incur costs for medical evaluation, including confirmatory testing in some cases, ongoing care, and treatment supplies such as antibiotics and dietary supplements. Specifically, such parties would incur human resources costs of approximately $300 for an initial comprehensive medical evaluation of an infant with an abnormal screening test 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 referred infants will ultimately be found not to be afflicted with the target condition, using clinical assessment and relatively simply confirmatory tests.

Hospitals, specialized care centers and independent providers will incur additional costs for providing post-evaluation and ongoing medical management services to the approximately two percent of identified 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 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 currently in the newborn screening panel, as well as that of children diagnosed with CF, CAH or MCADD, by targeted testing at the primary care level. Payors include indemnity health plans, managed care organizations, New York State's medical assistance program (Medicaid), Child Health Plus and the Children with Special Health Care Needs program. 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. Patients' families may also incur costs to the extent that a provider's charge for a service or supply item is not reimbursed in full by a third-party payor, and the provider is one of the few that balance-bill the patient. Some families may incur travel costs, since specialized care services are more readily available in large metropolitan areas.

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 CF, and to lesser extent CAH and MCADD, 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 the proposed rule's speeding early diagnosis may result in increased overall lifetime costs for patients who would have died in the absence of screening, *e.g.,* those with MCADD, substantial cost-savings are likely to be accrued from avoided 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 systems. Furthermore, early detection affords affected individuals with the opportunity for improved quality of life, a benefit that cannot be quantified.

The Department estimates that approximately 500 infants will screen as presumptively positive for CF annually. These presumptive-positive infants will require sweat tests and comprehensive level office visits at CF centers to determine final diagnosis. The cost of these services is estimated at $225,000 annually, using the prevailing rate of $300 and $150 for a comprehensive office visit and sweat test, respectively. Most presumptive-positive infants will be found to have at least one genetic mutation associated with CF. Many will be carriers of mutations for CF (*i.e.*, able to pass the gene on to their children). In addition to targeted testing and genetic counseling of families with affected infants, carriers' families should be offered further diagnostic testing and genetic counseling to determine risk for conceiving future children with CF. The annual cost of genetic counseling is estimated at $75,000, using the prevailing rate of $150 per session. For the approximate 86 confirmed CF cases expected annually, treatment is directed at improving nutrition, antibiotic therapy and chest physiotherapy, and is costly. However, emerging evidence of benefits from early treatment points to potential costs savings over a lifetime. Potential long-term savings include those associated with reductions in the number of outpatient treatments for respiratory illnesses and hospitalizations, as well as maintenance of an affected child's nutritional status from an early age in contrast to having to "catch up."

The Department estimates 5,000 infants to screen positive for CAH annually. CAH-positive infants would require additional testing at an endocrine center at a cost of approximately $150 each, plus one or more comprehensive office visits, for a total cost of $2 million. Approximately 50 infants would be diagnosed with the condition. If not treated, CAH can cause heart failure and death within a few days from birth. Although CAH cannot be cured, it can be effectively treated with hormone replacement therapy. The costs of medical management, hormone-replacing medication and special dietary needs for affected infants pale by comparison to the hundreds of thousands of dollars needed to care for a severely disabled child and the lost potential of an individual's contribution to society.

As many as 140 infants may screen positive for MCADD and require referral to endocrine centers for final diagnosis. These infants would require additional (confirmatory) testing and one or more comprehensive office visit(s), at a total cost of approximately $75,880. In 2000, the Program in Population Health at the University of Wisconsin collected data showing that costs for medical management of an affected child afforded early MCADD diagnosis are minimal. For example, families and/or payors would incur approximate annual costs of $4,000 and $300 for diet supplementation and laboratory testing, respectively. On the other hand, costs for treatment of infants not afforded early detection through newborn screening are significantly higher. A cost analysis conducted in 1999 by the National Newborn Screening and Genetics Resource Center in Austin, Texas, determined that costs for medical treatment of complications from a severe episode in an undiagnosed infant could be as high as $500,000, and total medical costs, including management of complications such as autism, seizures and cerebral palsy, could rise to more than $1 million for a lifespan of six years or under. Such costs may be translated into cost savings whenever early diagnosis is achieved through screening for MCADD.

Costs for Implementation and Administration of the Rule:

Costs to State Government:

New York State currently bears the cost of the annual appropriation for the State's Newborn Screening Program. Although funding for the 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. In addition to recent dedicated funding for program expansion, the Department expects that appropriations for staffing and non-personal services will continue. Department programs other than the Newborn Screening Program may incur minimal costs for distribution of informational material on testing for the three new conditions and for occasional use of existing public health nursing staff to track affected infants.

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.

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. Based on Department projections of increased numbers of specimens requiring follow-up under this proposed rule, facilities that submit such specimens will sustain a minimal increase in paperwork, specifically, that necessary to conduct and document follow-up and/or referral of one to three additional screening-positive cases per week. Pediatricians and other primary health care providers, as well as specialized care centers, involved in evaluation and management of affected infants, will experience minimal additional paperwork, including documentation of follow-up testing to the Department. Birthing facilities will need to complete and mail to the Department a single-page form to designate a staff physician to receive referrals of infants with presumptive-positive results for the new disorders.

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.

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. Moreover, failure to act upon the availability of new technologies for diagnosis of CF, CAH or MCADD in newborns contramands the Department's mandate to promote and protect the public health. 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 three conditions.

Federal Standards:

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

Compliance Schedule:

On October 16, 2000, the Commissioner of Health sent a letter to all New York State-licensed physicians informing them of the Department's intent to add tests for CF, CAH and MCADD to the State's newborn screening panel. The Newborn Screening Program distributed the Commissioner's letter to hospital CEOs and their designees responsible for newborn screening; directors of pediatric units; directors of specialized care centers; local health departments; and pediatricians and midwives identified by the program as involved with newborn screening. The Department received few comments from these mailings, the vast majority of which only posed specific questions about the initiative, to which written responses were provided. No adverse comments were submitted by the medical community. In June 2002, and as recently as September 23, 2002, the program sent a reminder letter to hospital CEOs and directors of specialized care centers about implementation of the new testing.

The Department also convened a Newborn Screening Task Force, comprised of directors of specialty care centers, payors, national experts in newborn screening quality assurance, health professionals working in other states' expanded screening programs and parents, to discuss this initiative, specifically, the scope of needed follow-up services and their availability at specialized care centers and other health care settings, and to review informational materials on CF, CAH and MCADD designed for distribution to medical professionals and lay persons. The Task Force met at least six times since November 2000, and, during July 2002, the Newborn Screening Program laboratory director met with representatives of

various specialty centers to assess and shape the infrastructure necessary for care of affected infants. The Task Force identified 17 CF clinics, 17 endocrine (for CAH) disorder clinics and six inherited metabolic (for MCADD) care centers available to evaluate presumptively identified infants and render medical care to affected infants. The only concern raised entailed access to genetic counseling for families of infants determined to be unaffected by CF but who are carriers of the predisposing gene for the condition. The concerned party was assured that access to genetic counseling for all State residents is available through contract facilities under the New York State Genetic Services Program, which includes CF specialty care centers Statewide.

Based on Department outreach efforts, strong support for the amendment is expected from patient advocacy organizations representing affected individuals, as well as the medical community at large. The Department is not aware of any opposition to expanded newborn testing, and there appears to be no prospect of organized opposition. It is believed that the health care system has been effectively primed for integrated care of identified infants. Consequently, regulated parties should be able to comply with these regulations as of their effective date, effective upon filing with the Secretary of State.

Regulatory Flexibility Analysis

Effect on Small Businesses and Local Governments:

This proposed amendment to add cystic fibrosis (CF), congenital adrenal hyperplasia (CAH) and medium-chain acyl-CoA dehydrogenase deficiency (MCADD) to the list of conditions 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 specialized care 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.,* nurse-midwives) would be required to follow-up infants screening positive for CF, CAH or MCADD, 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, effective 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 a positive screening test for CAH will be referred to the facility physician already designated to receive positive screening results for hypothyroidism, and those with positive screening for MCADD will be referred to the physician receiving positive screening results for phenylketonuria (PKU). Birthing facilities will need to identify a staff physician with the specialty training necessary for appropriate CF diagnosis and treatment.

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 CF, CAH or MCADD, primarily because the new testing proposed under this regulation is expected to result in no more than one additional referral per week. Communicating the need of 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 such as antibiotics and dietary supplements. Specifically, such providers would incur human resources costs of approximately $300 for an initial comprehensive medical evaluation of one infant with an abnormal screening test result. However, given the low specificity of screening tests to ensure no false negative test results, the Department anticipates that as many as 98 percent of infants will be found to not have the target condition, using clinical assessment and relatively simply 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 identified 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 visit and $150 for a genetic or nutritional counseling session. The Department believes that most infants presumptive-positive for CF will be found to have at least one gene mutation associated with CF; carriers of CF mutations would be able to pass the gene on to their children. Therefore, in addition to confirmatory testing and genetic counseling of families with affected infants, carriers' families should be offered genetic counseling at a cost of $150 per session, to determine their risk of conceiving future children with CF.

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 CF, CAH or MCADD 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 the 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 CF, and to lesser extent CAH and MCADD, 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 of 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.,* MCADD patients, 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:

On October 16, 2000, the Commissioner of Health sent a letter to all New York State-licensed physicians informing them of the Department's intent to add testing for CF, CAH and MCADD to the State's newborn screening panel. The Newborn Screening Program distributed the Commissioner's notification to local health departments, and small businesses and local government-operated facilities engaged in newborn screening, specifically: hospital chief executive officers and their designees; directors of pediatric units; and pediatricians and midwives identified by the program as involved in newborn screening. The Department received few comments in response to these mailings, the vast majority of which only posed specific questions about the initiative, to which written responses were provided. No adverse comments were submitted by the medical community.

Based on Department outreach efforts, strong support for the amendment is expected from patient advocacy organizations representing affected individuals, as well as the medical community at large. The Department is not aware of any opposition to expanded newborn testing, or of any prospect of organized opposition from small businesses or local government. It is believed that the health care system has been effectively primed for integrated care of identified infants. Consequently, regulated parties that are small business owners or facilities operated by local government should be able to comply with these regulations as of their effective date, effective upon filing with the Secretary of State.

Rural Area Flexibility Analysis

Effect of Rule:

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 cystic fibrosis (CF), congenital adrenal hyperplasia (CAH) and medium-chain acyl-CoA dehydrogenase deficiency (MCADD) to the list of conditions 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. No specialized care center operates in a rural area. New York State licenses 67,790 physicians and 350 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.

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. Activities related to 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 CF, CAH or MCADD, 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 in infants requiring referral of more than two per week. Therefore, the Department anticipates that regulated parties in rural areas will be able to comply with these regulations as of their effective date, effective 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 is expected to be able to assume the resulting minimal increase in workload. Infants screening positive for CAH will be referred to the facility physician designated to receive positive screening results for hypothyroidism, and those screening positive for MCADD, to the physician designated to receive positive screening results for phenyketonuria (PKU). Birthing facilities will need to designate a staff physician with the specialty training necessary for diagnosis and treatment of CF.

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 CF, CAH or MCADD, since the added testing proposed under this regulation is expected to result in no more than one more referral per week. Communicating the need of 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 such as antibiotics 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 simply 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 identified 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 visit, and $150 for a genetic or nutritional counseling session. The Department believes that most infants identified with CF will be found to have at least one mutation associated with CF; carriers of CF mutations will be able to pass the gene on to their children. Therefore, in addition to confirmatory testing and genetic counseling of families with affected infants, carriers' families should be offered genetic counseling at a cost of $150 per session, to determine the risk of conceiving children with CF in the future.

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 CF, CAH or MCADD, 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 CF, and to lesser extent CAH and MCADD, 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 the proposed rule's advancement of early diagnosis may result in increased overall lifetime costs for patients who would have died in the absence of screening, *e.g.*, those with MCADD, substantial cost-savings are likely to be accrued from prevented medical complications, to be 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. Moreover, early detection affords affected individuals with 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 facilities located in rural areas.

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 recordkeeping practices.

Participation by Parties in Rural Areas:

On October 16, 2000, the Commissioner of Health sent a letter to all New York State-licensed physicians informing them of the Department's intent to add testing for CF, CAH and MCADD to the State's newborn screening panel. The Newborn Screening Program distributed the Commissioner's letter to local health departments, and all rural facilities engaged in newborn screening, specifically, hospital chief executive officers and their designees; directors of pediatric units; and pediatricians and licensed midwives identified by the program as involved in newborn screening. The Department received few comments from these mailings, the vast majority of which only posed specific questions about the initiative, to which written responses were provided. No adverse comments were submitted by the medical community.

Based on Department outreach efforts, strong support for the amendment is expected from patient advocacy organizations representing affected individuals, as well as the medical community at large. The Department is not aware of any opposition to expanded newborn testing, or of any prospect of organized opposition from providers located or operating in rural areas. It is believed that the health care system has been effectively primed for integrated care of identified infants. Consequently, regulated parties should be able to comply with these regulations as of their effective date, effective upon filing with the Secretary of State.

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 three disorders – cystic fibrosis (CF), congenital adrenal hyperplasia (CAH) and medium-chain acyl-CoA dehydrogenase deficiency (MCADD) – to the scope of newborn screening services already provided by the Department. It is expected that, of the small number of regulated parties that will experience moderate rather than minimal impact on their workload, few, if any, will need to hire new personnel. Therefore, this proposed amendment carries no adverse implications for job opportunities.

EMERGENCY RULE MAKING

Treatment of Opiate Addiction

I.D. No. HLT-37-03-00001-E
Filing No. 1223
Filing date: Oct. 29, 2003
Effective date: Oct. 29, 2003

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

Action taken: Amendment of section 80.86 and addition of section 80.84 to Title 10 NYCRR.

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

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

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

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

The proposed amendments to Part 80 specifically state that buprenorphine may be utilized for the treatment of opiate addiction. Due to its significant potential for abuse and diversion, it is important that the department monitor the prescribing, administering and dispensing of buprenorphine by pharmacies and physicians. Such monitoring can be accomplished by the registration of physicians and pharmacies and by requiring dispensers to transmit such prescription data to the department.

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

Subject: Treatment of opiate addiction.

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

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

80.84 Physicians and pharmacies; prescribing, administering and dispensing for the treatment of narcotic addiction. Pursuant to the provisions of the federal Drug Addiction Treatment Act of 2000 (106 P.L. 310, Div. B, Title XXXV @ 3502(a), 114), an authorized physician may prescribe, administer or dispense an approved controlled substance, and a licensed registered pharmacist may dispense an approved controlled substance, to a patient participating in an authorized controlled substance maintenance program approved pursuant to Article 32 of the Mental Hygiene Law for the treatment of narcotic addiction.

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

(1) buprenorphine

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

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

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

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

(4) An authorized physician dispensing an approved controlled substance for the treatment of narcotic addiction shall file with the department a report summarizing the dispensing by the 10th day of the month following the month in which the approved controlled substance was dispensed. Such report shall be distinct from the patient's medical record, and prepared on forms provided by the department which will include but not be limited to the following information:

(i) patient name;
(ii) patient address, including street, city, state, zip code;
(iii) patient date of birth;
(iv) patient's sex;
(v) date of dispensing;
(vi) metric quantity;
(vii) national drug Code number of the drug;
(viii) number of days supply;
(ix) prescriber's Narcotic Addiction Drug Enforcement Administration number;
(x) date prescription written.

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

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

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

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

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

Section 80.86 is amended to read as follows:

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

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

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

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

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

(2) the date of the inventory;

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

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

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

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

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

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

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

This notice is intended to serve only as a notice of emergency adoption. This agency intends to adopt the provisions of this emergency rule as a permanent rule, having previously published a notice of proposed rule making, I.D. No. HLT-37-03-00001-P, Issue of September 17, 2003. The emergency rule will expire December 27, 2003.

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

Regulatory Impact Statement

Statutory Authority:

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

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

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

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

Legislative Objectives:

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

Needs and Benefits:

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

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

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

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

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

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

DOH/OASAS Task Force:

In the fall of 2000, the Department of Health (DOH) partnered with the Office of Alcoholism and Substance Abuse Services (OASAS) to begin planning for the implementation of DATA. The agencies established a

joint task force charged with establishing complementary regulations, as well as a joint application process by which New York State physicians could register to provide this new treatment modality.

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

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

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

Outreach:

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

Costs:

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

Local Government Mandates:

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

Paperwork:

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

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

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

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

Duplication:

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

Alternatives:

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

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

Federal Standards:

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

Compliance Schedule:

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

Regulatory Flexibility Analysis

Effect of Rule:

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

Compliance Requirements:

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

Professional Services:

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

Compliance Costs:

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

Economic and Technological Feasibility:

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

Minimize Adverse Impact:

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

Small Business and Local Government Participation:

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

Rural Area Flexibility Analysis

Finding:

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

The proposed amendment does not impose any adverse impact on rural areas. The proposed amendment makes the treatment of addiction in rural settings more feasible, as addicts will no longer have to travel to a metha-

done clinic to obtain their medication. Many rural areas do not have a methadone clinic in close proximity.

Measures Taken to A Certain Finding:

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

Job Impact Statement

Nature of Impact:

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

Categories and Numbers Affected:

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

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

Regions of Adverse Impact:

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

Minimizing Adverse Impact:

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

Self-Employment Opportunities:

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

EMERGENCY RULE MAKING

Monkeypox

I.D. No. HLT-46-03-00003-E
Filing No. 1222
Filing date: Oct. 29, 2003
Effective date: Oct. 29, 2003

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

Action taken: Amendment of sections 2.1 and 2.5 of Title 10 NYCRR.

Statutory authority: Public Health Law, sections 225(4), (5)(a), (g), (h), (i) and 206(1)(d) and (e)

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

Specific reasons underlying the finding of necessity: On July 11, 2003 The New York State Commissioner of Health designated monkeypox as a communicable disease pursuant to authority set forth in 10 NYCRR Section 2.1(a). In order for this designation to continue, emergency regulations adding monkeypox to the list of communicable diseases were adopted by the Public Health Council on July 25, 2003. By adopting this rule, the Public Health Council will continue monkeypox on the list of communicable diseases which providers are required to report to local and/or the State health departments and require physicians to submit specimens for laboratory examination when they suspect a person is infected with monkeypox. Continuing monkeypox on the list of communicable diseases will also permit isolation of patients if necessary for disease control. Immediate adoption of this rule is necessary for accurate identification and monitoring of monkeypox cases and to prevent community transmission through enforcement of isolation measures if needed.

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

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

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

Subject: Addition of monkeypox to the list of reportable diseases.

Purpose: To require reporting of suspected cases of monkeypox.

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

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

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

Amebiasis
Anthrax
Babesiosis
Botulism
Brucellosis
Campylobacteriosis
Chancroid
Chlamydia trachomatis infection
Cholera
Cryptosporidiosis
Cyclosporiasis
Diphtheria
E. coli 0157:H7 infections
Ehrlichiosis
Encephalitis
Giardiasis
Glanders
Gonococcal infection
Group A Streptococcal invasive disease
Group B Streptococcal invasive disease
Hantavirus disease
Hemolytic uremic syndrome
Hemophilus influenzae (invasive disease)
Hepatitis (A; B; C)
Hospital-associated infections (as defined in section 2.2 of this Part)
Legionellosis
Listeriosis
Lyme disease
Lymphogranuloma venereum
Malaria
Measles

Melioidosis
Meningitis
Aseptic
Hemophilus
Meningococcal
Other (specify type)
Meningococcemia
Monkeypox
Mumps
Pertussis (whooping cough)
Plague
Poliomyelitis
Psittacosis
Q Fever
Rabies
Rocky Mountain spotted fever
Rubella
Congenital rubella syndrome
Salmonellosis
Severe Acute Respiratory Syndrome (SARS)
Shigellosis
Smallpox
Staphylococcal enterotoxin B poisoning
Streptococcus pneumoniae invasive disease
Syphilis, specify stage
Tetanus
Toxic Shock Syndrome
Trichinosis
Tuberculosis, current disease (specify site)
Tularemia
Typhoid
Vaccinia disease (as defined in section 2.2 of this Part)
Viral hemorrhagic fever
Yellow Fever
Yersiniosis

* * *

Section 2.5 of Part 2 is amended as follows:

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

Anthrax
Babesiosis
Botulism
Brucellosis
Campylobacteriosis
Chlamydia trachomatis infection
Cholera
Congenital rubella syndrome
Conjunctivitis, purulent, of the newborn (28 days of age or less)
Cryptosporidiosis
Cyclosporiasis
Diphtheria
E. coli 0157:H7 infections
Ehrlichiosis
Giardiasis
Glanders
Gonococcal infection
Group A Streptococcal invasive disease
Group B Streptococcal invasive disease
Hantavirus disease
Hemophilus influenzae (invasive disease)
Hemolytic uremic syndrome
Legionellosis
Listeriosis
Malaria
Melioidosis
Meningitis
Hemophilus
Meningococcal
Meningococcemia
Monkeypox Plague
Poliomyelitis
Q Fever
Rabies
Rocky Mountain spotted fever
Salmonellosis
Severe Acute Respiratory Syndrome (SARS)
Shigellosis
Smallpox
Staphylococcal enterotoxin B poisoning
Streptococcus pneumoniae invasive
Syphilis
Tuberculosis
Tularemia
Typhoid
Viral hemorrhagic fever
Yellow Fever
Yersiniosis

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 26, 2004.

