

RULE MAKING ACTIVITIES

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

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

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

Department of Agriculture and Markets

EMERGENCY RULE MAKING

Golden Nematode Quarantine

I.D. No. AAM-32-05-00013-E
Filing No. 819
Filing date: July 26, 2005
Effective date: July 26, 2005

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

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

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

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

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

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

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

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

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

Subject: Golden nematode quarantine.

Purpose: To prevent the further spread of this pest.

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

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

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

This notice is intended to serve only as a notice of emergency adoption. This agency intends to adopt this emergency rule as a permanent rule and will publish a notice of proposed rule making in the *State Register* at some future date. The emergency rule will expire October 23, 2005.

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

Regulatory Impact Statement

1. Statutory authority:

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

Section 164 of the Agriculture and Markets Law provides, in part, that the Commissioner shall take such action as he may deem necessary to control or eradicate any injurious insects, noxious weeds, or plant diseases existing within the State.

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

2. Legislative objectives:

This rule amends the golden nematode quarantine in section 127.2 of 1 NYCRR by extending that quarantine to certain lands currently owned or operated by Martens Farms in the Town of Mentz in Cayuga County and to a field currently owned or operated by Hoeffner Farms in the Town of Fremont in Steuben County.

The modification of the golden nematode quarantine accords with the public policy objectives the Legislature sought to advance by enacting the statutory authority in that it will help to prevent the spread within the State of this injurious pest.

3. Needs and benefits:

The golden nematode, *Globodera rostochiensis*, non-indigenous to the United States, is a microscopic eelworm native to Europe. It is one of the world's most destructive crop pests, which attacks potatoes, tomatoes and eggplants by boring into their roots. The resulting damage by the golden nematode affects the growth and crop yield of the plant and may result in the death of the plant. Once established in the soil, the golden nematode is easily spread to non-infested areas through the movement of the infested plants and infested soil. The golden nematode was discovered in Europe

during the 19th century and was first detected in the United States on a potato farm on Long Island in 1941. The pest subsequently spread beyond that farm to other areas on Long Island. The emergence of this pest prompted the establishment of a cooperative federal-state golden nematode control program shortly after the end of World War II. The program was dedicated to the control of the golden nematode and included laboratory analysis, research, survey activities and quarantine enforcement. In 1967, the golden nematode was detected on a farm near the Town of Prattsburg in Steuben County and subsequently spread to parts of Cayuga, Genesee, Livingston, Orleans, Seneca and Wayne Counties. The establishment of federal and state golden nematode quarantines as well as restrictions on the movement of host materials played key roles in preventing the further spread of the golden nematode. As of 2002, the quarantines had effectively confined this pest to 6,000 acres of farmland in Nassau and Suffolk Counties on Long Island and the Counties of Cayuga, Genesee, Livingston, Orleans, Seneca, Steuben and Wayne in western New York State. However, the golden nematode has since been detected on a farm in the Town of Mentz in Cayuga County and a farm in the Town of Fremont in Steuben County. Accordingly, it is necessary to extend the golden nematode quarantine to certain lands owned or operated by these farms.

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

4. Costs:

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

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

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

(d) Costs to the regulatory agency:

- (i) The initial expenses the agency will incur in order to implement and administer the regulation: None
- (ii) It is anticipated that the Department will be able to use existing personnel to administer the extension of the quarantine and to perform the necessary cleaning and sanitizing of equipment in the extended quarantine area.

5. Local government mandate: None.
6. Paperwork: None.
7. Duplication: None.

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

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

10. Compliance schedule: Immediate.

Regulatory Flexibility Analysis

1. Effect on small business:

This rule amends the golden nematode quarantine in section 127.2 of 1 NYCRR by extending that quarantine to certain lands currently owned or operated by Martens Farms in the Town of Mentz in Cayuga County and to a field currently owned or operated by Hoeffner Farms in the Town of Fremont in Steuben County.

The rule will affect these two farms, both of which are small businesses.

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

2. Compliance requirements:

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

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

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

3. Professional services:

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

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

4. Compliance costs:

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

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

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

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

Any potatoes planted at the two farm locations affected by the extension of the quarantine will have to be varieties which are resistant to the golden nematode and rotated, as required by Part 127 of the Regulations. The approved rotation allows growers to continue to produce potatoes on regulated (*i.e.*, infested) acreage while maintaining populations of the

golden nematode below a level at which the pest can spread. Since the cost for seeds of resistant varieties is comparable to that for seeds of non-resistant varieties, the two farms will not incur any additional costs in the purchase of potato seeds.