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

Regulatory Impact Statement

Statutory Authority:

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

Legislative Objectives:

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

Needs and Benefits:

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

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

In May 2003, the first outbreak of human monkeypox in the United States was reported with 19 confirmed or suspected cases in Wisconsin, Illinois and Indiana. Clinical onset was as early as May 15th, as late as June 3rd. Since then, there have been other suspect cases in other states. To date, no cases have been identified in New York State. These human cases of monkeypox were a result of contact with ill prairie dogs. The sick prairie dogs became infected through contact with infected African rodents that had been imported to the United States. There is concern that monkeypox could spread to other animals housed with affected prairie dogs or African rodents from the infected shipment. The New York State Department of Health (NYSDOH) has identified 20 prairie dogs that have been shipped to dealers or individuals in New York State. Twelve of these prairie dogs

have been identified, collected and euthanized per guidance issued by CDC and lab results were negative. The NYSDOH continues to work with the local health department to track down the remaining 8 prairie dogs. The Centers for Disease Control has issued guidelines for pet owners so that they can be on the lookout for monkeypox symptoms. The NYSDOH is developing documents for pet owners and veterinarians providing monkeypox information and guidance for handling of sick animals and reporting and testing procedures.

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

COSTS:

Costs to Regulated Parties:

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

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

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

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

Costs to Local and State Governments:

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

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

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

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

Costs to the Department of Health:

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

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

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

To date, the Wadsworth Center has conducted testing on 2 human specimens and 13 animal specimens, costing several thousand dollars. Should an extensive outbreak occur, costs could be significant.

Paperwork:

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

Local Government Mandates:

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

Duplication:

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

Alternatives:

No other alternatives are available.

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

Federal Standards:

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

Compliance Schedule:

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

Regulatory Flexibility Analysis

Effect on Small Business and Local Government:

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

Compliance Requirements:

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

Professional Services:

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

Compliance Costs:

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

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

Minimizing Adverse Impact:

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

Feasibility Assessment:

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

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

Small Business and Local Government Participation:

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

Rural Area Flexibility Analysis

Effect on Rural Areas:

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

Compliance Requirements:

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

Professional Services:

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

Compliance Costs:

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

Minimizing Adverse Impact:

There are no alternatives to the reporting requirements. Adverse impacts have been minimized since familiar forms and reporting staff will be utilized by regulated parties. The approaches suggested in State Administrative Procedure Act Section 202-bb(2) were rejected inconsistent with the purpose of the regulation.

Rural Area Input:

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

Job Impact Statement

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

PROPOSED RULE MAKING NO HEARING(S) SCHEDULED

Hematopoietic Progenitor Cell Banks

I.D. No. HLT-46-03-00001-P

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

Proposed action: Amendment of Subpart 58-5 of Title 10 NYCRR.

Statutory authority: Public Health Law, section 3121(5)

Subject: Hematopoietic progenitor cell banks.

Purpose: To reflect changes in current operating procedures and update terminology and clarification on intent.

Text of proposed rule: Section 58-5.2(e)(1) is amended as follows:

(1) The director of a hematopoietic progenitor cell procurement service collecting hematopoietic progenitor cells from peripheral blood shall be a physician and have at least one year's experience in apheresis, including or supplemented by experience in the performance or supervision of at least twenty-five (25) peripheral blood hematopoietic progenitor cell collection procedures. The director of a hematopoietic progenitor cell procurement service collecting bone marrow shall be a physician and have at least one year's experience in bone marrow collection, including or supplemented by experience in the performance or supervision of at least [twenty-five (25)] *twelve (12)* bone marrow collection procedures. The director of a hematopoietic progenitor cell procurement service collecting cord blood only shall be a physician and have at least one year's experience in hematopoietic progenitor cell collection, including or supplemented by experience in the performance or supervision of at least twenty-five (25) hematopoietic progenitor cell collection procedures. Such director shall also demonstrate satisfactory knowledge in the area of hematopoietic progenitor cell collection, with particular emphasis on the unique characteristics of cord blood collection. A person who has been approved by the department to direct a hematopoietic progenitor cell procurement service as of the effective date of these amendments shall be deemed to qualify as director.

Section 58-5.3(f) is amended as follows:

(f) A physician shall explain the hazards of the donation procedure to the donor in such a manner that the donor is offered an opportunity to refuse consent. The donor shall be advised of the risks of hematopoietic progenitor cell donation and of the anesthesia method to be used, [as well as] the potential need for transfusional support and possible side effects of each procedure, *and options for disposition of hematopoietic progenitor cells no longer needed by the intended recipient.* All this information shall be provided to each prospective donor in written form. The written informed consent of the prospective donor shall then be obtained. Autogeneic donors shall also be informed of the risks associated with hematopoietic progenitor cell collection.

Section 58-5.3(h) is deleted in its entirety and a new Section 58-5.3(h) is added as follows:

(h) Hematopoietic progenitor cells from autogeneic donors shall not be destroyed or released for purposes other than infusion into the intended patient without written authorization from the director of the facility storing the hematopoietic progenitor cells and:

(1) if the donor/patient is deceased, written documentation of death; or

(2) if the donor/patient is living, written authorization from the physician currently responsible for treating the patient for the underlying disorder for which the hematopoietic progenitor cells were collected; and documented informed consent from the donor/patient or donor/patient's guardian, unless it is documented that no response was received within sixty (60) days to at least two (2) written requests for such consent sent at least thirty (30) days apart. Documentation of such written requests shall be maintained.

Section 58-5.4(a)(2) is amended as follows:

(2) any infectious skin disease [generalized to an extent] that creates a risk of contamination of the hematopoietic progenitor cells;

Section 58-5.4(a)(7) is amended as follows:

(7) any medical condition[, including unstable angina and severe valvular stenosis,] which may be affected adversely by the collection procedure;

Section 58-5.4(a)(8) is amended as follows:

(8) any medical condition, including a malignancy, [which] *that* would adversely affect the quality of hematopoietic progenitor cells collected;

Section 58-5.4(d) is amended as follows:

(d) For allogeneic hematopoietic progenitor cell donations in New York State, specimens of blood shall be collected from the donor, or in the case of umbilical cord blood, from the donor's mother, [within thirty (30) days prior to or seventy-two (72) hours after donation,] and the following tests shall be performed in a clinical laboratory under permit by the department. For out-of-state donations, all required clinical laboratory testing shall be performed by a laboratory which is approved by the regulatory authority in the state or jurisdiction where the laboratory is located, or by the department:

(1) within thirty (30) days prior to or seventy-two (72) hours after donation, *and prior to initiation of the transplant conditioning regimen in the recipient*:

(i) direct tests for indicators of infection with syphilis[,] *and* cytomegalovirus (CMV) [and, except in cases of cord blood donation, Epstein-Barr virus (EBV)];

(ii) HBsAg;

(iii) antibody to hepatitis B core antigen (anti-HBc), antibody to hepatitis C virus (anti-HCV), anti-HIV-1, anti-HIV-2, and antibody to human T-cell lymphotropic virus type I (anti-HTLV-I); and

(iv) except for cord blood donation, peripheral blood cell enumeration (red, white and platelet) and differential blood smear evaluation.

(2) prior to ablation of the recipient, major histocompatibility antigens (HLA-A, B and DR) and other minor histocompatibility antigens, including mixed lymphocyte culture or DNA typing, as indicated.

Section 58-5.6(d)(2) is amended as follows:

(2) additives shall be used as required to [assure] *ensure* the continued [effectiveness] *suitability* of hematopoietic progenitor cells for transplantation and retention of viability. *All changes in additives shall be validated on-site, and such validation shall be documented*;

Section 58-5.6(d)(4)(i) is amended as follows:

(i) if performed, the results of laboratory tests for syphilis, HBsAg, and antibodies to HBV, HCV, HIV-1, HIV-2, HTLV-I[, EBV] and CMV, unless the results were forwarded to the hematopoietic progenitor cell transplantation service in advance or included in records accompanying the hematopoietic progenitor cells; and

Section 58-5.7(a)(1) is amended as follows:

(1) unless otherwise specifically authorized in writing by the director of the hematopoietic progenitor cell processing facility, hematopoietic progenitor cells shall be frozen within [twenty-four (24)] *forty-eight (48)* hours of collection using [approved] cryopreservation techniques [acceptable to the hematopoietic progenitor cell transplantation service] *generally accepted by experts in transplantation medicine* and meeting the requirements of this Subpart;

Section 58-5.7(a)(3)(i) is amended as follows:

(i) maintained, at a minimum, [in] *on* dry ice [(minus 78 degrees Celsius) or in a lower temperature environment] *or in a liquid nitrogen dry shipper. Storage/transport procedures for the frozen hematopoietic progenitor cells shall be validated, and such validation shall be documented*;

Section 58-5.8(a) is amended as follows:

(a) Complete and accurate records of hematopoietic progenitor cells released for transplantation shall be kept for seven (7) years by the hematopoietic progenitor cell procurement service. Such records shall be open to inspection by the department. *For all donated hematopoietic progenitor cells, the donor's name, address, and any other information that would directly or indirectly identify the donor shall not be disclosed or released by the bank to any person or entity, except upon the written consent of the donor or the person authorized by law to make the donation, or to authorized employees of the department, or as permitted by law. The recipient's name, address, and any other information that would directly or indirectly identify the recipient shall not be disclosed or released by the hematopoietic progenitor cell bank to any person or entity, except upon the written consent of the recipient, or except to authorized employees of the department, or as permitted by law.*

Section 58-5.10 is amended as follows:

58-5.10 Compliance with standards. *(a)* Hematopoietic progenitor cell procurement services and/or processing facilities shall allow admission to representatives of the department for the purpose of inspecting the premises and evaluating operating procedures, equipment, and records, including financial records and lists of physicians or facilities to whom or to which hematopoietic progenitor cells are released, to determine compliance with the standards in this Subpart. If the Commissioner determines that a significant likelihood exists that adequate safeguards are not implemented, the department may require that cells not be released pending a hearing. Such hearing shall commence within fifteen (15) days of any suspension pursuant to this section.

(b) Whenever requested, a hematopoietic progenitor cell bank shall submit to the department reports containing such information and data concerning the bank's activities as may be required by this Subpart. Such reports shall be signed by the director of the hematopoietic progenitor cell bank.

Section 58-5.9(b)(5) is amended as follows:

(5) The hematopoietic progenitor cell bank shall have a written procedure for documenting any errors or accidents in retrieval, testing, processing, storage or disposition of hematopoietic progenitor cells that may affect the safety of the cells, and for reporting such errors or accidents to the medical advisory committee of the bank. If the error or accident is detected after issuance of the cells, the error or accident shall be reported to the receiving facility immediately upon detection by the distributing facility. All errors with the potential for serious adverse [affects] *effects* on the recipient shall also be reported to the department's Wadsworth Center within seven (7) calendar days of discovery.

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

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

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

Regulatory Impact Statement

Statutory Authority:

The Council on Human Blood and Transfusion Services is authorized by Section 3121(5) of Public Health Law (PHL) Article 31 to enact, amend, and repeal rules and regulations establishing minimum standards for the collection, processing, fractionation, storage, distribution and supply of blood, subject to the approval of the Commissioner of Health. This authority extends to banking of hematopoietic progenitor cells (HPCs), which are immature blood cells. Section 4365 of PHL Article 43-B also mandates Department oversight of tissue banks, including HPC banks; Section 4365(7) reserves for the Council on Human Blood and Transfusion Services the authority to establish standards for HPC banking.

Legislative Objectives:

The purpose of Article 31 of the PHL is to promote the public health, safety and welfare by establishing minimum standards, and formulating appropriate procedures and/or activities for blood banking, including HPC banking. Article 31 authorizes the Department to oversee tissue banking, including HPC banking, and to protect the public health by ensuring that donated HPCs are acquired, tested, processed, stored and distributed in a manner generally accepted by experts in the field.

Needs and Benefits:

Continuing advances in HPC harvesting and transplantation medicine necessitate modification of the existing regulation, 10 NYCRR Subpart 58-5. The Department's cumulative experience in this new and burgeoning field compels changes in the HPC donor informed consent process and imposition of a requirement for validation of HPC transport protocols. A concomitant accumulation of experience by practitioners in HPC banking calls for modifications in requisites for collection and transport of HPCs. The amendment facilitates expansion of the HPC supply without compromising the safety of the cells or endangering donors.

The donor consent process is amplified to include options for disposition of HPCs no longer needed by the intended recipient. These options are destruction or release for a use other than the originally intended use. This provision will ensure that the donor is informed that the HPCs may not be used as intended, and will clarify that options include HPC discarding or release for other uses.

The proposed amendment adds new requirements that must be met prior to destruction or release for another purpose of HPCs from autogeneic donors whenever those HPCs are no longer needed by the donor. The director of the facility must provide documented authorization in such cases. If the donor is deceased, written documentation of death must be obtained. Requirements for obtaining informed consent from the donor, if living, or his/her guardian are made more rigorous. Currently, a

written request for consent must be sent, and at least 30 days allowed for response. The proposed amendment specifies that two such notices must be sent at least 30 days apart, and at least 60 days allowed for response. Existing regulation requires written authorization from the donor's physician prior to destruction of HPCs or their release for another purpose. The proposed amendment clarifies that the written authorization must be obtained from the physician treating the donor/patient for the underlying disorder for which the HPCs were collected. These requirements will serve to safeguard the HPC product for the donor, while averting indefinite storage of cells and providing definitive documentation of donor consent.

As practitioners gain experience in the relatively new field of HPC collection, processing and transplantation, the standard of practice in the field is evolving. As HPCs are retrieved less frequently from bone marrow and more frequently from peripheral and cord blood, opportunities for gaining experience in bone marrow collection are diminishing. It is becoming less likely that otherwise qualified candidates for directorship of HPC procurement services will be able to obtain the current requisite experience in bone marrrow collection within a reasonable period of time. Accordingly, the amendment reduces the minimum experiential requirements for directors of HPC bone marrow procurement services from 25 to 12 collection procedures, consistent with the national standard established by the American Association of Blood Banks and the Foundation for Accreditation of Hematopoietic Cell Therapy. This relaxation of requirements reduces the burden on HPC banks to seek individuals with extensive experience, and may well allow the banks to offer lower starting salaries, resulting in a cost savings.

Two criteria for evaluating donors were modified to accommodate their applicability to facilities collecting HPCs from peripheral blood or umbilical cord blood, rather than from bone marrow. Under current regulation, donors with any medical condition which may be adversely affected by the collection procedure are precluded from donation. In the proposed revision, the specific exclusion for unstable angina and severe valvular stenosis has been deleted, as these conditions may not necessarily be relevant to HPC collection from peripheral or cord blood. Wording that defines the extent of an exclusionary infectious skin disease has been eliminated as well, as such determination is best made by the medical director of the collection service.

The requirement for testing HPC donors for Epstein-Barr virus is eliminated. The accumulated experience among transplant practitioners indicates that such testing adds no information of clinical significance to successful outcome of HPC transplantation.

The amendment clarifies that tests for infectious disease in allogeneic donors must be performed prior to initiation of pre-transplant treatment regimens in intended recipients of donated HPCs. The change will ensure that no intended recipient is immunocompromised unnecessarily in the event the designated HPCs are not acceptable for transplantation.

Under the proposed amendment, all changes in additives for HPC preservation would be validated on-site, and such validation documented. The requirement for validation underscores the need for HPC banks adopting new or alternative additives for HPC preservation to ensure that any change in procedure will not adversely affect cell viability. The maximum time from HPC collection to cryopreservation will be extended from 24 hours to 48 hours. Some procedures require a time period longer than 24 hours from HPC collection to cryopreservation, and the Council on Human Blood and Transfusion Services has noted that a 48-hour time period is already in place in other states without compromising efficacy of the cells. Thus, the supply of HPCs may increase due to an increase in the time allotted between collection and preservation, allowing longer physical distances between collection and preservation sites. Costs may be reduced because HPC collection sites need not rely on generally more costly special rapid delivery services. The amendment clarifies that cryopreservation techniques must be generally acceptable to experts in the field of HPC transplantation. The requirement for validating procedures for storage/transport of HPCs will ensure that the cells are frozen and viable upon arrival at the transplantation facility. Current temperature requirements for HPC transport are replaced with less prescriptive criteria designed to accommodate the need for low-temperature transport, while clarifying that transport using liquid nitrogen is still acceptable.

Donor and recipient confidentiality provisions are added to be consistent with confidentiality standards already in place for donors and recipients of blood and other tissues.

A requirement for reporting on HPC banking activities to the Department is codified to expedite oversight and enforcement capability. Similar reporting requirements in blood bank and tissue bank regulations have been found to promptly provide valuable information for effective oversight.

Costs:

Costs to Private Regulated Parties:

Costs and savings resulting from this amendment will vary for individual regulated parties. Minimal costs will be incurred for modification of standard operating procedures to document more rigorous informed consent, more stringent authorization for disposition of HPCs no longer needed by the intended recipient, and validation of changes in HPC additives and in storage/transport procedures. Such documents are routinely revised in the usual course of HPC banking operations to keep pace with new technology. The Department expects that these minimal costs will be offset by savings accrued from several new provisions, including a reduced requirement for directors' bone marrow collection experience, ability to release unneeded HPCs from storage, extension of the time allowed between collection and storage, and elimination of Epstein-Barr virus testing. The cost savings from the elimination of the Epstein-Barr virus testing requirement may be as high as $228 per donation.

Costs to State Government:

The costs to State facilities operating HPC banks will be the same as those to private regulated parties, as noted above.

Costs to the Department:

The Department already retains sufficient staff to monitor compliance and revise forms. Existing Department inspection checklists will need to be modified and printed at a total estimated cost of $200.

Costs to Local Government:

The costs to local government facilities operating HPC banks will be the same as those to private regulated parties, as noted above.

Local Government Mandates:

The proposed amendment imposes no new mandates on any county, city, town or village government, or school, fire or other special district unless the county, city, town or village government, or school, fire or other special district operates an HPC bank, and, therefore, would be subject to these regulations to the same extent as a private regulated party.

Paperwork:

The amendment entails minimal paperwork to revise informed consent documents and modify written procedures in standard operating procedure manuals.

Duplication:

These amendments do not duplicate any other State or federal regulations.

Alternatives:

The alternative of not amending Subpart 58-5 was considered and found to be unacceptable. Present requirements are largely relaxed, but are still consistent with the purpose of Article 31 of the Public Health Law to promote the public health, safety and welfare by establishing minimum standards and ensuring proper blood banking procedures and activities. The Council on Human Blood and Transfusion Services believes that these amendments constitute an appropriate balance between burdens imposed by regulation, resultant increase in donor and recipient safety, and protection of the public health.

Federal Standards:

The U.S. Food and Drug Administration, the federal regulatory agency for blood and tissue banking, has not established requirements for HPC donor selection and testing, or for processing, storage, and distribution of human HPCs.