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

5. Minimizing adverse impact:

The Department has designed the rule to minimize adverse economic impact on small businesses and local governments. The rule minimizes adverse economic impact by limiting the modified quarantined areas to only those areas where the golden nematode has been detected. The rule also minimizes adverse economic impact by providing that the USDA and/or Department will clean and sanitize farm and construction equipment free of charge, depending upon the availability of resources and personnel. The approaches for minimizing adverse economic impact required by section 202-a(1) of the State Administrative Procedure Act and suggested by section 202-b(1) of the State Administrative Procedure Act were considered. Given all of the facts and circumstances, it is submitted that the rule minimizes adverse economic impact as much as is currently possible.

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

6. Small business and local government participation:

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

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

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

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

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

Rural Area Flexibility Analysis

1. Type and estimated numbers of rural areas:

This rule amends the golden nematode quarantine in section 127.2 of 1 NYCRR by extending that quarantine to certain lands currently owned or operated by Martens Farms in the Town of Mentz in Cayuga County and to a field currently owned or operated by Hoeffner Farms in the Town of Fremont in Steuben County.

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

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

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

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

3. Costs:

Farming and construction equipment located on the two farms affected by the extension of the quarantine will have to be cleaned and sanitized prior to leaving the quarantine zone. However, cleaning and sanitizing is

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

4. Minimizing adverse impact:

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

5. Rural area participation:

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

Job Impact Statement

The rule will not have a substantial adverse impact on jobs and employment opportunities. The modification of the quarantine area is designed to prevent the spread of the golden nematode to other parts of the State. It is estimated that there are 530 potato producers, 1,212 tomato producers and 124 eggplant producers in New York. They employ an estimated 2,420 people and generate 92.7-million dollars in revenue per year. A spread of the infestation would have very adverse economic consequences to these industries in New York State, both from the destruction of the regulated articles upon which these industries depend, and from the more restrictive quarantines that could be imposed by the federal government and by other states. By helping to prevent the spread of the golden nematode, the rule will help to prevent such adverse economic consequences and in so doing, protect the jobs and employment opportunities associated with the production of potatoes, tomatoes and eggplant in New York State.

program to establish procedures for the allocation of tax credits and describing the application process, the due dates for the applications, the standards used to evaluate the applications and any other provisions deemed necessary and appropriate by October 31, 2004. Such legislation provides that, notwithstanding any other provisions to the contrary in the State Administrative Procedure Act, the rules and regulations may be adopted on an emergency basis.

Subject: Empire State Film Production Tax Credit Program.

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

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

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

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

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

Second, eligibility in the program is established through the definition of authorized applicant. In order to be eligible to apply for the program, a business must be a qualified film production company or sole proprietor thereof that is scheduled to begin principal photography on a qualified film within 180 days after submitting its initial application to the Office and it must intend to shoot a portion of that photography on a stage at a qualified film production facility on a set or sets.

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

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

Department of Economic Development

EMERGENCY RULE MAKING

Empire State Film Production Tax Credit Program

I.D. No. EDV-32-05-00005-E

Filing No. 818

Filing date: July 22, 2005

Effective date: July 22, 2005

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

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

Statutory authority: L. 2004, ch. 60

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

Specific reasons underlying the finding of necessity: As a matter of public policy, the Legislature has determined that a tax credit to eligible qualified film production companies would provide incentive for films to be produced in New York State and thereby help stimulate the State economy. The rule is necessary because section 7(c) of Chapter 60 of the Laws of 2004 mandates the Department to promulgate regulations for the

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

Fifth, within 60 days after the completion of production of their qualified film, the approved applicant must submit a final application to the Office. The final application is similar to the initial application, though it now contains actual expenditure data as opposed to expenditure projections. The Office then considers certain criteria in its review to determine whether the final application should be approved. Much like the criteria used for the initial application, this includes analysis of whether the application is complete, whether applicant actually shot principal photography on stage at a qualified film production facility on a set or sets, whether a qualified film was completed, and whether the actual qualified production costs equal or exceed 75% of the actual production costs on the film, etc. The proposed rule allows the Office to request additional documentation, including receipts of qualified production costs, to help the Office determine if the applicant meets the criteria. At this point, the applicant is either approved and issued a certificate of tax credit (stating the amount of tax credit they will be receiving) or provided a notice of disapproval.