Compliance Schedule:

Regulated parties should be able to comply with these amended regulations as of their effective date, upon publication of a Notice of Adoption in the New York *State Register*.

Regulatory Flexibility Analysis

Effect of Rule

Sixty-six facilities are approved to provide hematopoietic progenitor cell (HPC) banking services in New York State. Of these, seven are for-profit HPC banks with fewer than 100 employees, one is a HPC bank operated by a county-owned medical center, and three are HPC banks operated by State-owned medical centers. The proposed amendment will have no adverse effect on these regulated parties, as full compliance will not impose undue costs or burdensome reporting or recordkeeping requirements.

Compliance Requirements

These amended regulations prescribe minimum acceptable standards specific to collection, processing, storage, and distribution of HPCs intended for transplantation. The requirements reflect generally accepted

standards of practice which are largely already in place in established HPC banks.

The donor consent process is expanded to include options for disposition of HPCs no longer needed by the intended recipient. The proposed amendment includes new requirements that must be met prior to disposition of HPCs from autogeneic donors if those HPCs are no longer needed by the donor. Documented authorization from the director of the facility storing the cells will be required. If the donor is deceased, written documentation of death must be obtained. Requirements for obtaining informed consent from the donor, if living, or his/her guardian are made more rigorous. Currently, at least 30 days must be allowed for response to a written request for consent. The proposed amendment requires at least 60 days for response to two such requests sent at least 30 days apart. The existing regulation stipulates written authorization from the donor's physician prior to destruction of HPCs or their release for another purpose. The proposed amendment clarifies that such written authorization must be obtained from the physician treating the donor for the underlying disorder for which the HPCs were collected.

Required tests for infectious disease in allogeneic donors must be performed prior to initiation of pre-transplant treatment regimens in intended recipients of donated HPCs.

Transport procedures must be validated to ensure adequate HPC storage during such transport. All changes in additives used for HPC collection shall be validated on-site, and that validation must be documented.

All HPC facilities approved by the Department must report their HPC banking activities annually to the Department.

Professional Services

Regulated facilities may wish, but are not required, to engage the services of an attorney to review documents drafted to comply with this proposal's more rigorous requirements for informed consent and authorization for disposition of HPCs no longer needed by the intended recipient. No other need for additional professional services is anticipated.

Compliance Costs

The Department believes that most HPC banks currently operating already meet most or all the requirements proposed in these amendments. Costs and savings will vary for individual regulated parties. Minimal costs will be incurred for modification of standard operating procedures to document donor informed consent, document authorization for disposition of HPCs no longer needed by the intended recipient, and validate changes in HPC additives and storage/transport procedures. Such documents are routinely revised in the usual course of HPC banking operations to keep pace with new technology. The Department expects that any costs will be offset by savings accrued from several new provisions, including reduction in requirements for directors' bone marrow collection experience, release of unneeded HPCs from storage, extension of the time allowed between HPC collection and storage, and elimination of Epstein-Barr virus testing.

Economic and Technical Feasibility

The proposed rule presents no economic or technological difficulties to small businesses and local governments. The new requirements are not burdensome; for the most part, they represent a relaxation of previous requirements or reflect practices already in place in existing banks.

Minimizing Adverse Impact

The amended regulations will have no significant adverse impact on small businesses and local governments.

Small Business and Local Government Participation

The Department has notified directly all HPC banks, including those operating as small businesses or owned by local governments, regarding the proposed amendment, to solicit input.

Rural Area Flexibility Analysis

All facilities approved by the Department to provide hematopoietic progenitor cell (HPC) banking services in New York State, including collection, processing, storage and distribution of HPCs, are located in towns and cities with population densities in excess of 150 persons per square mile. Therefore, a Rural Area Flexibility Analysis is not required.

Job Impact Statement

A Job Impact Statement is not attached 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.

PROPOSED RULE MAKING NO HEARING(S) SCHEDULED

Blood Banks

I.D. No. HLT-46-03-00002-P

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

Proposed action: Amendment of Subpart 58-2 of Title 10 NYCRR.

Statutory authority: Public Health Law, section 3121(5)

Subject: Blood banks.

Purpose: To clarify terminology, address advances in technology and expand and protect the blood supply.

Text of proposed rule: Section 58-2.1(l) is amended as follows:

(l) Limited transfusion service means a facility, home care services agency, physician's office, or other entity which [transfuses] *administers* blood *or blood components*, and may temporarily store blood *or blood components*, and distribute [it] *them* within its own organization, but relies on a blood bank holding a permit in blood services-transfusion to perform laboratory tests required under section 58-2.17 of this Subpart.

Section 58-2.1(u) is amended as follows:

(u) Reinfusion procedure means the withdrawal of a small amount of blood or a component thereof from a patient, its processing by addition of substances or by culturing, and [reinfusion] *administration* of the product so obtained, in whole or in part, into the same patient for diagnostic or therapeutic purposes. Reinfusion procedures shall include, but not be limited to, radioisotopic tagging, and genetic and immunologic manipulation, but shall not include [the] processing of whole blood units into components for autogeneic reinfusion, such as platelet concentrates, packed red blood cells and plasma.

A new subdivision (w) is added to Section 58-2.1, as follows:

(w) Limited reinfusion service means a facility, home care services agency, physician's office or other non-hospital entity that performs reinfusion procedures.

Section 58-2.2(b) is amended as follows:

(b) Only those persons may be accepted as donors of blood for allogeneic use who are in good health as indicated by:

(1) freedom from acute respiratory diseases;

(2) freedom from infectious skin lesions at the phlebotomy site and from any infectious skin disease generalized to an extent that creates a risk of contamination of the blood;

(3) freedom from any disease transmissible by blood transfusion, insofar as can be determined by history and examinations required in this Subpart;

(4) freedom from active tuberculosis. A person with a history of tuberculosis may be accepted as a blood donor following completion of drug therapy;

(5) freedom from syphilis. However, blood for plasma fractionation into heat-treated or inactivated derivatives may be accepted;

(6) freedom from a history of viral hepatitis [after the eleventh birthday] *for a duration specified by the United States Public Health Service;*

(7) freedom from a history of malaria or travel to or residence in malarially endemic areas for periods of time considered to increase risks for malaria exposure, as determined by the United States Public Health Service. However, plasma for transfusion or fractionation may be accepted from donors with a history of malaria or travel to a malarially endemic area;

(8) freedom from signs and symptoms of human immunodeficiency virus (HIV) infection; and

(9) freedom from other medical contraindications.

Section 58-2.2(g) is amended as follows:

(g) Blood withdrawn in order to promote the health of a donor otherwise qualified under the provisions of this section shall not be used for transfusion unless the container label indicates the donor's disease that necessitated withdrawal of blood, *except that, in the case of a donor with hemochromatosis, blood without such labeling may be used for transfusion, provided that the blood bank has demonstrated that therapeutic phlebotomy is available free of charge to hemochromatosis patients and that all other requirements of this Subpart have been met.*

Section 58-2.4(c) is amended as follows:

(c) Frequency limitations. [For allogeneic collections, no blood donor shall donate or be permitted to] *No allogeneic blood donor may* donate more than 550 milliliters of blood within an eight-week period, *unless approved to do so by a physician who examines the potential donor at the time of the proposed second donation. In no event can an allogeneic blood donor donate more than twice in a sixteen-week period. The foregoing prohibition on donations does not apply to allogeneic blood donors diagnosed with hemochromatosis.* For autogeneic collections, the frequency of donation shall be as specified in section 58-2.2(e)(3) of this Subpart.

Section 58-2.14(g) is amended as follows:

(g) Return of red blood cells to donor. If it is not possible to return red cells to a plasmapheresis donor, or if whole blood is donated, the donor shall not be plasmapheresed again for eight weeks, unless the donor's extracorporeal red blood cell volume during the procedure is not expected to exceed 100 milliliters.

Section 58-2.15(d) is amended as follows:

(d) Volume and frequency of cytapheresis. Extracorporeal blood volume shall not exceed 15 percent of the donor's estimated blood volume. No more than 1,000 milliliters of plasma shall be removed per seven days from a donor weighing 175 pounds or less, and no more than 1,200 milliliters shall be removed per seven days from a donor weighing more than 175 pounds. [Red blood cell loss shall not exceed 200 milliliters per eight weeks.] The interval between procedures shall be at least 48 hours. The above volume and frequency requirements may be waived upon written authorization of the supervising physician, provided [that] the donor meets all other eligibility requirements. Red blood cell loss shall not exceed [200] *275* milliliters per eight weeks, unless the following requirements are met:

(1) for male donors, the donor's weight exceeds 130 pounds;

(2) for female allogeneic donors, the donor's weight exceeds 150 pounds;

(3) for female autogeneic donors, the donor's weight exceeds 130 pounds;

(4) the allogeneic donor's hemoglobin content exceeds 13.3 grams per deciliter or hematocrit exceeds 40 percent;

(5) the autogeneic donor's hemoglobin content exceeds 12.0 grams per deciliter or hematocrit exceeds 36 percent;

(6) the volume of packed red blood cells removed does not exceed 550 milliliters; and

(7) the volume removed is replaced with at least 225 milliliters of normal saline. Following a red cell apheresis procedure in which red blood cell loss exceeds [200] *275* milliliters, the allogeneic donor shall not donate whole blood or undergo another apheresis procedure for a minimum of 16 weeks. For autogeneic donors, frequency and volume to be removed shall be determined by the medical director *of the blood bank* in conformance with recommendations of the manufacturer of the apheresis device.

Section 58-2.16(j) is amended as follows:

(j) If blood is warmed prior to transfusion, the warming system shall be equipped with a visible thermometer to ensure that the blood is not warmed above [42 degrees Celsius] *the temperature specified by the director of the blood bank, in conformance with the system manufacturer's instructions.* Maintenance and operation of blood warmers must conform to the manufacturer's instructions.

Section 58-2.17(d) is amended as follows:

(d) In the case of patients requiring repeated blood transfusions, or those pregnant or transfused with allogeneic red blood cell-containing components within the previous three months, fresh blood specimens shall be drawn for compatibility testing and antibody screening at intervals of not more than [72 hours] *three days* prior to [a] *the day of* transfusion, except for neonates, to whom no time limits apply.

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

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

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

Regulatory Impact Statement

Statutory Authority:

The Council on Human Blood and Transfusion Services is authorized by Section 3121(5) of the Public Health Law to enact, amend and repeal rules and regulations establishing minimum standards for the collection, processing, fractionation, storage, distribution and supply of blood, subject to the approval of the Commissioner of Health.

Legislative Objectives:

The purpose of Article 31 of the Public Health Law is to promote the public health, safety and welfare by establishing minimum standards for the proper collection, processing, fractionation, storage, distribution and supply of human blood or blood products for use in transfusion.

In keeping with the legislative objective to maintain an adequate and safe blood supply by establishing minimum standards, the Council on Human Blood and Transfusion Services has proposed revision to Subpart 58-2 to clarify terminology whose application is essential for oversight of the blood supply. Several requirements now rendered unnecessary by recent advances in technology have also been deleted without compromising the safety of the blood supply. The proposal also would effectively expand the blood supply by relaxing donor qualification requirements without endangering the health of donors or recipients.

Needs and Benefits:

Advances in technology, changes in terminology and the need for clarification of intent make necessary the proposed modifications to present blood banking regulations. The amendment will facilitate expansion of the blood supply without compromising the safety of the blood supply or endangering donors.

1. Advances in Technology. The U.S. Food and Drug Administration (FDA) has approved new cytapheresis technology and protocols that may remove 275 milliliters of red blood cells from individual donors, as compared to the 200 previously permitted. The 275 milliliter volume ceiling is consistent with that for red blood cell volume removed during whole blood donation. The practice will expand the blood supply while protecting donor safety and permitting flexibility in management of donors. Currently, prospective donors with a history of viral hepatitis after the eleventh birthday are deferred from donation indefinitely. Such indefinite deferral is no longer necessary to ensure the safety of the blood supply because of improved sensitivity of laboratory testing for the infection. The proposed amendment reduces deferral time to one specified by the U.S. Public Health Service, as current tests are capable of detecting any such persons who are infectious.

2. Deletion of Unnecessary Requirements. The proposed amendment relaxes a requirement for labeling of blood donated for transfusion by individuals with hemochromatosis who otherwise meet donor criteria. Individuals with hemochromatosis routinely undergo therapeutic phlebotomy for the disorder, and this amendment facilitates the availability of blood so obtained for transfusion purposes. The current provision prohibiting such individuals from donating blood more often than once in eight weeks would also be modified to permit donation as frequently as approved by their physicians.

3. Clarification of Intent. The proposed revision includes a definition of limited reinfusion service. Requirements for reinfusion procedures are described in current regulation; the definition clarifies the entities to which they apply. Since blood components such as platelet gel, growth factors and wound healing preparations are administered, rather than transfused or reinfused, definitions for limited transfusion services and limited reinfusion services are clarified to include administration of blood components, in addition to transfusion of blood. For consistency with present limitations on cytapheresis procedures, language has been proposed to permit plasmapheresis to be conducted again within eight weeks of the first procedure, provided the donor's extracorporeal red blood cell volume during the procedure does not exceed 100 milliliters.

4. Less Restrictive Measures. The current requirement specifies that blood donated for transfusion by individuals with hemochromatosis must be so labeled. In the proposed amendment, blood so donated need no longer be specially labeled, and may be collected more frequently than that from other donors, provided therapeutic phlebotomy is made available free of charge to hemochromatosis patients. Individuals with hemochromatosis routinely undergo therapeutic phlebotomy for the disorder, and this amendment facilitates availability of the blood from this procedure for transfusion purposes, thus expanding the available blood supply. A requirement that blood not be warmed above 42 degrees Celsius is deleted. The regulation now specifies that such maximum temperature be established by the director of the blood bank. The blood would not be at greater risk of hemolysis because any FDA-approved warming device must have demonstrated that it does not rupture blood cells as a condition for approval.

Allogeneic donation is permitted no more than twice within a 16-week period, provided the patient is examined by a physician at the time of the second donation if it is within eight weeks of the first donation. In order to be consistent with the limitations placed on cytapheresis, language has been added to permit plasmapheresis to be performed again within an eight-week period, provided the donor's extracorporeal red blood cell volume during the procedure does not exceed 100 milliliters. The maximum interval between transfusion and drawing of fresh blood specimens for compatibility testing and antibody screening is extended from 72 hours to three days, to be consistent with national American Association of Blood Banks standards referring to "days" and to facilitate compliance. A standard of three days permits the drawing of fresh blood early on day zero (*e.g.,* Monday) and transfusion anytime before the end of the day on the

following third day (*e.g.*, Thursday), avoiding the need to record the hour, as well as the date, of sample collection.

Costs:

Costs to State Government:

The costs to State government facilities operating blood banks will be the same as those to private regulated parties, as noted below. There is no additional cost incurred in State oversight activities.

Costs to Local Government:

The costs to local government will be the same as those to private regulated parties, as noted below.

Costs to Private Regulated Parties:

The proposed amendments are less restrictive than are current regulations. Regulated parties choosing to implement relaxed requirements will need to modify written procedures in their standard operating procedure manuals, thus incurring minimal costs. Some facilities may realize savings in donor recruitment costs through better donor management made possible under these amendments.

Costs to the Department:

Monitoring compliance with these revisions will entail minimal Department staff time. Costs incurred by the Department due to these revisions will include the costs of revising text files stored on computer diskettes and the training curriculum for staff who conduct compliance inspections of regulated facilities. These one-time costs are estimated to be $920, and would be recovered by the Department through the Clinical Laboratory Inspection and Reference Fees.

Paperwork:

Regulated parties choosing to implement the amendments will need to modify written procedures in their standard operating procedure manuals. However, the overall paperwork burden related to donor management for attendant collection, testing and recordkeeping, will be reduced since greater volumes of blood will be collected from eligible donors at less frequent intervals.

Local Government Mandates:

These amendments impose no new mandates on any county, city, town or village government, or school, fire or other special district.

Duplication:

These amendments do not duplicate any other State regulations, as Subpart 58-2 is the only State regulation governing blood banking. These amendments do not duplicate federal rules pertaining to blood banks found at Parts 600 through 640 of Title 21 of the Code of Federal Regulations (CFR).

Alternatives:

The Council on Human Blood and Transfusion Services is charged with ensuring the safety and adequacy of the blood supply in the State of New York through promulgation and amendment of regulations. No alternatives exist which would adequately clarify requirements essential for protecting the public health, recognize technological advances, and ensure the least restrictive practices consistent with national standards.

Federal Standards:

The FDA has established extensive requirements to protect the blood supply in interstate commerce. Subpart 58-2 applies to New York State-licensed blood banks operating intra-state and interstate, and is consistent with federal requirements where they exist. The proposed rules do not exceed minimum federal standards which exist in the same or related subject areas, except that the New York State Council on Human Blood and Transfusion Services has determined that setting a maximum annual limit on blood donation protects donor health and has promulgated standards on this issue accordingly.

The proposed amendments delete a requirement that blood donated for transfusion by individuals with hemochromatosis must be so labeled. New language permits more frequent donation by these individuals as compared to other donors, provided therapeutic phlebotomy is provided free of charge. This provision is consistent with the December 2000 FDA draft guidance that details federal procedures and criteria for variances, and which states an intent to propose similar revisions to the federal regulations. The donation by persons with a history of viral hepatitis, but who are asymptomatic for a period specified by the U.S. Public Health Service, is consistent with the recommendation of FDA's Blood Products Advisory Committee on March 16 and 17, 2000, that corresponding federal regulations at CFR 640.3(c) be amended. Consistent with 21 CFR 640.3(f), the frequency of allogeneic donation has been increased in this proposal, provided the donor is examined by a physician prior to donation. The amendment to allow removal of 275 rather than the previous 200 milliliters of blood during apheresis is consistent with FDA's "Guidance for Industry: Recommendations for Collecting Red Blood Cells by Automated Apheresis Methods," July, 1998. The maximum temperature to which blood may be warmed is now less restrictive, consistent with national standards of the American Association of Blood Banks (AABB Standard 3.5.2). The maximum interval between transfusion and drawing fresh blood specimens for compatibility testing and antibody screening is revised from 72 hours to three days to permit a specimen draw for a slightly longer period of time, *i.e.*, to the end of the third day following the draw day and to avoid the need to record the hour, as well as the date, of sample collection. This approach is consistent with AABB Standard 5.13.3.2. No proposed provision in this amendment compromises the safety of the blood supply or increases any risks posed to individual donors.

Compliance Schedule:

The Department has notified all regulated parties to solicit preliminary comments regarding the proposed amendments. Regulated parties should be able to comply with these amended regulations as of their effective date, upon publication of a Notice of Adoption in the New York *State Register*.

Regulatory Flexibility Analysis

The Department of Health finds that these amendments will not impose an adverse economic impact and will not impose recordkeeping, reporting or other compliance requirements on small businesses or local governments.

These amendments would not extend regulatory oversight to any parties not already presently regulated. Most facilities approved to transfuse blood would be affected by some of the provisions of the proposal, but not in an adverse manner. The amendments would have no adverse effect on small businesses or local governments, as full compliance would not increase overall costs or reporting or recordkeeping requirements on any regulated parties, including small businesses and local governments, because of the ability to collect blood donations more frequently. Regulated parties may, but would not be required to, relax present requirements to comply with the proposed amendments.

Four hundred and forty-five (445) facilities are approved by New York State to provide blood services. Approximately 138 (31 percent) are small businesses, including about six of 268 facilities holding a permit in blood services and about 132 (75 percent, including mostly ambulatory surgery and dialysis centers) of 177 facilities approved to provide limited transfusion or reinfusion services. All facilities guided by national standards, and federal and State requirements would benefit from the amendments' objectives to achieve consistency in requirements for donor qualifications (related to hepatitis, hemochromatosis and apheresis), frequency and amount of donation, maximum temperatures for blood warming, and maximum intervals between drawing of specimens for compatibility testing. The 81 facilities collecting blood, of which four are small businesses, would benefit from the proposed expanded donor pool, including individuals who have been diagnosed with hepatitis but have been asymptomatic for a period specified by the U.S. Public Health Service; individuals who meet criteria for apheresis; and individuals who have hemochromatosis but meet all other criteria for donation. Limited transfusion service and limited reinfusion service providers and blood banks would benefit from the amendments' clarification that these services cover administration, as well as transfusion and reinfusion of blood and blood components. Providers of limited transfusion services include 46 dialysis centers, 17 physician office laboratories, 10 home care agencies, 10 skilled nursing facilities, 10 ambulatory surgery centers, two private intraoperative recovery services, one correctional facility hospital, one cancer treatment center, and one diagnostic and treatment center. Providers of limited reinfusion services include 22 dentists, 14 nuclear pharmacies, 14 diagnostic imaging facilities, five physician office laboratories, and two wound treatment centers.

Rural Area Flexibility Analysis

The Department of Health finds that these amendments will not impose an adverse economic impact and will not impose recordkeeping, reporting or other compliance requirements on public or private entities in rural areas.

The amendment would affect some 445 facilities approved to provide blood services in New York State. Approximately 145 of these facilities are located in rural counties or rural areas of urban counties. These include roughly 37 percent of the 268 facilities holding permits to provide blood services, 33 percent of 120 approved to provide limited transfusion services, and 21 percent of 57 approved to provide limited reinfusion services.

None of the proposed amendments is more restrictive than current regulations. Regulated parties may, but would not be required to, relax present requirements to comply with the proposed amendments.

Job Impact Statement

A Job Impact Statement is not attached 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.

PROPOSED RULE MAKING
NO HEARING(S) SCHEDULED

Personal Care Services Reimbursement

I.D. No. HLT-46-03-00006-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 505.14 of Title 18 NYCRR.

Statutory authority: Social Services Law, sections 363-(a)(2) and 365-a(2)(e)

Subject: Personal care services reimbursement.

Purpose: To revise Medicaid reimbursement regulations to include a two percent penalty for late submission of cost reports and institute a 30-day advance notification of January personal care rates.

Text of proposed rule: Subclause (6) of clause (a) of subparagraph (i) of paragraph (7) of subdivision (h) of Section 505.14 of Title 18 NYCRR is repealed and a new subclause (6) is added to read as follows:

[(6) If a provider fails to submit the cost report or any corrected or additional information regarding the cost report by the original or extended date on which such report or such corrected or additional information is due, the provider's existing approved payment rate will remain in effect until such time as the provider submits such cost report or such corrected or additional information and otherwise complies with the requirements of this clause, and the department is able to determine a rate for the provider. The rate will be effective for the full rate year regardless of the date on which the provider submitted such cost report or such corrected or additional information and otherwise complied with the requirements of this clause.]

(6) (i) In the event a provider fails to file the required cost report on or before the due date, or as the same may be extended pursuant to subclause (3) of this clause, the State Commissioner of Health shall reduce the current rate paid by state governmental agencies by two percent for a period beginning on the first day of the calendar month following the original due date of the required report and continuing until the last day of the calendar month in which the required report is filed.

(ii) Failure to timely file the corrected or additional data as required pursuant to subclause (4) of this clause will result in application of item (i) of this subclause. Lack of certification by the operator or by the accountant, as required pursuant subclauses (8) and (9) of this clause, shall render a cost report incomplete.

Clause (a) of subparagraph (iii) of paragraph (7) of subdivision (h) of Section 505.14 of Title 18 NYCRR is repealed and a new clause (a) is added to read as follows and subclause (1) of clause (b) of subparagraph (iii) of paragraph (7) of subdivision (h) is amended to read as follows:

(iii) Revisions to rates.

[(a) The department will notify each personal care services provider in writing of the provider's payment rate. The provider may request a revision to the rate in accordance with the procedures set forth in this subparagraph.]

(a) The department will notify each provider of its approved rates of payment at least thirty days prior to the beginning of an established rate period for which the rate is to become effective. In the case of payments to be made by state governmental agencies notification shall be made only after approval of rate schedules by the state director of the budget. The advance notification of rates shall not apply to prospective or retroactive adjustments to rates that are based on rate appeals filed by the provider, audits, corrections of errors or omission of data or errors in the computation of such rates or the submission of cost report data from providers without an estimated cost basis.

(b)(1) Within [60] *90* calendar days after the provider receives the written notification of its rate, the provider must notify the department of any errors in the rate resulting either from the provider's submission of erroneous information in its cost report or the department's erroneous computation of the rate and of the provider's request for a revised rate.

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

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

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

Regulatory Impact Statement

Statutory Authority:

Social Services Law (SSL) Section 363-a(2) gives the Department specific rule making authority to adopt regulations necessary to implement the State's Medical Assistance (Medicaid) program. Pursuant to SSL Section 365-a(2)(e), the Medical Assistance program includes personal care services.

Legislative Objectives:

The Legislature has declared Medical Assistance for needy persons to be a matter of public concern and necessity in promoting the public health and welfare and the State's goal of making uniform high quality medical care available to everyone. Promulgation of rates of reimbursement for these services in a timely and accurate manner assists in promoting this goal.

Needs and Benefits:

The purpose of these revisions is to enable the Department to streamline the rate setting process and give it the ability to promulgate rates in a more timely and accurate manner. Currently, the Department is hampered in its ability to meet these goals because many cost reports are not filed timely and some not at all. Each year, 20 percent or approximately 100 cost reports are not filed on time. Ten percent or approximately 50 cost reports are not filed at all. Delayed reporting creates a significant amount of additional processing time and results in rates being issued well after the start of the effective period. A total failure to report results in an extension of the prior rate, which may not accurately reflect more recent costs. In addition, in order to grant a county-wide exemption from the personal care rate methodology, all providers must have a rate calculated based on a cost report.

The proposed amendments to current regulations will require submission of all cost reports by a certain date. It is anticipated that the due date will be August 31; however, circumstances may arise necessitating a change from this date. Extensions of time to submit the cost report will be considered but only in cases of emergency. The penalty for personal care providers that file late cost reports will be a two percent reduction in the current published Medicaid rate. The penalty will begin on the first day of the month following the original due date of the cost report and will continue until the first day of the month following the submission of the cost report to the Department of Health.

The amendments will also establish in regulation that personal care providers will receive notice of their initial rates thirty days prior to the effective date of the rate. This will allow agencies to perform more accurate budget projections.

Costs:

Costs to State Government:

Each year, 20 percent or approximately 100 cost reports are not filed on time. Of this total, 50 percent or approximately 50 cost reports are not filed at all. Assuming that approximately 50 of the cost reports will be filed within 1 month of the due date and the remaining 50 will be filed within 3 months of the due date, the department estimates that the two percent rate reduction penalty will result in a savings of $65,777 in annual Medicaid expenditures to state government. In the event there are fewer cost reports filed after the due date, savings will be less than such maximum amount. The institution of a notice rate will not result in additional costs to state government.

Costs to Local Government:

Each year, 20 percent or approximately 100 cost reports are not filed on time. Of this total, 50 percent or approximately 50 cost reports are not filed at all. Assuming that approximately 50 of the cost reports will be filed within 1 month of the due date and the remaining 50 will be filed within 3 months of the due date, the department estimates that the 2 percent rate reduction penalty will result in a savings of $16,035 in annual Medicaid expenditures to local government. In the event there are fewer cost reports filed after the due date, savings will be less than such maximum amount. The institution of a notice rate will not result in additional cost to local government.

Local government staff does not calculate the penalty or administer it. As such, there will be no cost to local government for staff or resources.

Costs to Private Regulated Parties:

There will be no additional costs to private regulated parties. There will be a reduction in Medicaid revenues for those providers that fail to file the personal care cost report within the time frame established by the Department of Health.

Costs to the Department of Health:

There will be no additional costs to the Department of Health. These regulations will be implemented by existing staff.

Local Government Mandates:

This regulation affects the costs to counties and New York City for services provided to Medicaid beneficiaries. If a personal care provider fails to file a cost report within the time frame established by the Department of Health, there will be a reduction in the Medicaid rate, which will result in a savings to the county. It imposes no program, service, duty or other responsibility upon any other city, town village, school, fire district or other special district.

Paperwork:

The proposed amendments will not impose a new reporting requirement on personal care services providers. Each provider is now required to report its costs on an annual basis to the Department. The Department will issue a letter and Medicaid rates to each provider, thirty days prior to the effective date of the initial Medicaid rate. This will not affect costs.

Duplication:

These regulations do not duplicate existing State or Federal regulations.

Alternatives:

No significant alternatives were considered because current statute for other health care providers authorizes a penalty for late filing of cost report data of up to 2% of the Medicaid rate.

Federal Standards:

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

Compliance Schedule:

Cost reports will be due on August 31 of each year unless a different due date is announced.

The proposed regulations will require the department to issue notice of January rates thirty days prior to implementation.

Contact Person:

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

Comments submitted to department personnel, other than to this contact person, may not be included in any assessment of public comment issued for this regulation.

Regulatory Flexibility Analysis

Effect on Small Business and Local Governments:

The proposed amendments are needed to streamline the rate setting process and give it the ability to promulgate rates in a timelier manner. The amendments will give providers notice of their initial rates prior to their effective date. This does not occur now and will be a benefit for providers by allowing them to perform accurate budget projections.

For purposes of the regulatory flexibility analysis, small businesses were considered to be personal care agencies with 100 or fewer full time equivalents. Based on recent financial and statistical data reported on the annual personal care cost report, the majority of the 530 contracted personal care agencies were identified as employing fewer than 100 employees.

Four county Departments of Health are under contract with their local departments of Social Services to provide Medicaid personal care service. These counties are: Erie County Department of Health, Madison County Department of Health, Schuyler County Department of Health and Yates County Public Health.

Reporting and Recordkeeping Requirements:

No new reporting or recordkeeping requirements is imposed by these rules. The proposed rule establishes a two percent rate penalty for those personal care programs that do not timely file a cost report. Second, the proposed rule provides an additional thirty days for personal care programs to file an appeal to the rate issued by the department. Third, the proposed rule requires the department to issue notice of January Medicaid rates for personal care agencies thirty days prior to the effective date of the rate.

Professional Services:

No new professional services will be needed for compliance with this rule.

Compliance Requirements:

Cost reports will be due on August 31 of each year unless a different due date is announced.

The proposed regulations will require the department to issue notice of January rates thirty days prior to implementation. No new capital or annual costs of compliance are imposed by this rule.

Economic and Technological Feasibility:

Agencies and local governments can easily comply with this proposal.

Minimizing Adverse Impact:

The Department of Health considered the approaches in section 202-b(1) of the State Administrative Procedure Act. The proposed regulation does not change the existing rate methodology. Exemption of small businesses or local governments from coverage of the rule or use of different standards for small businesses or local governments is not necessary and would defeat the purpose of the rule.

Small Business and Local Government Participation:

Small businesses and local health departments under contract for the provision of personal care services were given notice of the proposed changes in a letter dated October 26, 1999. This letter, signed by the Assistant Director of the Division of Health Care Financing, was sent to all personal care agencies.

Rural Area Flexibility Analysis

Effect on Rural Areas:

Rural Areas for purposes of this regulation are the following counties:

Allegany	Cattaraugus	Chautauqua
Chemung	Chenango	Clinton
Columbia	Cortland	Delaware
Essex	Franklin	Greene
Hamilton	Herkimer	Jefferson
Lewis	Livingston	Madison
Orleans	Otsego	Putnam
Schoharie	Schuyler	Seneca
St. Lawrence	Steuben	Sullivan
Tioga	Tompkins	Ulster
Warren	Washington	Wyoming
Yates		

Reporting and Recordkeeping Requirements:

No new reporting or recordkeeping requirements is imposed by this rule.

The proposed rule establishes a two percent rate penalty for those personal care programs that do not timely file a cost report. The requirement to file the cost report is not a new rule. Second, the proposed rule provides an additional thirty days for personal care programs to file an appeal to the rate issued by the department. Third, the proposed rule requires the department to issue notice of January Medicaid rates for personal care agencies thirty days prior to the effective date of the rate.

Professional Services:

No new professional services are likely to be needed in a rural area for compliance with this rule.

Compliance Costs:

No new capital or annual costs of compliance are imposed by this rule.

Minimizing Adverse Impact:

The Department of Health considered the approaches in section 202-bb(2)(b) of the State Administrative Procedure Act. The proposed regulation change does not change the existing rate methodology, which considers geographic differentials through the ceiling calculation. Exemption of personal care agencies located in rural areas from coverage of the rule or use of different standards is not necessary and would defeat the purpose of the rule.

Opportunity for Rural Area Participation:

Personal Care Agencies located in rural areas were given notice of the proposed changes in a letter dated October 26, 1999. This letter, signed by the Assistant Director of the Division of Health Financing, was sent to all personal care agencies.

Job Impact Statement

A Job Impact Statement is not required pursuant to Section 201-a(2)(a) of the State Administrative Procedure Act since it is apparent, from the nature and purpose of the proposed rule, that it will not have a substantial adverse impact on jobs or employment opportunities. Only agencies that choose not to file their cost report in a timely manner will be impacted by the penalty. Furthermore, agencies that choose to file timely will have the positive benefit of 30-day advance notice of their initial rates. This will allow the agency to better prepare their budgets prior to the start of the rate year.

PROPOSED RULE MAKING
NO HEARING(S) SCHEDULED

Public Notification, Disinfectants/Disinfection Byproducts and Interim Enhances SWTR

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

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

Proposed action: Amendment of Part 5 of Title 10 NYCRR.

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

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

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

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

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

Section 5-1.1 Definitions

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

Section 5-1.30 Providing treatment for public water systems

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

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

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

Section 5-1.51 Maximum contaminant levels

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

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

Section 5-1.52 Tables

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

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

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

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

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

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

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

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

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

Table 10A. Turbidity – Monitoring Requirements.

Additional turbidity monitoring requirements have been included.

Table 13 Required Notifications.

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

Table 15 Disinfection Monitoring for Systems using Chlorine or Chloramines.

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

Table 15A Disinfectant Residual Minimum Monitoring Requirements.

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

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

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

Section 5-1.72 Operation of a public water system

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

Section 5-1.77 State notification

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

Section 5-1.78 Public notifications

Section 5-1.78: Content of Consumer and Public notifications is repealed in its entirety and will be replaced with the new Section 5-1.78 (Public notifications). The new section adds general requirements and

amends the content, form, manner, and frequency requirements for public notifications.

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

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

Appendix 5-C

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

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

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

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

Regulatory Impact Statement

Statutory Authority and Legislative Objectives

Section 201(l) of the Public Health Law empowers the Department of Health to supervise and regulate the sanitary aspects of water supplies. Section 225 of the Public Health Law empowers the Public Health Council to establish, amend or repeal regulations of the State Sanitary Code, to insure the protection of public health. The proposed amendments are necessary in order to assure the continued validity of New York State's drinking water standards within the regulatory framework established by the United States Environmental Protection Agency under federal law.

The United States Environmental Protection Agency (USEPA) promulgated the Interim Enhanced Surface Water Treatment Rule (IESWTR) and the Stage 1 Disinfectants and Disinfection Byproducts Rule (DBP Rule) on December 16, 1998. These rules comprise the first two of a cluster of rules, the "Microbial-Disinfectants/Disinfection Byproducts (M-DBP) Cluster", to be promulgated over the next several years intended to improve control of microbial pathogens in drinking water while simultaneously controlling the public health risks of disinfectants and disinfection byproducts. USEPA also promulgated two related rules, the Filter Backwash Recycling Rule (FBRR) and the Long Term 1 Enhanced Surface Water Treatment Rule (LT1ESWTR), the costs and benefits of which are included with the IESWTR. The Public Notification (PN) Rule was promulgated on May 4, 2000 and revises the requirements that all public water systems (PWSs) must follow regarding the form, manner, frequency and content of a public notice.

As a condition of primacy, States must have rules or other authority no less stringent than the federal rules in order to assure that PWSs comply with the requirements of the these federal rules. Accordingly, the requirements of the federal rules must be incorporated into Subpart 5-1, Public Water Systems.

Needs and Benefits

The revisions associated with the IESWTR will improve public health by increasing the level of protection from exposure to Cryptosporidium and other pathogens in drinking water supplies through improvements in filtration at water systems.

The DBP Rule is expected to reduce the risks associated with exposure to disinfectants and DBPs. In the Regulatory Impact Analysis for the DBP Rule, the USEPA estimated that the rule will result in a national annual reduction in total trihalomethane levels of 24 percent.

The PN rule is an integral part of the public health protection and the consumer right-to-know provisions in the 1996 Amendments to the federal Safe Drinking Water Act (SDWA). The proposed revisions will ensure persons served by public water systems are effectively notified about potential health risks from their drinking water.

Costs

Approximately 2,200 public water systems will have to comply with the requirements of the IESWTR and/or the DBP Rule in New York State. These public water systems include community water systems using groundwater or surface water, as well as nontransient, noncommunity water systems that use surface water or ground water under direct influence of surface water as a source. Approximately 1,800 of these 2,200 systems provide disinfected groundwater. Costs to these systems will vary depending on system size, source water type, and method of treatment. Cost estimates are derived separately for each of the federal regulations, then itemized by owner type.

Estimated costs for this rulemaking are based primarily on two referenced studies prepared by the USEPA: "Regulatory Impact Analysis for the Interim Enhanced Surface Water Treatment Rule", November 12, 1998; and, "Regulatory Impact Analysis for Stage 1 Disinfectants/Disinfection Byproducts Rule", November 12, 1998. These studies considered the potential for exposure to surface water pathogens and disinfection byproducts, the related health hazards, compliance costs and impacts to industry and consumers, treatment effectiveness, and national and household benefit comparisons.

The estimated annual cost for New York State's public water systems to comply with the monitoring and treatment technique requirements of the DBP Rule will be approximately $17.9 million. The cost to implement and comply with the IESWTR (including the related FBRR and LT1ESWTR) is expected to be an additional $11.8 million (approximately). Accordingly, total additional cost to New York State Public Water systems for monitoring, treatment, implementation, and compliance are expected to be approximately $29.7 million.

However, it should be noted that most public water systems may actually save money with regard to compliance and implementation costs as they relate to notice of deficiencies. For public water systems, the cost of complying with such public notification requirements is divided into three activities: notice preparation costs, notice distribution costs, and costs of repeat notices. Only public water systems with a violation or other situation requiring a public notice will incur costs.

Nationally, the EPA estimates that the total cost for systems to comply with the revised public notification rule will be approximately 38.9 percent less than such costs under the existing rule.

The total number of active public water systems in the State is approximately 11,420. In 1999, there were approximately 2,250 violations committed by approximately 1,300 of the State's public water systems. If NYS achieves the same cost reduction per violation as estimated by the EPA, then the average total cost for public water systems to comply with the public notification rule would be reduced by about $150,000 annually.

A more conservative estimate of cost savings, based solely on the changes in issuing notification for monitoring violations, would result in a projected annual savings to public water systems of $30,000 to $50,000.

Costs to State Government

Increased cost to state government will be limited primarily to those State agencies that operate water systems as defined in Part 5 of the State Sanitary Code. If the water system uses surface water or groundwater under the direct influence of surface water and serves at least 10,000 people, it will have to comply with the requirements of the IESWTR in January 2002. Systems serving less than 10,000 people will have to comply with the related LT1ESWTR by January 2004. All community and nontransient noncommunity water systems that disinfect will also have to comply with the requirements of the DBP Rule.

Approximately 60 State-owned systems will have to comply with the DBP Rule. Total annual cost to State-owned systems for compliance with both regulations is estimated to be approximately $682,000 (of which $350,000 relates to State government compliance with the DPB Rule, and $332,000 to State government compliance with the IESWTR).

Costs to Local Government

The amended regulations apply to all local governments (town, village, county, authorities or area-wide improvement districts) that own or operate community water systems. Nontransient noncommunity water systems are also affected, such as those serving local government buildings and day schools (elementary or central schools, and community colleges). Based on the Department's data, there are 800 community systems owned and operated by local governments in New York State. Approximate annual costs for these systems to comply with the requirements of the IESWTR and the DBP Rule will be as follows: $2.7 million for surface water systems serving less than 10,000 people; $21.0 million for surface water systems serving at least 10,000 people; and $0.5 million for disinfected groundwater systems.