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

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

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

This notice is intended to serve only as a notice of emergency adoption. This agency does not intend to adopt the provisions of this emergency rule as a permanent rule. The rule will expire October 19, 2005.

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

Regulatory Impact Statement

STATUTORY AUTHORITY:

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

LEGISLATIVE OBJECTIVES:

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

NEEDS AND BENEFITS:

The proposed rule is required to be promulgated by October 31, 2004 (see section 7(c) of Chapter 60 of the Laws of 2004). It is necessary to properly administer the tax credit program. The statute itself does not set out the specifics of the program; rather, it deals primarily with its creation and calculation of the actual tax credit. There are several administrative

benefits that would be derived from this proposed rulemaking. First, the proposed rule establishes a clear and precise application process, complete with due process as there is an opportunity for applicants to appeal from denials of applications or a disagreement regarding the actual amount of the tax credit. Second, the proposed rule describes in detail the standards to be used to evaluate the initial and final applications created under this program. Third, it describes the documentation that will be provided to taxpayers to substantiate to the State Tax and Finance Department the amount of the tax credits allocation. Finally, it clarifies some existing definitions and creates several new definitions in order to help facilitate an effective and efficient administration of the program.

COSTS:

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

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

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

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

LOCAL GOVERNMENT MANDATES:

None.

PAPERWORK:

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

DUPLICATION:

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

ALTERNATIVES:

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

FEDERAL STANDARDS:

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

COMPLIANCE SCHEDULE:

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

Regulatory Flexibility Analysis

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

nesses may enjoy a film production tax credit if they qualify for the program's tax credit.

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

Rural Area Flexibility Analysis

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

Job Impact Statement

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

Education Department

EMERGENCY RULE MAKING

Middle-Level Education

I.D. No. EDU-23-05-00019-E

Filing No. 823

Filing date: July 26, 2005

Effective date: Aug. 22, 2005

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

Action taken: Amendment of sections 100.3, 100.4 and 80-5.12 of Title 8 NYCRR.

Statutory authority: Education Law, sections 101 (not subdivided), 207 (not subdivided), 208 (not subdivided), 215 (not subdivided), 305(1) and (2), 308 (not subdivided), 309 (not subdivided), 4403(3) and 3713(1) and (2)

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

Specific reasons underlying the finding of necessity: The proposed amendment is necessary to implement policy adopted by the Board of Regents in February 2005.

Under existing regulations, middle-level schools (those with grades 5, 6, 7, and 8 or a lesser combination of these grades) have limited programmatic flexibility. This makes it difficult for low-performing schools to respond to the academic and personal needs of their students and for new or high-performing schools to develop new approaches to enhance their students' education. The proposed amendment offers districts with low-performing schools and high-performing schools additional flexibility to develop programs that address their students' academic and personal needs.

Under the proposed amendment, districts with low-performing schools will be allowed to propose a program that strengthens core academic subjects and effective academic intervention services, and provides all

students with exploratory subjects that address the learning standards, are of high interest to students, and further reinforce core academic learning (Model B). The low-performing schools would receive regulatory relief from the prescribed time requirements for units of study in the exploratory courses in order to implement their proposed program. Under the proposed amendment, districts with new or high-performing schools will be allowed to propose new ideas for restructuring the full educational program (Model C#1) or specific program refinements (Model C#2) and be granted relief from programmatic regulatory requirements.

The proposed amendment offers school districts additional flexibility in meeting the State's intermediate learning standards and in increasing student proficiency in English language arts and mathematics consistent with the No Child Left Behind federal legislation. With large numbers of middle grades students regularly not achieving proficiency (in 2003-04, 52% of grade 8 students did not achieve proficiency in English language arts and 42% of grade 8 students did not achieve proficiency in mathematics), districts, especially those with schools in which large numbers of students are not achieving proficiency, need additional flexibility to develop programs that target the academic core and strengthen their academic intervention services. Districts with high-performing schools also need additional flexibility to develop creative approaches to restructure the educational experience in the middle grades or to enhance specific aspects of the middle grades program in order to meet their students needs.

The proposed amendment also makes technical changes to align the Commissioner's regulations with the State learning standards, clarifies testing requirements related to students with disabilities, and reauthorizes the experiment in school organization to provide additional flexibility to all schools.