The approximately 1,680 public water systems owned and operated by local government will be required to comply with the revised public notification requirements when there is a drinking water violation or other situation that may pose a risk to public health. However, the revised regulations will be less burdensome and costly to municipalities compared to the current code requirement.

Costs to Private Regulated Parties

The requirements of the IESWTR and the DBP Rule also apply to community and nontransient noncommunity systems that are privately

owned or operated. Approximately 1,246 privately owned or operated systems will be affected by the proposed amendments. Estimated annual costs for these systems to comply with the requirements of the IESWTR and the DBP Rule will be as follows: $0.64 million for surface water systems serving less than 10,000 people; $1.36 million for surface water systems serving at least 10,000 people; and $1.1 million for disinfected groundwater systems.

Costs to State and Local Health Departments

Health department costs include program start-up and ongoing implementation costs, including sanitary surveys for all surface water systems. The estimated additional annual cost to the New York State and local health departments for implementation of these rules is $1.2 million, of which $600,000 is estimated to be expended by NYS DOH.

Local Government Mandates

The stricter monitoring, reporting and treatment requirements of the IESWTR apply to all water systems using surface water or groundwater under the direct influence of surface water and treating their water using either conventional or direct filtration. The stricter monitoring and treatment requirements of the DBP Rule apply to all community and nontransient noncommunity water systems. Many of these systems are owned and operated by a county, city, town, village, or school district. However, it should be noted that the obligation imposed on local government in this case is imposed simply because of the local government's status as a water system operator. These requirements are being proposed for purposes of consistency with federal requirements, and do not constitute an additional mandate.

Paperwork

In order for public water systems to comply with the DBP requirements of this proposal, they must report to the State disinfectant, disinfection byproduct precursor, and disinfection byproduct monitoring information. The latter two categories must be done by an approved laboratory.

Two of the public notification revisions will result in reduced paper work. The revised rule requires notice within one year after the occurrence of most monitoring violations rather than within three months, as required by the current rule. The revised rule allows the option of issuing a Tier 1 notice by electronic media, hand delivery, or posting, whereas the current rule requires notice by radio, television, newspaper, and mail. Public water systems must certify to the State that they have complied with the public notification requirements within 10 days of completing a public notification requirement for an initial public notice and any repeat notices.

Duplication

Any duplication with federal regulations will be temporary because the result of the rule will be the continuation of New York State's "primacy" vis a vis the Federal Government (U.S. EPA) to regulate public water systems under the Safe Drinking Water Act. If this rule is not adopted, then the operators of public water systems may be subject to differing state and federal requirements.

Alternatives

The revisions incorporating the requirements of the IESWTR, the DBP Rule and the PN Rule are federally mandated. NYS DOH did not consider any significant alternatives to the rule, because to maintain "primacy" to administer and enforce the requirements of these two rules, the DOH must amend State Sanitary Code Subpart 5-1 to be no less stringent than the federal requirements.

Federal Standards

The revisions associated with the IESWTR, the DBP Rule, and the Public Notification Rule are as protective as, and generally conform to, the U.S. EPA's National Primary Drinking Water Regulations as specified in Subparts G, P, and Q of 40 CFR Part 141. There are a limited number of reporting or notification requirements that were not relaxed to the extent that federal regulations allow.

Compliance Schedule

This proposal requires that beginning January 1, 2002, (consistent with the already promulgated Federal regulation) all water systems using surface water or groundwater under the direct influence of surface water and serving at least 10,000 people must comply with the IESWTR and DBP Rule requirements. According to the department's data, 84 public water systems in New York State will have had to comply with the proposed code amendments beginning January 1, 2002. Community and nontransient noncommunity water systems using surface water or groundwater under the direct influence of surface water and serving fewer than 10,000 people (258 systems in New York State), and community and nontransient noncommunity systems that disinfect and use groundwater (approximately 1,830 in New York State), must comply with the proposed code amendment beginning January 1, 2004. Upon adoption, all public water systems must comply with the public notification rule.

Regulatory Flexibility Analysis

Effect of Rule

IESWTR/DBP Rule

There are approximately 1,150 small privately owned community and nontransient noncommunity water systems in New York State that will be affected by the proposed amendments incorporating the requirements of this proposed code amendment. For the purpose of this analysis, a small system is defined as one classified as a community or nontransient noncommunity system that serves 3,300 people or less. The small privately owned systems consist of mobile home parks, colleges, boarding schools, nursing homes, apartment complexes, condominiums, and realty subdivisions, among others.

There are also approximately 629 community and nontransient noncommunity water systems owned or operated by local governments that will be subject to the requirements of the proposed amendments. These are water systems that serve small communities, town, city and municipally owned nursing homes and colleges, among others.

Some of these small systems may be located near or adjacent to larger water systems. For these systems, there is a greater opportunity to connect to a larger municipal system. For this type of system, consolidation may be a less costly compliance alternative than complying with the new regulation.

Public Notification Rule

All public water systems in New York State must follow the requirements of the public notification rule. There are approximately 9,410 small privately owned water systems in New York State that are affected by this regulation. For the purpose of this analysis, a small system (business) is defined as one classified as either a community water system or a noncommunity water system that serves 3,300 people or less. The small private regulated systems consist of mobile home parks, colleges, daycare centers, apartment complexes, condominiums, realty subdivisions, restaurants, stores, and others.

There are approximately 1,680 water systems that are owned or operated by the local government (city, town, public schools, and municipally owned colleges and daycare centers, etc.) that will be subject to the standards in the revised regulation.

Compliance Requirements

IESWTR/DBP Rule

Water systems operated by small businesses and local governments will require the professional services of a certified or approved laboratory to perform water analyses for disinfection byproduct precursors and disinfection byproducts. The laboratory used must be approved by the New York State Department of Health under its Environmental Laboratory Approval Program. It is estimated that sufficient laboratory capability and capacity are available.

Reporting and recordkeeping requirements will be increased for small businesses and local governments that are operating small public water systems in that public water systems will have to report to the State their disinfectant, disinfection byproduct precursor, and disinfection byproduct monitoring information. Systems with conventional treatment will have to calculate their percent removal of total organic carbon (TOC) and report to the State whether they are in compliance with the TOC percent removal requirements. In addition, systems that are in violation of the proposed amendments may be required to give public notice notifying consumers that the system failed to comply with the regulations.

A licensed professional engineer may be required to design treatment facilities to meet the disinfection byproduct standards or to design facilities to provide an alternate water source.

Public Notification Rule

Only public water systems with a violation or other situation requiring a public notice will have to undertake actions under this rule. Reporting and recordkeeping requirements will decrease overall for small businesses and local governments that operate public water systems and are required to issue a public notice. The majority of drinking water violations are failure to fully follow monitoring or testing procedures. Systems will now be able to reduce the number of notices issued by consolidating all notices for monitoring and testing procedure violations and reporting them annually instead of every three months. Situations with significant potential to have serious adverse effects on human health as a result of short-term exposure will require a Tier 1 notice. Currently, notices for these types of violations must be issued by radio, TV, newspaper and mail delivery, however, the proposed rule allows Tier 1 notices to be issued by electronic media, hand delivery or posting.

The proposed rule adds new certification requirements. Public water systems, within 10 days of completing the public notification requirements for the initial public notice and any repeat notices, must submit to the State a certification that it has fully complied with the public notification regulations. The public water system must include with this certification a representative copy of each type of notice distributed, published, posted, and made available to the persons served by the system and to the media. Under the current rule, only a copy of the notice has to be sent to the State. The number of violations and situations that would require public notice will increase slightly because of several new contaminants and situations that will be regulated under new federal/state rules (Disinfection Byproduct Rule and Interim Enhanced Surface Water Treatment Rule).

Compliance Costs

IESWTR/DBP Rule

The proposed amendments will incur costs to small businesses and local governments in the form of water treatment costs, monitoring and reporting costs, and start-up costs. As discussed in the Regulatory Impact Statement, the additional annual cost for a small surface water system to comply with the proposed requirements of the DBP rule will be approximately $8,920. The additional capital cost is expected to vary by system size from $50,000 for a system serving 3,300 persons to $20,000 for one serving 500 persons. Annual operation and maintenance costs are projected to increase by $4,000 and $2,000 per system for systems serving 3,300 and 500 persons respectively. The additional annual cost for a groundwater system to comply with the proposed requirements will all be in the form of operational costs and is projected to increase by $1,000 for a system serving 3,300 persons and by $200 for a system serving fewer than 500 persons. According to the Safe Drinking Water Information System, there are 129 community and nontransient noncommunity surface water systems serving 3,300 or fewer people that are privately owned or owned by local governments. The total additional cost, therefore, to small surface water systems owned and operated by small businesses or local governments will be approximately (129 systems) ($8,920 per system) = $1.15 million. The total annual cost for rural surface water systems for additional monitoring due to the IESWTR will be approximately (129 systems) ($2500) = $322,500. There are 1,650 disinfected groundwater systems that are community or nontransient noncommunity supplies that serve 3,300 or fewer people and are owned or operated privately or by local governments. The total additional cost, therefore, to small groundwater systems owned and operated by small businesses or local governments will be approximately (1,650 systems) ($937 per system) = $1.55 million. Therefore, the total estimated additional annual cost to public water systems serving 3,300 or fewer people that are owned or operated by small businesses or local governments for compliance with the proposed amendments will be ($1.15 million) + ($0.3 million) + ($1.55 million) = $3.0 million.

Public Notification Rule

Only public water systems with a violation or other situation requiring a public notice will incur costs under this rule. No initial capital costs will be incurred by small businesses or local governments under this rule. If public notices do have to be issued, the annual costs incurred by small public water systems under this rule will be less than the annual costs incurred under the previous regulations by amounts ranging from $25,000 to $42,000.

Economic and Technological Feasibility

Compliance with the IESWTR/DBP Rule and the Public Notification Rule proposed amendments is both economically and technologically feasible. There will be, however, an increase in monitoring costs and, frequently, an increase in treatment costs for small businesses or local governments that operate small systems, as noted in the Compliance Cost section, above.

Methods currently exist for the analysis of total trihalomethanes and haloacetic acids. Treatment techniques to reduce disinfection byproduct formation are well understood, and technologically feasible alternatives are available for disinfection byproduct treatment. The Department of Health has the staff and the expertise to provide technical guidance.

Minimizing Adverse Impact

The revisions incorporating the requirements of the IESWTR, the DBP Rule and the PN Rule are federally mandated. NYS DOH did not consider any significant alternatives to the rule, because to maintain "primacy" to administer and enforce the requirements of these two rules, the DOH must amend State Sanitary Code Subpart 5-1 to adopt the federal requirements.

The costs described above are the result of the requirements of the federal DBP Rule, which will take effect regardless of state action. The New York State Department of Health plans to provide owners and operators of public water systems with training, guidance documents, and monitoring report forms to help alleviate some of the labor costs associated with the regulations.

According to the proposed amendments, public water systems with low levels of disinfection byproducts in their water will be allowed to reduce monitoring frequency, and thereby reduce labor and laboratory costs. The Department of Health will assist systems and local health departments with determining which systems can reduce disinfection byproduct monitoring based on levels found in samples previously collected.

The proposed Public Notification Rule will have no adverse economic impact on small businesses or local governments. The rule is designed to reduce the burden of complying with the public notification requirements.

Small Business and Local Government Participation

The DOH assembled meetings of all affected parties to assist in the development of the regulations. The meetings included the following representatives with interests associated with small business and local government:

- New York Rural Water Association
- American Water Works Association
- New York State Conference of Directors of Environmental Health Services
- New York State Conference of Mayors
- New York State Association of Towns
- New York State Association of County Health Officials

The IESWTR/DBP Rule have been discussed at a series of workshops across the State. The majority of small business and local government water systems are small systems which will not be required to comply with the new IESWTR/DBP Rules until January 2004. Outreach and training will continue through the American Water Works Association and the New York Rural Water Association, organizations that represent small water systems. A representative of the DOH made a public presentation on the Public Notification Rule at a New York Rural Water Association meeting. The New York Rural Water Association is dedicated to the improvement and development of small public and privately owned water and wastewater systems.

Rural Area Flexibility Analysis

Types and Estimated Numbers of Rural Areas

The requirements of the Interim Enhanced Surface Water Treatment Rule (IESWTR) have applied to public water systems serving at least 10,000 people since January 1, 2002, and will apply to smaller systems on January 1, 2004. The requirements of the Disinfectants/Disinfection Byproducts Rule (DBP Rule) have applied to all community and nontransient noncommunity water systems that disinfect on the same dates as those for the IESWTR, based upon the size of the system. The proposed revisions will impact approximately 2,000 small rural water systems located throughout all rural areas as defined by New York State (SAPA 102[10]) and Executive Law 481[7]. The Public Notification Rule, effective May 6, 2002 will impact approximately 900 of these systems who have had one or more violations per year.

Some of these small rural systems may be located near or adjacent to larger water systems. For these systems, there is a greater opportunity to connect to a municipal water system. For this type of system, consolidation may be a less costly compliance alternative than complying with the new regulations. For the greater majority of systems that are truly rural, however, this option does not exist.

Reporting, Recordkeeping, or Other Compliance Requirements

The IESWTR and DBP Rule will increase recordkeeping requirements for small rural systems. Systems will have to report to the State their disinfectant, disinfection byproduct precursor, and disinfection byproduct monitoring information, as well as turbidity monitoring results. Systems with conventional treatment will have to calculate their percent removal of total organic carbon (TOC) and report to the State information regarding whether they are in compliance with the TOC percent removal requirements.

Small rural systems will require the professional services of a certified or approved laboratory to perform water analyses for disinfection byproduct precursors and disinfection byproducts. The laboratory used must be one approved by the New York State Department of Health under its Environmental Laboratory Approval Program. It is estimated that sufficient laboratory capability and capacity are available. Public notice will be required if the system violates these regulations.

In some cases, a licensed professional engineer will be required to design treatment facilities to meet the disinfection byproduct standards or to design facilities for accessing an alternate source.

The Public Notification Rule will decrease the reporting and recordkeeping requirements for small rural public water systems that are required

to issue a public notice. The majority of drinking water violations are failure to fully follow monitoring or testing procedures. Systems will now be able to reduce the number of notices issued by consolidating all notices for monitoring and testing procedure violations in an annual report instead of every three months. Situations with significant potential to have serious adverse effects on human health as a result of short term exposure will require a Tier 1 notice. Currently notices for these types of violations must be issued by both newspaper and mail delivery. The proposed rule allows Tier 1 notices to be issued by electronic media, hand delivery or posting.

The Public Notification Rule adds new certification requirements. Public water systems, within 10 days of completing the public notification requirements for the initial public notice and any repeat notices, must submit to the State a certification that it has fully complied with the public notification regulations. The public water system must include with this certification a representative copy of each type of notice distributed, published, posted, and made available to the persons served by the system and to the media. Under the current rule, only a copy of the notice has to be sent to the State. The number of violations and situations that could require public notice will increase slightly because of several new contaminants and situations that will be regulated under new federal/state rules (Disinfection Byproduct Rule and Interim Enhanced Surface Water Treatment Rule).

Costs

IESWTR/DBP Rule

The proposed amendments will incur costs to small rural systems in the form of treatment costs, monitoring and reporting costs, and start-up costs. As discussed in the Regulatory Impact Statement, the additional annual cost for a small surface water system to comply with the proposed requirements of the DBP rule will be approximately $8,920. The additional capital cost is expected to vary by system size from $50,000 for a system serving 3,300 persons to $20,000 for one serving 500 persons. Annual operation and maintenance costs are projected to increase by $4,000 and $2,000 per system for systems serving 3,300 and 500 persons respectively. The additional annual cost for a groundwater system to comply with the proposed requirements will all be in the form of operational costs and is projected to increase by $1,000 for a system serving 3,300 persons and by $200 for a system serving fewer than 500 persons. There are an estimated 130 community and nontransient noncommunity surface water systems located in rural areas. The total annual additional cost for the DBP rule, therefore, to small rural surface water systems will be approximately (130 systems) ($8,920 per system) = $1.2 million. The total annual cost for rural surface water systems for additional monitoring due to the IESWTR will be approximately (130 systems) ($2500) = $325,000. There are an estimated 1,710 groundwater systems disinfected with chlorine that are community or nontransient noncommunity supplies in rural areas. The total annual additional cost, therefore, to small, rural groundwater systems will be approximately (1,710 systems) ($937 per system) = $1.6 million . The total estimated additional annual cost to public water systems serving 3,300 or fewer people for compliance with the proposed amendments will be ($1.2 million) + ($0.3 million) + ($1.6 million) = $3.1 million.

Public Notification Rule

Only public water systems with a violation or other situation requiring a public notice incur costs under this rule. No initial capital costs will be incurred by small rural water systems under this rule. If public notices do have to be issued, the costs incurred under this rule will be less than the costs incurred under the previous public notification regulations, varying from $20,000 to $40,000 for small rural water systems.

Minimizing Adverse Impact

IESWTR/DBP Rule

The revisions incorporating the requirements of the IESWTR, the DBP Rule and the PN Rule are federally mandated. NYSDOH did not consider any significant alternatives to the rule, because to maintain "primacy" to administer and enforce the requirements of these two rules, the DOH must amend State Sanitary Code Subpart 5-1 to adopt the federal requirements.

The costs described above are the result of the requirements of the federal IESWTR and DBP Rule, which will take effect regardless of state action. The New York State Department of Health plans to provide owners and operators of public water systems with training, guidance documents, and monitoring report forms to help alleviate some of the labor costs associated with these regulations.

Public water systems with low levels of disinfection byproducts in their water will be allowed to reduce monitoring frequency, and thereby reduce labor and laboratory costs. The Department of Health will assist systems and local health departments with determining which systems can reduce disinfection byproduct monitoring based on levels found in samples previously collected.

Public Notification Rule

The proposed rule will have no adverse economic impact on small rural public water systems. The rule is designed to reduce the burden and cost of complying with the public notification requirements.

Rural Area Participation

Many of the public water systems that will be affected by the proposed amendments are towns and villages operating municipal water systems. The New York State Department of Health has been discussing the proposed amendments at organizational meetings where small public water systems are represented. Department of Health representatives have and will continue to explain the new requirements at local meetings of the New York Rural Water Association, the American Water Works Association, the Conference of Environmental Health Directors, the New York State Association of County Health Officials, the New York Association of Towns, and the New York Conference of Mayors.

Job Impact Statement

The amended regulation does not mandate a reduction or increase of employment opportunities. The nature of the impact will be a transfer of some jobs to the operation of public water systems and supporting industries from the general economy of the state.

Initially, as capital facilities are constructed, the job impact will be offset by the generation of 120 construction jobs, both labor and professional engineering services, and jobs in material and equipment supply industries. Longer term, the increased employment is estimated to be 60 jobs for increased water treatment plant operation and oversight, as well as, in companies providing chemicals, energy and laboratory services.

The impacts of this rule will be primarily in the upstate areas of the state, which are more reliant on surface water sources.

The New York State Department of Health (NYSDOH) did not consider any significant alternatives to the rule because to maintain "primacy" to administer and enforce the requirements of mandated federal rules, the NYSDOH must amend the State Sanitary Code Subpart 5-1 to adopt federal requirements.

Insurance Department

NOTICE OF ADOPTION

Allocation of Income and Expenses

I.D. No. INS-30-03-00004-A
Filing No. 1228
Filing date: Oct. 29, 2003
Effective date: Oct. 29, 2003

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

Action taken: Amendment of Part 91 (Regulation 33) of Title 11 NYCRR.

Statutory authority: Insurance Law, sections 201 and 301

Subject: Allocation of income (receipts) and expenses.

Purpose: To repeal an obsolete regulation.

Text or summary was published in the notice of proposed rule making, I.D. No. INS-30-03-00004-P, Issue of July 30, 2003.