The proposed amendment was adopted at the May 16-17, 2005 Regents meeting, as an emergency measure effective May 24, 2005, in order to immediately establish criteria for middle-level education program models, consistent with Regents policy, to ensure sufficient time for districts with eligible low-performing schools and eligible new or high-performing schools to prepare and submit Model B, C#1 or C#2 applications, for the Department to review and act on the applications, and for the districts to make the necessary programmatic adjustments to begin implementing their approved programs in the 2005-06 school year. A Notice of Emergency Adoption and Proposed Rule Making was published in the *State Register* on June 8, 2005.

It is anticipated that the proposed amendment will be presented to the Board of Regents for adoption as a permanent rule at their September 8-9, 2005 meeting, which is the first scheduled meeting after expiration of the 45-day public comment period mandated by the State Administrative Procedure Act. Pursuant to SAPA section 202(5), the permanent adoption cannot become effective until after its publication in the *State Register* on September 28, 2005. However, the May emergency adoption will expire on August 21, 2005, 90 days after its filing with the Department of State on May 24, 2005. A second emergency adoption is therefore necessary to ensure that the amendment remains continuously in effect until the effective date of its adoption as a permanent rule.

Subject: Middle-level education.

Purpose: To implement Regents policy statement on middle-level education.

Substance of emergency rule: The Commissioner of Education proposes to amend sections 100.3, 100.4 and 80.5-12 of the Regulations of the Commissioner of Education, effective August 22, 2005, relating to implementation of the Regents Policy Statement on Middle-Level Education in grades five, six, seven, and eight. The following is a summary of the substance of the proposed amendment:

Section 100.3 is amended to:

- (1) apply only to pre-kindergarten through grade four so that it is in alignment with the State's elementary learning standards;
- (2) clarify language related to testing accommodations for students with disabilities, consistent with the federal No Child Left Behind Act (NCLB); and
- (3) include language related to the annual testing in English language arts and mathematics in grades 3 and 4 to conform to the NCLB.

Section 100.4 is amended to:

- (1) include existing provisions pertaining to grades five and six (previously located in section 100.3) so as to align section 100.4 with the State's intermediate learning standards and the Regents Policy Statement on Middle-Level Education;
- (2) allow schools to begin to meet the unit of study requirements for technology education and home and career skills in grade 5;

(3) clarify language related to instruction in languages other than English in grades five, six, seven and eight, the administration of the second language proficiency examination, and the awarding of high school credit;

(4) clarify language dealing with home instruction to conform with Regents policy;

(5) clarify language related to testing accommodations and alternative assessments for students with disabilities, consistent with the NCLB;

(6) include language related to the annual testing in English language arts and mathematics in grades 5, 6, 7 and 8, consistent with the NCLB; and

(7) add a new subdivision (h) to implement the Regents Policy Statement on Middle-Level Education through the establishment of a three model system for middle-level education programs: a Model A middle-level education program meets all the requirements in section 100.4 and all other applicable sections of the Rules of the Board of Regents and the Regulations of the Commissioner of Education; a Model B middle-level education program strengthens the attainment of the learning standards measured by required State assessments, provides effective academic intervention services, and ensures all students receive instruction in those areas where there are no required State assessments; a Model C middle-level education program either restructures the delivery of the instruction designed to facilitate the attainment of the State's intermediate learning standards (Model C#1) or enhances instruction related to one or more of the State's intermediate learning standards for which there are no required State assessments (Model C#2).

Section 100.4(h)(1) establishes definitions for the Model middle-level education programs.

Section 100.4(h)(2) requires each school district to conduct its middle-level education program in accordance with either Model A, Model B or Model C.

Section 100.4(h)(2)(i) prescribes eligibility, application, plan and compliance requirements for Model A programs. All school districts are eligible to select Model A. No application or plan is required. All schools not approved to operate under Models B or C shall operate under Model A. A Model A program shall meet the requirements of section 100.4 and all other applicable sections of Rules of the Board of Regents and the Regulations of the Commissioner of Education and shall also meet the following six design principles:

(1) districts shall administer required middle grade State assessments in English language arts, mathematics, social studies and science;

(2) districts shall employ teaching staff that are properly certified to teach assigned subjects and classes;

(3) districts shall ensure that the middle-level program is aligned with the Regents Policy Statement on Middle-Level Education and the State Education Department's Essential Elements of Standards-Focused Middle-Level Schools and Programs;

(4) students who are at risk of not meeting the State learning standards shall receive academic intervention services in accordance with section 100.2(ee) of the Commissioner's Regulations;

(5) students shall receive instruction in all of the State learning standards, with instruction in English language arts, mathematics, social studies, science and physical education occurring each year in each of the middle grades;

(6) students shall be provided opportunities for taking high school courses on an accelerated basis in accordance with section 100.4(d).