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

Text of rule and any required statements and analyses may be obtained from: Terri Marchon, Public Affairs, Insurance Department, 25 Beaver St., New York, NY 10004, (212) 480-2283, e-mail: tmarchon@ins.state.ny.us

Assessment of Public Comment

The agency received no public comment.

NOTICE OF ADOPTION

Fees or Other Allowances

I.D. No. INS-33-03-00001-A
Filing No. 1225
Filing date: Oct. 29, 2003
Effective date: Nov. 19, 2003

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

Action taken: Amendment of Part 2002 (Regulation 65) of Title 11 NYCRR.

Statutory authority: Insurance Law, sections 201 and 301

Subject: Compensation to agents and fees or other allowances payable for individual life insurance issued on a mass merchandising basis under plans sponsored by union – management welfare funds.

Purpose: To update obsolete references to statutory provisions and delete a provision.

Text or summary was published in the notice of proposed rule making, I.D. No. INS-33-03-00001-P, Issue of August 20, 2003.

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

Text of rule and any required statements and analyses may be obtained from: Terri Marchon, Public Affairs, Insurance Department, 25 Beaver St., New York, NY 10004, (212) 480-2283, e-mail: tmarchon@ins.state.ny.us

Assessment of Public Comment
The agency received no public comment.

NOTICE OF ADOPTION

Statements of Financial Condition and Advertisements

I.D. No. INS-33-03-00009-A
Filing No. 1231
Filing date: Oct. 29, 2003
Effective date: Nov. 19, 2003

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

Action taken: Repeal of Part 75 (Regulation 2) of Title 11 NYCRR.

Statutory authority: Insurance Law, sections 201 and 301

Subject: Statements of financial condition and advertisements.

Purpose: To repeal an obsolete regulation whose provisions are irrelevant or inapplicable because of statutory changes and revisions of the format of certain schedules to the annual statement.

Text or summary was published in the notice of proposed rule making, I.D. No. INS-33-03-00009-P, Issue of August 20, 2003.

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

Text of rule and any required statements and analyses may be obtained from: Terri Marchon, Public Affairs, Insurance Department, 25 Beaver St., New York, NY 10004, (212) 480-2283, e-mail: tmarchon@ins.state.ny.us

Assessment of Public Comment
The agency received no public comment.

NOTICE OF ADOPTION

Reporting of Income and Expenses

I.D. No. INS-33-03-00010-A
Filing No. 1227
Filing date: Oct. 29, 2003
Effective date: Nov. 19, 2003

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

Action taken: Repeal of Part 90 (Regulation 33) of Title 11 NYCRR.

Statutory authority: Insurance Law, sections 201 and 301

Subject: Reporting of income and expenses.

Purpose: To repeal obsolete provisions.

Text or summary was published in the notice of proposed rule making, I.D. No. INS-33-03-00010-P, Issue of August 20, 2003.

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

Text of rule and any required statements and analyses may be obtained from: Terri Marchon, Public Affairs, Insurance Department, 25 Beaver St., New York, NY 10004, (212) 480-2283, e-mail: tmarchon@ins.state.ny.us

Assessment of Public Comment
The agency received no public comment.

NOTICE OF ADOPTION

Treatment of Excess Profits in Motor Vehicle Insurance

I.D. No. INS-34-03-00006-A
Filing No. 1226
Filing date: Oct. 29, 2003
Effective date: Nov. 19, 2003

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

Action taken: Amendment of Part 166 (Regulation 105) of Title 11 NYCRR.

Statutory authority: Insurance Law, sections 201, 301, 2323 and 2329; and L. 2003, ch. 85

Subject: Treatment of excess profits in motor vehicle insurance; general rules.

Purpose: To remove outdated references and implement an amendment to the Insurance Law.

Text or summary was published in the notice of proposed rule making, I.D. No. INS-34-03-00006-P, Issue of August 27, 2003.

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

Text of rule and any required statements and analyses may be obtained from: Terri Marchon, Public Affairs, Insurance Department, 25 Beaver St., New York, NY 10004, (212) 480-2283, e-mail: tmarchon@ins.state.ny.us

Assessment of Public Comment
The agency received no public comment.

PROPOSED RULE MAKING
NO HEARING(S) SCHEDULED

Healthy New York Program

I.D. No. INS-46-03-00004-P

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

Proposed action: Amendment of sections 362-2.3 and 362-4.3 (Regulation 171) of Title 11 NYCRR.

Statutory authority: Insurance Law, sections 201, 301, 1109, 3201, 3216, 3217, 3221, 4235, 4303, 4304, 4305, 4318, 4326 and 4327

Subject: Healthy NY standardized application and clarification on household income requirements.

Purpose: To simplify the application process.

Text of proposed rule: Section 362-2.3 is hereby amended to read as follows:

§ 362-2.3 Enrollment.

(a) Applications for qualifying health insurance contracts shall be made directly to health maintenance organizations and participating insurers.

(b) Health maintenance organizations and participating insurers shall provide all necessary information and enrollment forms when requested by applicants.

(c) Health maintenance organizations and participating insurers shall collect the initial eligibility certifications required by section 4326(i) of the Insurance Law and necessary supporting documentation and shall be responsible for examination of such certifications and supporting documentation for verification that applicants meet applicable eligibility requirements. *Health maintenance organizations and participating insurers shall accept any standardized application form that may be prescribed by the superintendent.*

(d) Unless the superintendent suspends enrollment in the Healthy New York program pursuant to section 4327(k) of the Insurance Law or approves a request to suspend qualifying individual enrollment pursuant to subsection (h) of this section, all applicants meeting eligibility criteria shall be accepted and coverage must be issued on the first day of the month next succeeding the date a complete application has been submitted for all applications submitted on or prior to the 20th day of such month. For applications submitted after the 20th day of a month, coverage shall be issued no later than the first of the month next following. Dependent children up to at least age 19 and full-time students up to at least age 23

shall be considered eligible dependents under qualifying health insurance contracts.

(e) Health maintenance organizations and participating insurers shall provide applicants which have failed to demonstrate eligibility with a written notice of denial which clearly sets forth the basis for the denial.

(f) Health maintenance organizations and participating insurers must submit monthly enrollment reports which detail total enrollment in the Healthy New York program in the format specified by the superintendent. Such reports shall identify the health maintenance organization's or participating insurer's total enrollment in the Healthy New York program as of the first day of the following month and must be submitted to the superintendent no later than the fifteenth day of the following month.

(g) In the event that the enrollment in the small employer or individual Healthy New York program is suspended pursuant to section 4327(k) of the Insurance Law, participating insurers and health maintenance organizations shall:

(1) notify applicants that enrollment has been suspended; and

(2) maintain a waiting list to be filled in the order of receipt in the event that enrollment is reactivated.

(h) Commencing June 1, 2001, if monthly enrollment reports indicate that a given health maintenance organization or participating insurer's total enrollment under qualifying individual health insurance contracts exceeds 50% of that health maintenance organization's or participating insurer's total enrollment in the Healthy New York program, the health maintenance organization or participating insurer may submit a request to the superintendent to suspend the issuance of its qualifying individual health insurance contracts. If approved by the superintendent, the suspension shall take effect on the date specified by superintendent and shall be for the period specified by the superintendent. A participating insurer or health maintenance organization that has received approval to issue such a suspension shall:

(1) notify applicants that enrollment has been suspended;

(2) maintain a waiting list to be filled in the order of receipt in the event that enrollment is reactivated; and

(3) on a quarterly basis, submit reports detailing the claims experience of the Healthy New York product. Such reports shall segregate the claims experience of qualifying individuals from the claims experience of qualifying small employers and individual proprietors.

(i) An enrollment suspension pursuant to section 4327(k) of the Insurance Law or pursuant to subsection (h) of this section shall not preclude the addition of dependents or new employees to existing qualifying health insurance contracts. Additionally, an enrollment suspension shall not prevent the enrollment of persons exercising a statutory right of conversion to a qualifying individual insurance contract.

(j) Nothing herein is intended to preclude, diminish or in any way impair the involvement of chambers of commerce, trade associations and other similar entities in the Healthy New York Program in any manner otherwise permitted by law or regulation.

Section 362-4.3 is hereby amended to read as follows:

§ 362-4.3 Verification of net household income.

(a) To qualify for coverage under the Healthy New York program, individual proprietors and working uninsured individuals must satisfy the household income criteria set forth in Sections 4326(c)(1)(A)(ii) and 4326(c)(3)(A)(iii) of the Insurance Law. *For the purpose of determining household income eligibility, household members shall include the applicant, the applicant's legal spouse if residing in the household, and any children eligible for coverage under the policy.* Income received by the applicant[, their] *and the applicant's* legal spouse [and any other family members] residing in the household shall be counted.

(b) Income shall include, but shall not be limited to, the following:

(1) monetary compensation for services including wages, salary, commissions, overtime compensation, fees or tips;

(2) net income from farm and non-farm self-employment;

(3) Social Security payments or benefits;

(4) dividends, interest on savings or bonds, regular income from estates or trusts, or net rental income;

(5) unemployment compensation;

(6) government, civilian employee or military retirement or pension or veteran's payments;

(7) private pension or annuity;

(8) alimony or child support payments received;

(9) regular contributions from persons not living in the household;

(10) net royalties; and

(11) such other income as determined by the superintendent.

(c) Income shall not include public assistance; SSI; foster care payments; capital gains; any assets drawn down as withdrawals from a bank; receipts from the sale of property; or payments for compensation for injury. Also excluded are non-cash benefits, such as employee fringe benefits, food or housing received in lieu of wages, and receipts from federal non-cash benefit programs.

(d) Health maintenance organizations and participating insurers shall collect such documentation as is necessary and sufficient to initially, and annually thereafter, verify that the household income requirements of the Healthy New York program have been satisfied. Such documentation may include, but not be limited to one or more of the following:

(1) annual income tax returns and, if not prohibited by federal law for purposes of income verification, the social security account number;

(2) paycheck stubs;

(3) written documentation of income from all employers; or other documentation of income (earned or unearned) as determined by the superintendent to be acceptable, provided however, such documentation shall set forth the source of such income.

Text of proposed rule and any required statements and analyses may be obtained from: Theresa Marchon, Insurance Department, 25 Beaver St., New York, NY 10004, (212) 480-2280, e-mail: tmarcho@ins.state.ny.us

Data, views or arguments may be submitted to: Patricia Swolak, Insurance Department, One Commerce Plaza, Albany, NY 12257, (518) 486-7815, e-mail: pswolak@ins.state.ny.us

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

Regulatory Impact Statement

1. Statutory authority: The authority for the amendment to 11 NYCRR 362 is derived from sections 201, 301, 1109, 3201, 3216, 3217, 3221, 4235, 4303, 4304, 4305, 4318, 4326 and 4327 of the Insurance Law. Sections 201 and 301 authorize the superintendent to prescribe regulations interpreting the provisions of the Insurance Law as well as effectuating any power granted to the superintendent under the Insurance Law, to prescribe forms or otherwise to make regulations. Section 1109 authorizes the superintendent to promulgate regulations in effectuating the purposes and provisions of the Insurance Law and Article 44 of the Public Health Law with respect to the contracts between a health maintenance organization and its subscribers. Section 3201 authorizes the superintendent to approve accident and health insurance policy forms for delivery or issuance for delivery in this state. Section 3216 sets forth the standard provisions to be included in individual accident and health insurance policies written by commercial insurers. Section 3217 authorizes the superintendent to issue regulations to establish minimum standards, including standards of full and fair disclosure, for the form, content and sale of accident and health insurance policies. Section 3221 sets forth the standard provisions to be included in group or blanket accident and health insurance policies written by commercial insurers. Section 4235 defines group accident and health insurance and the types of groups to which such insurance may be issued. Section 4303 sets forth benefits that must be covered under accident and health insurance contracts. Section 4304 includes requirements for individual health insurance contracts written by non-profit corporations. Section 4305 includes requirements for group health insurance contracts written by not-for-profit corporations. Section 4326 authorizes the creation of a program to provide standardized health insurance to qualifying small employers and qualifying working uninsured individuals. Section 4327 creates two stop-loss funds from which health maintenance organizations and participating insurers may receive reimbursement for certain claims paid on behalf of members covered under qualifying health insurance contracts and authorizes the superintendent to prescribe regulations to implement the establishment of such funds.

2. Legislative objectives: A significant number of New York residents are currently uninsured. Due in part to the rising cost of health insurance coverage, many small employers are currently unable to provide health insurance coverage to their employees. A large portion of New York State's uninsured population is made up of individuals employed in small businesses. The Legislature enacted Chapter 1 of the Laws of 1999 to provide for the Healthy New York Program, which was a new initiative designed to encourage small employers which do not currently provide health insurance coverage to their employees to offer such coverage and also designed to make coverage available to uninsured employees whose employers do not provide group health insurance coverage. As a result of a tremendous working relationship with the participating insurers, the New York State Insurance Department was able to obtain valuable input in reducing the complexity of the Healthy New York application process.

Interested parties recommended that standard application forms be created, one for small employers and another for individuals/sole proprietors. Furthermore, health maintenance organizations sought clarification on who is considered a household member. By creating simplified and standardized Healthy New York applications to be accepted by all health maintenance organizations and participating insurers, the application process will be eased, facilitating the appropriate enrollment of eligible small employers and uninsured employed individuals. With simplified standard applications accepted by all participating providers, the applications will be readily available from a number of sources, reducing the timeframes involved in obtaining and completing an application. As a result, the eligibility and application procedures will be streamlined and will ease administrative processes for both enrollees and providers, encouraging more to purchase health insurance coverage. In addition, clarification on who is a household member eliminates confusion in determining household income, which is necessary in ascertaining eligibility for Healthy New York program.

3. Needs and benefits: The amendment to Part 362 of 11 NYCRR is necessary to clarify eligibility for the Healthy New York Program and to simplify the application and administrative process for both enrollees and providers. Clarifying which persons are to be considered household members will eliminate the uncertainty involved in determining household income levels. The correct calculation of household income is crucial, as this is a major component in determining eligibility for Healthy New York. A simplified standardized application forms will streamline the eligibility and administrative process facilitating enrollment. These provisions should enhance the implementation and operation of the Healthy New York program while improving the efficiency that individuals and small employers will have to access comprehensive health insurance, as the standard application forms will be made available from many sources.

4. Costs: The enacting legislation for the Healthy New York program requires that health maintenance organizations and participating insurers have a system in place to accept applications. This amendment will require that they adjust their procedures in order to allow for the acceptance of a standardized application form. A common request from insurers participating in the Healthy New York program has been that a small employer standardized application form and an individual/sole proprietor standardized application form be created. We would expect that any costs associated with implementing the simplified application process would be minimal since health maintenance organizations and participating insurers are already required to accept applications for enrollment into Healthy New York. The standardized applications will be shorter and more easily understood by applicants. Since the standardized applications are shorter than those currently used in the marketplace, printing costs will be reduced. Similarly, small business and individuals wishing to participate in the Healthy New York program are currently obligated to complete an initial form certifying their eligibility for the program. This regulation will permit such applicants to satisfy this certification requirement by completing a simplified, standardized application form which will be more readily available. This amendment does not impose any additional costs upon small businesses and individuals applying to the program. There will be no costs to local governments associated with this amendment.

5. Local government mandates: This amendment imposes no new mandates on any county, city, town, village, school district, fire district or other special district.

6. Paperwork: This amendment will not impose any additional reporting requirements.

7. Duplication: There are no known federal or other states' requirements that duplicate, overlap, or conflict with this regulation.

8. Alternatives: Throughout, input was sought from interested parties including consumer groups; health plan associations; business groups; associations groups; local chambers of commerce and academics. The amendment is primarily designed to provide clarification of eligibility criteria by eliminating uncertainty in determining household income levels. The amendment also eases the application process by simplifying administrative processes for both enrollees and providers. The small employer and individual/sole proprietor standardized applications will streamline the eligibility and enrollment process facilitating the appropriate enrollment of eligible individuals and employees into the Healthy New York program, thus reducing the number of uninsureds in the state. A common request from insurers participating in the Healthy New York program has been that a simplified, standardized application forms be created.

9. Federal standards: There are no known federal standards addressing the programs addressed in this amendment.

10. Compliance schedule: These changes were previously effectuated through an emergency filing of this amendment, and the health plans have already been in successful compliance with these changes. As health maintenance organizations and participating insurers already have begun utilizing the State's standardized application forms, compliance should be undemanding.

Regulatory Flexibility Analysis

1. Effect of rule: The Healthy New York program was designed to provide small employers, including individual proprietors, with an option to purchase comprehensive health insurance at a premium rate which will be favorably impacted by the availability of state funded stop loss relief. The program is available to qualifying small employers that do not currently offer group health insurance coverage if they have fifty or fewer eligible employees and if 30 percent of their eligible workforce earns annual wages of $30,000 or less. Individual proprietors must meet specified household income requirements. The amendment will affect qualifying small employers, including individual proprietors, by providing them with access to a standardized, streamlined application process for the Healthy New York program. The amendment will also simplify the income eligibility requirements of the Healthy New York program for the purpose of further simplifying the application process. The amendment will not affect local governments. The proposed regulation will also affect health maintenance organizations and licensed insurers in New York State, none of which fall within the definition of small business as found in Section 102(8) of the State Administrative Procedure Act, because there are none which are both independently owned and have under 100 employees.

2. Compliance requirements: Qualifying small employers and individual proprietors wishing to participate in the Healthy New York program may utilize the standardized application for the purpose of certifying initial eligibility for the program. Supporting documentation of eligibility may be required, as appropriate.

3. Professional services: The qualifying small employer and individual proprietor should not require professional services to comply with the amendment.

4. Compliance costs: The implementing legislation requires that small businesses wishing to participate in the Healthy New York program complete an initial form certifying as to their eligibility to participate in the program. Any costs associated with completing this form should be minimal since the information requested in support of an applicant's eligibility certification should be readily available to the small employer. This regulatory amendment designed to simplify the application process for small employers will not impose any additional costs. The amendment imposes no costs to local governments.

5. Economic and technological feasibility: The Healthy New York program is designed to make health insurance premiums more affordable to small businesses. Compliance with the amendment should be economically and technologically feasible for small businesses since it merely allows small businesses to utilize a simplified and standardized application form in order to demonstrate eligibility for the Healthy New York Program.

6. Minimizing adverse impact: The amendment minimizes the adverse impact on small employers by requiring health maintenance organizations and insurers, which are not small businesses within the definition of Section 102(8) of the State Administrative Procedure Act to accept a simplified standardized application to verify a small employer's eligibility for participation in the Healthy New York Program.

7. Small business and local government participation: This Notice is intended to provide small businesses, local governments, and public and private entities in rural and non-rural areas with the opportunity to participate in the rule-making process.

Rural Area Flexibility Analysis

1. Types and estimated numbers of rural areas: Health maintenance organizations and insurers to which this regulation is applicable do business in every county of the state, including rural areas as defined under Section 102(13) of the State Administrative Procedure Act. Small businesses and working uninsured individuals meeting the eligibility criteria for participation in the Healthy New York program and individuals purchasing coverage on the direct payment market are located in every county of the state including rural areas as defined under Section 102(13) of the State Administrative Procedure Act.

2. Reporting, recordkeeping and other compliance requirements; and professional services: Health maintenance organizations are currently required to collect and examine Healthy New York program applications in order to verify that applicants for the Healthy New York program meet all applicable eligibility requirements. Insurers that voluntarily choose to par-

ticipate in this market must do so under the same terms and conditions as health maintenance organizations. This amendment will require Health Maintenance Organizations and Participating Insurers to accept a simplified standardized application for the Healthy New York program. Health Maintenance Organizations and Participating Insurers will have to adjust their Healthy New York application screening processes and procedures to accommodate the introduction of this standardized form. Small businesses and individuals wishing to participate in the Healthy New York program will now be permitted to utilize the standardized form in order to meet the requirement imposed by the enacting legislation that they provide an initial certification as to their eligibility for the program. However, because these requirements apply to both rural and non-rural entities, this regulation does not impose any requirement that would be unique to rural areas.