Section 100.4(h)(2)(ii) prescribes eligibility, application, plan, compliance and approval requirements for Model B programs.

Section 100.4(h)(2)(iii) prescribes eligibility, application, plan, compliance and approval requirements for Model C programs.

The following school districts are eligible for Model B: a district proposing a program for a school identified as a school requiring academic progress (SRAP) in year 3, 4 or 5, including a school identified for school improvement for three or more consecutive years under 20 USC section 6316(b), or a school or schools under registration review (SURRE) pursuant to section 100.2(p) of the Commissioner's Regulations.

The following school districts are eligible for Model C: a district proposing a program for a newly formed, or an existing, school or schools, other than those schools that are eligible for Model B.

A district seeking to operate under Model B or Model C shall have its application approved by the superintendent of schools prior to its submission to the Commissioner. The district shall submit with its application a report from the district's shared decision-making team, that provides evidence that consultation took place at the district and building levels and that identifies the concerns expressed by the constituents. Special application requirements are provided for Model B and Model C applications

submitted by the New York City School District. Model C applications for specified program enhancements (Model C#2) submitted by a school district, other than a city school district with 125,000 inhabitants or more, shall be approved by the superintendent of schools and the board of education, and submitted to the district superintendent of the supervisory district in which the school district is located for his or her recommendation, prior to submission of the application to the Commissioner for approval;

Each district submitting a Model B application shall prepare a plan consistent with the requirements of section 100.2(p), which shall address the results of a State-developed, locally conducted self-study, shall conform to the six design principles described above under Model A, and be submitted as part of the application.

A district selecting Model C and proposing to restructure the delivery of instruction designed to facilitate the attainment of the State intermediate learning standards shall prepare a plan that, where applicable, is consistent with the requirements of section 100.2(p), which shall address the results of a State-developed, locally conducted self-study, shall conform to the six design principles described above under Model A, and be submitted as part of the application. A district proposing specific program enhancements (Model C#2) shall not be required to complete the State-developed, locally conducted self-study but must include in its application a description of the program enhancement, its relationship to student achievement, student interests, and/or student development, and a plan for evaluating its effectiveness and the impact of the program enhancement on student learning and development.

All Model B programs shall meet the requirements of section 100.4 and all other applicable sections of the Rules of the Board of Regents and the Regulations of the Commissioner of Education and the six design principles described above under Model A, except that the prescribed time requirements for units of study in courses where there are no required State assessments as set forth in 100.4(c)(1) shall be met subject to such modifications as set forth in the approved application and plan.

All Model C programs shall meet the requirements of section 100.4 and all other applicable sections of the Rules of the Board of Regents and the Regulations of the Commissioner of Education, subject to any modifications of such requirements as provided for in the district's approved application and plan, and shall also meet the six design principles described above under Model A.

Approval of a Model B or C application shall be based upon the Commissioner's acceptance of the measurable indicators and evidence of school change and improvement as proposed in the application and plan. Approval shall be for a five-year implementation period. A district may reapply for continued approval for one additional five-year period. The district shall monitor and publicly report its progress on specified criteria. The Commissioner may terminate approval at any time upon a determination that the district has failed to comply with the requirements of its approved application and the prescribed compliance requirements.

The proposed amendment also requires that, in those districts where public school choice is required under section 120.3 of the Commissioner's Regulations, the district's Model C application for any newly formed school must include an agreement that a minimum of 20% of seats shall be offered to students seeking transfer, consistent with State and federal law.

In addition the proposed amendment specifies that applications for no more than 75 schools for Model C shall be approved, of which no more than 30 schools shall be approved for restructuring the full education program (Model C#1) and no more than 45 schools shall be approved for specified program enhancements (Model C#2).