3. Costs: The enacting legislation for the Healthy New York program requires that Health Maintenance Organizations and Participating Insurers have a system in place to accept applications. This amendment will require that they adjust their procedures in order to allow for the acceptance of a standardized application form. We would expect that any costs associated with implementing this simplified application process would be minimal, since the affected organizations are already required to process Healthy New York applications. Similarly, small business and individuals wishing to participate in the Healthy New York program are currently obligated to complete an initial form certifying their eligibility for the program. This amendment will permit such applicants to satisfy this certification requirement by completing a standardized application form. This amendment does not impose any additional costs upon small businesses and individuals applying to the program. Since these requirements apply to both rural and non-rural entities, the amendment does not impose any impact unique to rural areas.

4. Minimizing adverse impact: Because the same requirements apply to both rural and non-rural entities, the amendment will impact all affected entities the same. Furthermore, the impact of the amendment should ultimately be a favorable one, since it simplifies and shortens the application process.

5. Rural area participation: This Notice is intended to provide small businesses, local governments, and public and private entities in rural and non-rural areas with the opportunity to participate in the rule making process.

Job Impact Statement

This amendment will not adversely impact jobs or employment opportunities in New York State. This amendment is intended to improve access to comprehensive health insurance for individuals, the working uninsured and small employers through the simplification of the Healthy New York application process and clarification of household income determinations.

Office of Mental Retardation and Developmental Disabilities

ERRATUM

A Notice of Proposed Rule Making, I.D. No. MRD-43-03-00046-P pertaining to Rate Setting for Intermediate Care Facilities for Persons with Developmental Disabilities, published in the October 29, 2003 issue of the *State Register*, contained incorrect information in the Proposed Action. The language erroneously indicated that the rule was a consensus rule making. The rule was a standard proposed rule making.

The Department of State apologizes for any confusion this may have caused.

New York State 911 Board

ERRATUM

An Information Notice of Proposed Standards published in the November 12, 2003 issue of the *State Register* contained an incorrect Part title. The title of 21 NYCRR Part 5203 should read: Minimum Standards Regarding Equipment, Facilities and Security for Public Safety Answering Points.

The Department of State apologizes for any confusion this may have caused.

Public Service Commission

NOTICE OF WITHDRAWAL

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

The following rule makings have been withdrawn from consideration:

I.D. No.	Publication Date of Proposal
PSC-23-00-00033-W	June 7, 2000
PSC-44-00-00019-W	November 1, 2000
PSC-44-00-00020-W	November 1, 2000
PSC-49-00-00010-W	December 6, 2000
PSC-04-01-00010-W	January 24, 2001
PSC-09-01-00008-W	February 28, 2001
PSC-09-01-00016-W	February 28, 2001
PSC-19-01-00011-W	May 9, 2001
PSC-20-01-00011-W	May 16, 2001
PSC-20-01-00013-W	May 16, 2001
PSC-34-01-00008-W	August 22, 2001
PSC-39-01-00027-W	September 26, 2001
PSC-42-01-00015-W	October 17, 2001
PSC-46-01-00024-W	November 14, 2001
PSC-07-02-00036-W	February 13, 2002
PSC-20-02-00008-W	May 15, 2002
PSC-22-02-00019-W	May 29, 2002
PSC-23-02-00017-W	June 5, 2002
PSC-30-02-00011-W	July 24, 2002
PSC-34-02-00016-W	August 21, 2002
PSC-42-02-00019-W	October 16, 2002
PSC-42-02-00020-W	October 16, 2002
PSC-51-02-00004-W	December 18, 2002
PSC-09-03-00018-W	March 5, 2003
PSC-22-03-00016-W	June 4, 2003
PSC-22-03-00017-W	June 4, 2003
PSC-30-03-00010-W	July 30, 2003
PSC-32-03-00010-W	August 13, 2003
PSC-33-03-00013-W	August 20, 2003
PSC-33-03-00014-W	August 20, 2003

NOTICE OF ADOPTION

Deferred Accounting by United Water New York, Inc.

I.D. No. PSC-06-01-00014-A
Filing date: Oct. 31, 2003
Effective date: Oct. 31, 2003

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

Action taken: The commission, on Oct. 22, 2003, adopted an order in Case 00-W-2233, approving a request by United Water New York, Inc.'s (United Water) to defer property tax appeal costs of $93,181.

Statutory authority: Public Service Law, section 89-c(3)

Subject: Request for deferred accounting.

Purpose: To defer property tax appeal costs.

Substance of final rule: The Commission authorized United Water New York, Inc. to defer calendar year 2000 property tax appeal costs in the amount of $93,181, 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.

(00-W-2233SA1)

NOTICE OF ADOPTION

Water Rates and Charges by United Water New York, Inc.

I.D. No. PSC-36-02-00014-A
Filing date: Oct. 31, 2003
Effective date: Oct. 31, 2003

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

Action taken: The commission, on Oct. 22, 2003, adopted an order in Case 02-W-0992, directing United Water New York, Inc.'s (United Water) to refund customers for its over-collection of revenues and property taxes.

Statutory authority: Public Service Law, section 89-c(10)

Subject: Reconciliation of revenues and property taxes.

Purpose: To refund customers for over-collection of revenues.

Substance of final rule: The Commission authorized United Water New York, Inc. to defer $650,471 for subsequent return to customers through the Revenue Reconciliation Clause resulting from a $692,221 over-collection of property tax expense for the rate year ended April 30, 2002, 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.

(02-W-0992SA1)

NOTICE OF ADOPTION

Water Rates and Charges by United Water New York, Inc.

I.D. No. PSC-03-03-00009-A
Filing date: Oct. 31, 2003
Effective date: Oct. 31, 2003

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

Action taken: The commission, on Oct. 22, 2003, adopted an order in Case 94-W-0486, allowing United Water New York, Inc.'s (United Water) to recover revenues through the revenue reconciliation clause.

Statutory authority: Public Service Law, section 89-c(10)

Subject: Reconciliation of revenues and property taxes.

Purpose: To recover revenues.

Substance of final rule: The Commission authorized United Water New York, Inc. (United Water) to recover $901,222 of under-collection revenues, offset by the Hands-Off Meter Reading adjustment (HOMER), for the rate year ended April 30, 2001, 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.

(94-W-0486SA5)

NOTICE OF ADOPTION

Deferred Property Taxes by United Water New York, Inc.

I.D. No. PSC-03-03-00011-A
Filing date: Oct. 31, 2003
Effective date: Oct. 31, 2003

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

Action taken: The commission, on Oct. 22, 2003, adopted an order in Case 02-W-1111, directing United Water New York, Inc.'s (United Water) to refund customers for its over-collection of property taxes.

Statutory authority: Public Service Law, section 89-c(10)

Subject: Petition for deferred property taxes.

Purpose: To refund customers for over-collection of property tax.

Substance of final rule: The Commission authorized United Water New York, Inc. to defer $371,678 for subsequent return to customers through the Revenue Reconciliation Clause for the rate year ended April 30, 2001, 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.

(02-W-1111SA1)

NOTICE OF ADOPTION

Water Rates and Charges by Rowlands Hollow Water Works, Inc.

I.D. No. PSC-10-03-00008-A
Filing date: Oct. 29, 2003
Effective date: Oct. 29, 2003

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

Action taken: The commission, on Oct. 22, 2003, adopted an order in Case 03-W-0186, approving with modifications Rowlands Hollow Water Works, Inc.'s (Rowlands Hollow) new tariff schedule, P.S.C. No. 2—Water.

Statutory authority: Public Service Law, section 89-c(10)

Subject: Initial tariff schedule.

Purpose: To allow the electronic tariff schedule to take effect Nov. 1, 2003.

Substance of final rule: The Commission authorized Rowlands Hollow Water Works, Inc.'s (Rowlands Hollow) to implement its tariff schedule, P.S.C. No. 2—Water, with modifications, to become effective November 1, 2003, 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.

(03-W-0186SA1)

NOTICE OF ADOPTION

Water Rates and Charges by Arbor Hills Waterworks, Inc.

I.D. No. PSC-24-03-00010-A
Filing date: Oct. 30, 2003
Effective date: Oct. 30, 2003

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

Action taken: The commission, on Oct. 22, 2003, adopted an order in Case 03-W-0791, approving revisions to Arbor Hills Waterworks, Inc.'s (Arbor Hills) tariff schedule, P.S.C. No. 3—Water.

Statutory authority: Public Service Law, section 89-c(10)

Subject: Rate filing by Arbor Hills.

Purpose: To increase annual revenues and establish an escrow account.

Substance of final rule: The Commission authorized Arbor Hills Waterworks, Inc. to increase annual water revenues and establish a $10,000 replenishable escrow account for extraordinary repairs, 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.

(03-W-0791SA1)

NOTICE OF ADOPTION

Water Rates and Charges by Boniville Water Company, Inc.

I.D. No. PSC-24-03-00011-A
Filing date: Oct. 30, 2003
Effective date: Oct. 30, 2003

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

Action taken: The commission, on Oct. 22, 2003, adopted an order in Case 03-W-0792, approving revisions to Boniville Water Company, Inc.'s (Boniville) tariff schedule, P.S.C. No. 4—Water, effective Nov. 1, 2003.

Statutory authority: Public Service Law, section 89-c(10)

Subject: Rate filing by Boniville.

Purpose: To increase annual revenues and establish an escrow account.

Substance of final rule: The Commission authorized Boniville Water Company, Inc. to increase annual water revenues and establish a $10,000 replenishable escrow account for extraordinary repairs, 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.

(03-W-0792SA1)

NOTICE OF ADOPTION

Intercarrier Telephone Service Quality Standard and Metrics

I.D. No. PSC-25-03-00007-A
Filing date: Oct. 29, 2003
Effective date: Oct. 29, 2003

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

Action taken: The commission, on Oct. 22, 2003, adopted an order in Case 97-C-0139 approving revisions to certain metrics and standards contained in the carrier-to-carrier service quality guidelines.

Statutory authority: Public Service Law, sections 4 and 92(2)

Subject: Service quality standards for telephone companies.

Purpose: To promote a competitive local exchange market.

Substance of final rule: The Commission adopted an Order establishing modifications to the Inter-Carrier Telephone Service Quality Guidelines and delegating authority, 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.

(97-C-0139SA17)

NOTICE OF ADOPTION

Mandatory Hourly Pricing by Central Hudson Gas and Electric Corporation

I.D. No. PSC-25-03-00008-A

Filing date: Oct. 30, 2003

Effective date: Oct. 30, 2003

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

Action taken: The commission, on Sept. 17, 2003, adopted in Case 03-E-0641, directing Central Hudson Gas and Electric Corporation, Consolidated Edison Company of New York, Inc., New York State Electric and Gas Corporation, Rochester Gas and Electric Corporation and Orange and Rockland Utilities, Inc. to revise their existing voluntary real-time pricing (RTP) programs.

Statutory authority: Public Service Law, sections 2(13), 5, 65, 66(1), (2), (12) and 66-c

Subject: Expansion of voluntary RTP programs.

Purpose: To enhance the targeted promotion of the electric utilities voluntary RTP programs.

Substance of final rule: The Commission directed Central Hudson Gas and Electric, Consolidated Edison Company of New York, Inc., New York State Electric and Gas Corporation, Rochester Gas and Electric Corporation and Orange and Rockland Utilities, Inc. to submit plans, by February 2, 2004, modifying their existing voluntary Real-Time Pricing programs to include more extensive customer education and outreach efforts, targeting their largest customers, and to assess the potential impacts that real-time pricing has on their largest customers, 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.

(03-E-0641SA1)

NOTICE OF ADOPTION

Sublease of Real Property by The Brooklyn Union Gas Company and ANB Sportswear, Inc.

I.D. No. PSC-25-03-00011-A
Filing date: Oct. 31, 2003
Effective date: Oct. 31, 2003

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

Action taken: The commission, on Oct. 22, 2003, adopted an order in Case 03-G-0793, approving a joint petition of The Brooklyn Union Gas Company d/b/a KeySpan Energy Delivery New York (KeySpan) and ANB Sportswear, Inc. (ANB)

Statutory authority: Public Service Law, sections 5(b), (c), 65(1), 66(1), (2), (5), (8), (9), (10), (11), (12) and 70

Subject: Joint petition for the sublease of certain property.

Purpose: To approve the sublease agreement.

Substance of final rule: The Commission authorized The Brooklyn Union Gas Company d/b/a KeySpan Energy Delivery New York to sublease a building located at 6614 Bay Parkway, Brooklyn, New York to ANB Sportswear, Inc.

Final rule compared with proposed rule: No changes.

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

Assessment of Public Comment

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

(03-G-0793SA1)

NOTICE OF ADOPTION

Gas Meters and Accessories by KeySpan Energy Delivery

I.D. No. PSC-25-03-00012-A
Filing date: Oct. 31, 2003
Effective date: Oct. 31, 2003

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

Action taken: The commission, on Oct. 22, 2003, adopted an order in Case 03-G-0796, approving KeySpan Energy to use the TGT PROV-CNG50 transfer prover manufactured by Tulsa Gas Technologies.

Statutory authority: Public Service Law, section 67(1)

Subject: Types of gas meters and accessories.

Purpose: To allow KeySpan Energy to use the TGT Model PROV-CNG50 in New York State.

Substance of final rule: The Commission authorized KeySpan Energy to utilize the TGT Model PROV-CNG50 Transfer Prover to calibrate meters used to dispense compressed natural gas to public vehicles.

Final rule compared with proposed rule: No changes.

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

Assessment of Public Comment

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

(03-G-0796SA1)

NOTICE OF ADOPTION

Submetering of Electricity by 1400 5th LLC

I.D. No. PSC-28-03-00014-A
Filing date: Nov. 4, 2003
Effective date: Nov. 4, 2003

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

Action taken: The commission, on Oct. 22, 2003, adopted an order in Case 03-E-0884, allowing 1400 5th LLC to submeter electricity at 1400 5th Ave., New York, NY.

Statutory authority: Public Service Law, sections 65(1), 66(1), (2), (3), (4), (5), (12) and (14)

Subject: Submetering of electricity.

Purpose: To authorize submetering of electricity.

Substance of final rule: The Commission approved a request by 1400 5th LLC for the submetering of electricity at 1400 5th Avenue, New York, New York.

Final rule compared with proposed rule: No changes.

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

Assessment of Public Comment

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

(03-E-0884SA1)

NOTICE OF ADOPTION

Electronic Tariff Schedule by Forest Park Water Company, Inc.

I.D. No. PSC-30-03-00013-A
Filing date: Oct. 29, 2003
Effective date: Oct. 29, 2003

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

Action taken: The commission, on Oct. 22, 2003, adopted an order in Case 03-W-0979, approving Forest Park Water Company, Inc.'s (Forest Park) new electronic tariff schedule, P.S.C. No. 2—Water.

Statutory authority: Public Service Law, section 89-c(10)

Subject: New tariff schedule.

Purpose: To convert to an electronic tariff format.

Substance of final rule: The Commission authorized the conversion of Forest Park Water Company, Inc.'s existing paper tariffs of the water systems to one new electronic tariff, effective November 1, 2003, 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.

(03-W-0979SA1)

NOTICE OF ADOPTION

Reconciliation of Revenues by United Water New Rochelle, Inc.

I.D. No. PSC-31-03-00012-A
Filing date: Oct. 30, 2003
Effective date: Oct. 30, 2003

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

Action taken: The commission, on Oct. 22, 2003, adopted an order in Case 03-W-1000, allowing United Water New Rochelle, Inc. (United Water) to establish a surcharge to recover additional purchased water costs.

Statutory authority: Public Service Law, section 89-c(10)

Subject: Reconciliation of revenues for the year ended July 11, 2002.

Purpose: To recover additional purchased water costs.

Substance of final rule: The Commission authorized United Water New Rochelle, Inc. (United Water) to recover $212,996 in additional purchased water costs through a surcharge on customers' bills of $0.0272 per hundred cubic feet and directed United Water to file, on not less than one day's notice, a Purchased Water Adjustment Statement No. 10 with an effective date of November 1, 2003, 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.

(03-W-1000SA1)

NOTICE OF ADOPTION

Issuance of Securities by Bayswater Peaking Facility, LLC and Jamaica Bay Peaking Facility, LLC

I.D. No. PSC-35-03-00016-A
Filing date: Nov. 4, 2003
Effective date: Nov. 4, 2003

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

Action taken: The commission, on Oct. 22, 2003, adopted an order in Case 03-E-1145, allowing Bayswater Peaking Facility, LLC and Jamaica Bay Peaking Facility, LLC to issue securities.

Statutory authority: Public Service Law, section 69

Subject: Issuance of long-term indebtedness.

Purpose: To authorize the financing of two electric generating facilities.

Substance of final rule: The Commission adopted an Order authorizing Bayswater Peaking Facility, LLC and Jamaica Bay Peaking Facility, LLC to borrow up to $75 million each for the financing of their two electric generating facilities, 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.

(03-E-1145SA1)

NOTICE OF ADOPTION

Lightened Regulation by Equus Power 1, L.P.

I.D. No. PSC-36-03-00012-A
Filing date: Oct. 30, 2003
Effective date: Oct. 30, 2003

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

Action taken: The commission, on Oct. 30, 2003, adopted an order in Case 03-E-1179, approving Equus Power 1, L.P.'s request for lightened regulation as an electric corporation.

Statutory authority: Public Service Law, sections 41(1), 66(1), 69, 70 and 110

Subject: Request approving financing for a generating facility.

Purpose: To grant lightened regulatory treatment.

Substance of final rule: The commission granted Equus Power 1, L.P. lightened regulation as an electric corporation, 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.

(03-E-1179SA1)

PROPOSED RULE MAKING NO HEARING(S) SCHEDULED

Interconnection Agreement between Verizon New York Inc. and ICG Telecom Group, Inc.

I.D. No. PSC-46-03-00009-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 whether to approve or reject, in whole or in part, a modification filed by Verizon New York Inc. and ICG Telecom Group, Inc. to revise the interconnection agreement effective on March 29, 2002.

Statutory authority: Public Service Law, section 94(2)

Subject: Intercarrier agreement to interconnect telephone networks for the provisioning of local exchange service.

Purpose: To amend the interconnection agreement.

Substance of proposed rule: The Commission approved an Interconnection Agreement between Verizon New York Inc. and ICG Telecom Group, Inc. in March 2002. The companies subsequently have jointly filed amendments to clarify the provisions regarding Resale Attachment. The Commission is considering these changes.

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

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

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

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

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

(02-C-1018SA2)

PROPOSED RULE MAKING NO HEARING(S) SCHEDULED

Interconnection of Networks between Frontier Communications of Seneca-Gorham, Inc. and Cat Communications International, Inc.

I.D. No. PSC-46-03-00010-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 Frontier Communications of Seneca-Gorham, Inc. and Cat Communications International, Inc. for approval of an interconnection agreement executed on Oct. 2, 2003.

Statutory authority: Public Service Law, section 94(2)

Subject: Interconnection of networks for local exchange service and exchange access.

Purpose: To review the terms and conditions of the negotiated agreement.

Substance of proposed rule: Frontier Communications of Seneca-Gorham, Inc. and Cat Communications International, Inc. have reached a negotiated agreement whereby Frontier Communications of Seneca-Gorham, Inc. and Cat Communications International, Inc. will interconnect their networks at mutually agreed upon points of interconnection to provide Telephone Exchange Services and Exchange Access to their respective customers. The Agreement establishes obligations, terms and conditions under which the parties will interconnect their networks lasting until October 1, 2004, or as extended.

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

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

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

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

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

(03-C-1516SA1)

PROPOSED RULE MAKING NO HEARING(S) SCHEDULED

Interconnection of Networks between Frontier Communications of New York, Inc. and Frontier Communications of America, Inc.

I.D. No. PSC-46-03-00011-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 Frontier Communications of New York, Inc., and Frontier Communications of America, Inc. for approval of an interconnection agreement executed on Sept. 22, 2003.

Statutory authority: Public Service Law, section 94(2)

Subject: Interconnection of networks for local exchange service and exchange access.

Purpose: To review the terms and conditions of the negotiated agreement.