Section 80.5-12 is amended to re-authorize the "Experiment in Organization" regulation that expired in February 2004, and additional provisions are added to require that teachers assigned to the proposed experiment shall meet the qualification requirements of section 120.6 of the Commissioner's Regulations, relating to the NCLB; and to require that a school district may not continue the assignment of a teacher for more than five school years unless the teacher has obtained the teaching certificate or certificate extension appropriate to such assignment. A new subdivision (c) is added to provide that a person who holds a permanent or professional certificate in English language arts (7-12), language other than English (7-12), mathematics (7-12), biology (7-12), chemistry (7-12), earth science (7-12), physics (7-12), or social studies (7-12) and whose teaching assignment covered by an experiment in organizational change during three of the five years of an experiment approved by the Commissioner on or before February 1, 2004 is in the subject of the certificate held but is in grades 5-6, may be issued a statement of continued eligibility pursuant to

which such person may continue to teach in such assignment without the extension prescribed in section 80-4.3(b) of this Part to teach the subject in grades 5-6. In order for such person to be eligible for the statement of continuing eligibility, his or her experience in teaching the subject in grades 5-6 must have occurred on or after July 1, 1993. A statement of continued eligibility shall be limited to the specific permanent or professional certificate that was extended to authorize such service but shall be valid for service in any school district. Applications for the statement of continued eligibility must be filed with the Department.

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 emergency/proposed rule making, I.D. No. EDU-23-05-00019-EP, Issue of June 8, 2005. The emergency rule will expire September 23, 2005.

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

Regulatory Impact Statement

STATUTORY AUTHORITY:

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

Education Law section 207 authorizes the Regents and the Commissioner to adopt rules and regulations to carry out the laws of the State regarding education and the functions and duties conferred on the Department by law.

Education Law section 208 authorizes the Regents to establish examinations as to attainments in learning and to award and confer suitable certificates, diplomas and degrees on persons who satisfactorily meet the requirements prescribed.

Education Law section 215 provides the Commissioner with authority to require schools to submit reports containing such information as the Commissioner may prescribe.

Education Law section 305(1) and (2) provide that the Commissioner, as chief executive officer of the State system of education and of the Board of Regents, shall have general supervision over all schools and institutions subject to the provisions of the Education Law, or of any statute relating to education, and authorizes the Commissioner to enforce laws relating to the educational system and to execute the Regents' educational policies.

Education Law section 308 authorizes the Commissioner to enforce and give effect to any provision in the Education Law or in any other general or special law pertaining to the school system of the State or any rule or direction of the Regents.

Education Law section 309 charges the Commissioner with the general supervision of boards of education and their management and conduct of all departments of education.

Education Law section 4403(3) authorizes the Commissioner to formulate such rules and regulations pertaining to the physical and educational needs of such children as the Commissioner shall deem to be in their best interests.

Education Law section 3713(1) and (2) authorizes the State and school districts to accept Federal law making appropriations for educational purposes and authorizes the Commissioner to cooperate with Federal agencies to implement such law.

LEGISLATIVE OBJECTIVES:

The proposed amendment is consistent with the above statutory authority and is necessary to implement Regents policy.

NEEDS AND BENEFITS:

The proposed amendment is necessary to implement policy adopted by the Board of Regents in February 2005, and will help ensure that school districts have the flexibility they need to ensure that all students in State public schools are provided instruction in the State learning standards areas and have the skills, knowledge, and understanding necessary for success.

Under existing regulations, middle-level schools (those with grades 5, 6, 7 and 8 or a lesser combination of these grades) have limited programmatic flexibility. This makes it difficult for low-performing schools to respond to the academic and personal needs of their students and for new or high-performing schools to develop new approaches to enhance their students' education. The proposed amendment offers districts additional flexibility in meeting State intermediate learning standards and increasing

student proficiency in English language arts and mathematics consistent with the federal No Child Left Behind Act.

Districts with low-performing schools will be allowed to propose a program that strengthens core academic subjects and effective academic intervention services, and provides all students with exploratory subjects that address the learning standards, are of high interest to students, and further reinforce core academic learning (Model B). Low-performing schools would receive regulatory relief from the prescribed time requirements for units of study in the exploratory courses in order to implement their proposed program. Districts with new or high-performing schools will be allowed to submit proposals for restructuring the full educational program (Model C#1) or specific program refinements (Model C#2) and be granted relief from programmatic regulatory requirements.

With large numbers of middle-grade students regularly not achieving proficiency (in 2003-04, 52% of grade 8 students did not achieve proficiency in English language arts and 42% of grade 8 students did not achieve proficiency in mathematics), districts, especially those with schools in which large numbers of students are not achieving proficiency, need additional flexibility to develop programs that target the academic core and strengthen their academic intervention services. Districts with high-performing schools also need additional flexibility to develop creative approaches to restructure the educational experience in the middle grades or to enhance specific aspects of the middle grades program in order to meet their students needs.