Substance of proposed rule: Frontier Communications of New York, Inc. and Frontier Communications of America, Inc. have reached a negotiated agreement whereby Frontier Communications of New York, Inc. and Frontier Communications of America, Inc. will interconnect their networks at mutually agreed upon points of interconnection to provide Telephone Exchange Services and Exchange Access to their respective customers. The Agreement establishes obligations, terms and conditions under which the parties will interconnect their networks lasting until July 1, 2004, or as extended.

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

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

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

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

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

(03-C-1515SA1)

PROPOSED RULE MAKING NO HEARING(S) SCHEDULED

Interconnection of Networks between Citizens Telecommunications Company of New York, Inc. and Cat Communications International, Inc.

I.D. No. PSC-46-03-00013-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 whether to approve or reject, in whole or in part, a proposal filed by Citizens Telecommunications Company of New York, Inc. and Cat Communications International, Inc. for approval of an interconnection agreement executed on Oct. 2, 2003.

Statutory authority: Public Service Law, section 94(2)

Subject: Interconnection of networks for local exchange service and exchange access.

Purpose: To review the terms and conditions of the negotiated agreement.

Substance of proposed rule: Citizens Telecommunications Company of New York, Inc. and Cat Communications International, Inc. have reached a negotiated agreement whereby Citizens Telecommunications Company of New York, Inc. and Cat Communications International, Inc. will interconnect their networks at mutually agreed upon points of interconnection to provide Telephone Exchange Services and Exchange Access to their respective customers. The Agreement establishes obligations, terms and conditions under which the parties will interconnect their networks lasting until October 1, 2005, or as extended.

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

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

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

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

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

(03-C-1517SA1)

PROPOSED RULE MAKING NO HEARING(S) SCHEDULED

Interconnection of Networks between Frontier Communications of New York, Inc., *et al.* and Citizens Telecommunications Company of New York, Inc., *et al.*

I.D. No. PSC-46-03-00014-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 Frontier Communications of New York, Inc., Frontier Communications of Sylvan Lake, Inc. and Citizens Telecommunications Company of New York, Inc. d/b/a Frontier Communications of New York and RCN Telecom Services, Inc. for approval of an interconnection agreement executed on Oct. 8, 2003.

Statutory authority: Public Service Law, section 94(2)

Subject: Interconnection of networks for local exchange service and exchange access.

Purpose: To review the terms and conditions of the negotiated agreement.

Substance of proposed rule: Frontier Communications of New York, Inc., Frontier Communications of Sylvan Lake, Inc. and Citizens Telecommunications Company of New York, Inc. d/b/a Frontier Citizens Communications of New York and RCN Telecom Services, Inc. have reached a negotiated agreement whereby Frontier Communications of New York, Inc., Frontier Communications of Sylvan Lake, Inc. and Citizens Telecommunications Company of New York, Inc. d/b/a Frontier Citizens Commu-

nications of New York and RCN Telecom Services, Inc. will interconnect their networks at mutually agreed upon points of interconnection to provide Telephone Exchange Services and Exchange Access to their respective customers. The Agreement establishes obligations, terms and conditions under which the parties will interconnect their networks lasting until October 8, 2004, or as extended.

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

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

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

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

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

(03-C-1518SA1)

PROPOSED RULE MAKING NO HEARING(S) SCHEDULED

Deferral and Recovery of Costs by Consolidated Edison Company of New York, Inc.

I.D. No. PSC-46-03-00015-P

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

Proposed action: The Public Service Commission is considering whether to approve or reject, in whole or in part, a petition of Consolidated Edison Company of New York, Inc. (Con Edison) for deferral and recovery of program costs and lost revenues associated with the implementation of a demand side management program for its service territory.

Statutory authority: Public Service Law, sections 65 and 66

Subject: Deferral and recovery of costs.

Purpose: To recover costs associated with the implementation of a demand side management program.

Substance of proposed rule: The Public Service Commission (Commission) is considering whether to approve or reject, in whole or in part, the petition of Consolidated Edison Company of New York, Inc. (Con Edison) requesting deferral and recovery of costs associated with implementation in its service territory of a demand side management program (program). Among the issues to be considered include the program costs associated with implementing the program and the recovery by Con Edison of lost revenues that may arise due to the program's affect on reducing energy consumption in its service territory.

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

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

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

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

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

(03-E-1332SA1)

Racing and Wagering Board

EMERGENCY RULE MAKING

Testing Horses for Drugs

I.D. No. RWB-46-03-00012-E
Filing No. 1232
Filing date: Oct. 30, 2003
Effective date: Nov. 1, 2003

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

Action taken: Amendment of sections 4038.18, 4043.6, 4043.7, 4109.7, 4113.3, 4120.10 and 4120.11 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 deterrance. 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 deterrance. 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 rulemaking 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 rulemaking 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 in order to deter drug use in horses that compete in pari-mutuel racing; provide for the exclusion from racing or those horses that are the subject of a positive test until there is a subsequent negative test; and give claimants of horses 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 27, 2004.

Text of emergency rule and any required statements and analyses may be obtained from: Robert A. Feuerstein, Counsel, 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, Sections 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: This emergency rule amendment is effective on November 1, 2003. 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 and Professional Services: 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. 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.

4. 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.

5. 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.

6. Economic and Technological Feasibility: There are no economic or technological requirements imposed on the industry for compliance with these rules. Compliance may be achieved by restraint from the use of the specified drugs and substances on race horses.

Rural Area Flexibility Analysis

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.

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.

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.

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 detectible 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 famili-

arity with the conduct of pari-mutuel wagering throughout New York State.

EMERGENCY RULE MAKING

Trifecta Wagering

I.D. No. RWB-46-03-00016-E
Filing No. 1230
Filing date: Oct. 30, 2003
Effective date: Oct. 30, 2003

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

Action taken: Amendment of section 4011.22(i) of Title 9 NYCRR.

Statutory authority: Racing, Pari-Mutuel Wagering and Breeding Law, sections 101(1) and 227

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

Specific reasons underlying the finding of necessity: This rule amendment provides authorization for the conduct of trifecta wagering on thoroughbred stakes races, handicap races or allowance races in the event there are five betting entries in the race, rather than the mandatory minimum of six as prescribed by the current rule. Vast amounts of wagers would be subject to loss in the event trifecta wagering was cancelled due to the reduction in available betting entries from six to five. This would result in the loss of significant revenues to the State, breeders and the industry. An emergency rule making is necessary because the board has determined that emergency adoption is necessary for the preservation of the general welfare and that standard rule making procedures would be contrary to the public interest.

Subject: Authorization for the conduct of trifecta wagering in thoroughbred stakes races, handicap races or allowance races in those situations where there are five betting entries.

Purpose: To authorize the conduct of trifecta wagering in thoroughbred stakes races, handicap races or allowance races in those situations where there are five betting entries.

Text of emergency rule: Paragraph (i) of 9 NYCRR section 4011.22 Trifecta is hereby amended to read:

(i) No trifecta wagering shall be conducted on any race having fewer than six betting entries, *provided however, that in a stakes race, handicap race or allowance race no trifecta wagering shall be conducted on any race having fewer than five betting entries.* If fewer than six betting entries start *in other than a stakes race, handicap race or allowance race,* the trifecta shall be declared off and the gross pool refunded. *If fewer than five betting entries start in a stakes race, handicap race or allowance race, the trifecta shall be declared off and the gross pool refunded. The board's steward may, in the exercise of discretion to protect the wagering public, require that there be at least six betting entries for the conduct of trifecta wagering.* If a trifecta pool is cancelled and if time permits, with the approval of the board's steward, a track may schedule exacta wagering in place of trifecta wagering.

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 27, 2004.

Text of emergency rule and any required statements and analyses may be obtained from: Robert A. Feuerstein, Counsel, 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: Section 101(1) of the Racing, Pari-Mutuel Wagering and Breeding Law vests the Board with general jurisdiction over all horse racing and all pari-mutuel wagering activities in New York State. Section 227 of the Racing, Pari-Mutuel Wagering and Breeding Law provides that the Board shall make rules regulating the conduct of pari-mutuel betting.

Legislative objectives: This proposed amendment advances the legislative objective of regulating the conduct of pari-mutuel racing in a manner designed to maintain the integrity of racing while generating a reasonable revenue for the support of government.

Needs and benefits: This rule amendment is necessary to address those situations where, in stakes races, handicap races, or allowance races, the trifecta wagering opportunity would be eliminated or cancelled because there are not six betting interests, as required by the existing Rule 4011.22(i). The benefit of the rule amendment would be the retention of the wagering opportunities with the corresponding preservation of revenues to the State, localities, and the racing and breeding industries.

Costs: This rules amendment affects only the required minimum number of betting interests in a thoroughbred trifecta Graded Stakes race. The rule will impose no new costs for state or local governments. The rule will impose no costs upon regulated parties. The rule will not impose any new costs on the Racing & Wagering Board for the implementation and continued administration of the rule.

Paperwork: There is no additional paperwork required by or associated with this rule amendment.

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 narrowly drafted to accomplish the stated benefits in thoroughbred races of significant merit and interest.

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

Compliance schedule: This emergency rule amendment is effective upon filing. Compliance can be accomplished immediately without need for modification of existing procedures.

Regulatory Flexibility Analysis

A regulatory flexibility analysis is not submitted with this notice because the rule will not impose any adverse economic impact or reporting, recordkeeping or other compliance requirements on small businesses or local governments. The rule will apply only to associations and corporations that conduct pari-mutuel thoroughbred racing and those facilities that accept wagers on races conducted at those facilities. Those associations, corporations and entities do not qualify as a small business or local government.

Rural Area Flexibility Analysis

A rural area flexibility analysis is not submitted with this notice because the rule amendment will not impose any adverse economic impact on rural areas or reporting, recordkeeping or other compliance requirements on public or private entities in rural areas. The Racing & Wagering Board has made this determination based upon the nature of the rule amendment, which merely changes the number of required betting interests for trifecta wagering on certain thoroughbred races. Trifecta wagering is an existing form of approved wagering. Further, the Racing & Wagering Board has made these determinations based upon its knowledge and familiarity with the various pari-mutuel wagering operations throughout New York State.

Job Impact Statement

A job impact statement is not submitted with this notice because the New York State Racing & Wagering Board has determined that the rule will not have a substantial adverse impact on jobs and employment opportunities. This is evident from the nature of the rule, which preserves wagering opportunities and associated revenues. The New York State Racing and Wagering Board has made this determination based upon its knowledge and familiarity with pari-mutuel wagering operations throughout New York State.

State University of New York

NOTICE OF ADOPTION

Code and Standards and Procedures for the Administration and Operation of Community Colleges

I.D. No. SUN-31-03-00007-A
Filing No. 1220
Filing date: Oct. 28, 2003
Effective date: Nov. 19, 2003

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

Action taken: Amendment of Parts 600-607 of Title 8 NYCRR.

Statutory authority: Education Law, sections 355(1)(c), 6304, 6305 and 6306

Subject: The Code of Standards and Procedures for the Administration and Operation of Community Colleges under the Program of State University of New York.

Purpose: To eliminate obsolete material, clarify ambiguous provisions of the code, bring the code into conformity with existing practices, procedures, legislation, and judicial authority, and clarify the authority of the sponsor, the boards of trustees, and the president as delegated by the Education Law.

Substance of final rule: Section

600.1(a), (b) and (c)

Adds a regional option to each section, for establishment, local board and local sponsor

600.2(a)

Add to "accepting title to college property" the new phrase "to be held in trust for the college's use and purposes." Clarifies budget approval language to mean that sponsor approval applies to the budget total (bottom line) rather than the total (line item) budget. Delete "and for the payment of bills and accounts" as a responsibility of the sponsor in terms of establishing procedures

601.1(b)

Updates sponsor valuation requirements for college establishment

601.1(c)(2)(ii)

Revises wording on library holdings for establishment to delete reference to "books" and substitute "instructional resources"

601.2

Wording pertaining to programs is updated to reflect the comprehensive mission of community colleges. For example, the requirement for programs to be based on surveys of high school graduates is changed to being based on surveys of the population of the sponsorship area. Wording is also updated to show a special emphasis on community service and economic development programs and services.

601.6(a)

Revise to reflect practicing definition of "full opportunity." Delete "previous June" for high school graduates and "regardless of high school graduation date" for veterans. Thus, any applicant who is a resident of the sponsorship area may be admitted.

601.6(b)

Makes the language gender neutral

601.7(d)

Deletes requirement for annual report on inter-institutional arrangements, associations and corporations to reflect actual practice (no such reports are required or submitted).

602.1(a)

Makes the language gender neutral

602.1(b)

Clarifies that records and accounts shall be maintained in accordance with national accounting standards, as prescribed by the SUNY Board of Trustees (rather than the Uniform System of Accounts of the State Comptroller), reflecting actual practice.

602.1(c)

Deletes sponsor option to provide the audit agency (as an alternative to the college retaining a CPA)

602.2

Refines wording for the process of filing the operating budget estimate, to be consistent with actual practice. Changes requirement for submitting an operating budget for the next "calendar" year to the next "college fiscal" year

602.3(a) and (d)

Makes the language gender neutral

602.3(b)

Clarifies budget submittal language to mean that sponsor approval applies to the budget total (bottom line) rather than the total (line item) budget.

602.4(a)

List of revenue sources is illustrative only. Language is changed from "shall include" to "may include."

602.4(c)

List of appropriation categories is illustrative only. The list is updated in accordance with NACUBO guidelines.

602.4(d)(2)

Under listing of allowable expenditures, clarifies wording pertaining to space rental, subject to Chancellor approval

602.4(d)(23)

Under listing of expense categories, clarifies wording pertaining to alumni program expenses

602.4(d)(24)

Adds new item, collection agency fees for delinquent student accounts, to the listing of expense categories (and previous item 24 now becomes item 25). This item is moved here from section 602.4(e)(12), now deleted from that section

602.5(a) through (i)

Clarifies and updates terms pertaining to state aid for non-credit remedial courses. Section (b) clarifies definition of aidable remedial courses; section (c) clarifies courses not eligible for aid; section (g) deletes detail pertaining request for course approval while section (h) creates a general clause for request for course approval. Other changes merely re-order the sections.

602.6(b)

Clarifies that donated funds may be deposited with the college or Foundation

602.6(b)(2)

Deletes "subject to the approval of the sponsor" in reference to uses of unrestricted gifts

602.7(a)

Regarding definition of "sponsor services", deletes "for determining State operating aid" as irrelevant and clarifies definition as "direct services rendered on behalf of a community college, by the sponsor, which have been determined by the college board of trustees to be necessary for the maintenance and operation of the college, and which would otherwise be provided by the college staff or a vendor."

602.7(e)

Deletes section requiring DOB approval of sponsor services, to be consistent with actual practice

602.7(f)

Clarifies direct sponsor services definition, including that the cost of these services be competitive as demonstrated by bidding process

602.7(g)

Adds new prohibition against sponsor billing college for indirect costs

602.8(a) sub-sections (5), (10) and (11)

Deletes sections that define disadvantaged, technical programs and business programs, respectively, for the express purpose of the Ingler formula which no longer applies

602.8(b)

Deletes phrase "or in items therein" to clarify that SUNY Trustees approve and adjust college budgets only in the aggregate

602.9(b)

Adds clause clarifying that the local college trustees are authorized to amend the total operating budget for increases that do not affect state aid or sponsor contribution

602.10(c)(1)

Creates an exception to the prohibition on charging student revenue fees by allowing a technology fee to be charged

602.10(c)(2)

Removes the dollar cap on tuition and specifies that tuition shall be fixed in accordance with levels established by and under the authority of the SUNY Board of Trustees

602.10(c)(7)

Clarifies wording to be consistent with actual practice for the definitions of full-time and part-time tuition rates

602.11(a)(2)

Provides that student tuition liability for miscellaneous academic terms shall be proportionate to the schedule for regular terms

602.12(b)

Clarifies that programs supported by state aid at off campus locations are also entitled to operating chargeback payments

602.12(c)

Clarifies that certificates of residency are valid for one year from the date of issuance, aligning the code with the statute regarding this matter

602.12(d)

Clarifies for the purposes of billing for chargebacks that the billing shall be for the FTE student load as of the census date

602.12(e)

This section, pertaining to operating chargeback rates prior to 1983, was deleted as no longer relevant.

602.12(f)

Deletes previous section (f) and substitutes new section (e) to update procedure for calculating operating chargeback rate

602.13(b)

Deletes reference to "Uniform System of Accounts for Community Colleges" as no longer applicable for requirements pertaining to annual financial report

602.14

Clarifies that policies and procedures relating to internal business practices (listed) are to be determined by the local board of trustees

602.15

Section is added to specify the disbursement schedule for quarterly state operating aid payments

603.7(b)

Clarifies the definition of allowable capital chargeback equipment expenditures and lowers the dollar threshold limits for allowable equipment purchases to more realistic levels

603.7(f)

Aligns code with actual practice by requiring that a request for approval of a capital chargeback rate be submitted with each college's annual budget

604.1(b)

Adds a sentence that provides that the local sponsor will transfer community college appropriated funds to the college board of trustees for expenditure

604.1(c)

Clarifies that title to all real property is held by the local sponsor in trust for the uses and purposes of the college. Title to all personal property shall be held and used by the local board of trustees for college purposes.

604.4(a)(1)

Adds phrase clarifying that there shall be rules and regulations governing the election of the student member of the college board of trustees

604.4(a)(2)

Clarifies the term of membership of the elected student member of the college board of trustees as annual and running from July 1 through June 30

605.2

Clarifies that admission to college programs "shall be granted in a nondiscriminatory manner"

605.4

Under regulations governing students, clarifies that student organizations shall "offer open membership on a nondiscriminatory basis"

605.3(b)(3)

Clarifies that student records will be held in accordance with State and Federal regulations

605.6 Clarifies that college facilities may be used by outside organizations (not limited by type or purpose), in a non-discriminatory manner, subject to approval by the college trustees, and in accordance with college policies for facilities use

606

Overall

Makes numerous minor wording adjustments and grammatical/capitalization corrections

606.2(a)

Clarifies wording under Faculty Council of Community Colleges (FCCC) purpose to include "make recommendations regarding academic concerns and issues"

606.3

Expands membership of the Faculty Council voting members to include the Vice Chancellor for Community Colleges and the Associate Provost for Community Colleges

606.7(a)

Revises the definition of the office of Faculty Council President to provide the option of two half-time co-Presidents, and to require that candidates for the office of President obtain advance permission of the home campus President for release time during their tenure in office. This section also provides for elections at the annual spring Council meeting

606.9(a)(1)

Provides that the Secretary keep the minutes of the Faculty Council and the Executive Committee

606.10

Adds the Associate Provost for Community Colleges as a member of the Executive Committee

607.1 Adds a clause requiring that this code be reviewed every five years

Final rule as compared with last published rule: Nonsubstantive changes were made in section 604.1(b).

Text of rule and any required statements and analyses may be obtained from: Dona S. Bulluck, State University of New York, Office of University Counsel, State University Plaza, Albany, NY 12246, (518) 443-5400, e-mail: bullucdo@sysadm.suny.edu

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

A non-substantive change was made to one of the proposed regulations. However the change does not require the submission of a revised RIS, RFA, RAFA or JIS since there was no substantive change to what was previously published.

Assessment of Public Comment

Only one comment was received during the Public Comment Period. The Commentor suggested a further modification of the Section 604.1(b), which read:

"In addition, upon approval of the college's budget, the sponsor's governing body shall direct that payment of all sponsor appropriations for the community college be made within the college's fiscal year to the college's board of trustees for expenditure by the board and without further pre-audit by the sponsor."

It was suggested that the word "further" be eliminated since it could be interpreted as meaning that "some prior level" of pre-audit is appropriate, when in fact, no pre-audit is sanctioned [as intended by the 1988 amendment to section 6304(6) of the Education Law].

The recommended modification was adopted.

Department of Taxation and Finance

ERRATUM

A Notice of Proposed Rule Making, I.D. No. TAF-43-03-00045-P pertaining to New York State, New York City and Yonkers Withholding Tables, published in the October 29, 2003 issue of the *State Register* contained incorrect information in the Proposed Action. The language erroneously indicated that the rule was a consensus rule making. The rule was a standard proposed rule making.

The Department of State apologizes for any confusion this may have caused.