In addition, the proposed amendment will allow districts under certain circumstances to apply for approval to implement an "Experiment in Organization" that provides for the flexible assign of certified teaching staff.

The proposed amendment also makes technical changes to align the Commissioner's regulations with the State learning standards and clarifies testing requirements related to students with disabilities.

COSTS:

(a) Costs to the State: None. The Education Department will be required to fund the development of the new English language arts and mathematics tests for grades 3, 5, 6 and 7. Such testing is required by the accountability provisions of the federal No Child Left Behind Act of 2001 [Pub. L. 107-110, (NCLB)]. The State is required to comply with the NCLB as a condition to its receipt of federal funding under Title I of the ESEA, as amended. The proposed amendment will not impose any additional costs on the State beyond those imposed by State and Federal law.

(b) Costs to local government: School districts will be required to assume the cost burden of scoring the new assessments in grades 3, 5, 6 and 7. Such testing is required by the accountability provisions of the NCLB. School districts and other local educational agencies (LEAs) are required to comply with the NCLB as a condition to their receipt of federal funding under Title I of the ESEA, as amended. The proposed amendment will not impose any costs on these entities beyond those imposed by State and Federal law. Costs to implement the other provisions of the proposed amendment, including those related to implementation of the Models for Middle-Level Education programs and Experiments in Organizational Change, will not place an additional cost burden on LEAs and may result in cost savings due to the increased flexibility provided by the amendment.

(c) Cost to private regulated parties: None. The proposed amendment does not impact private parties in any way.

(d) Cost to regulating agency for implementation and continued administration of this rule: The Education Department will be required to fund the development of the new English language arts and mathematics tests for grades 3, 5, 6 and 7, and to review and approve Model B, C#1 and C#2 applications. The Department will be required to fund the data collection activities associated with the implementation of the new regulations including the development and maintenance of a database to track and monitor the implementation of approved Model B, C#1 and C#2 applications. It is anticipated that any implementation costs will be absorbed using existing staff and resources.

LOCAL GOVERNMENT MANDATES:

The proposed amendment does not impose any additional program, service, duty or responsibility on school districts or other local governments but instead aligns the Commissioner's Regulations with policy enacted by the Regents to provide districts with low-performing schools and high-performing schools additional flexibility to develop programs that address their students' academic and personal needs.

Districts with low-performing schools may propose a program that strengthens core academic subjects and effective academic intervention services, and provides all students with exploratory subjects that address the learning standards, are of high interest to students, and further reinforce

core academic learning (Model B). The low-performing schools would receive regulatory relief from the prescribed time requirements for units of study in the exploratory courses in order to implement their proposed program. Districts with new or high-performing schools may propose new ideas for restructuring the full educational program (Model C#1) or specific program refinements (Model C#2) and be granted relief from programmatic regulatory requirements. In the alternative, a district may choose to continue to comply with all applicable regulations (Model A).

Districts must conduct annual testing in English language arts and mathematics in grades 3, 5, 6 and 7 (in addition to grades 4 and 8) as is now required by the NCLB. Districts with eligible schools may request relief from specific regulatory requirements related to the amount of instructional time devoted to specific standards areas if such instruction provides for excellence in education and is in the best interests of students. Districts may also request approval of an "Experiment in Organization" that provides for the flexible assignment of certified staff.

PAPERWORK:

Districts that wish to proceed under Model B or Model C must submit an application and plan in a form and according to such timelines as prescribed by the Commissioner, including a report from the district's shared decision-making team. Districts proceeding under Model A will not be required to submit an application or plan. Districts with approved applications must submit an annual report on the implementation of their application. Districts may also apply to the Commissioner for approval of an "Experiment in Organization" that provides for the flexible assignment of staff.

DUPLICATION:

The proposed amendment does not duplicate existing State or federal requirements.

ALTERNATIVES:

Since February 2004, the Board of Regents has discussed several possible strategies for implementing the Regents Policy Statement on Middle-Level Education. One alternative was to require all schools to continue to comply with the existing regulations. This approach was rejected because it did not allow sufficient flexibility, based upon local needs and circumstances, for schools to develop programs consistent with the Regents Policy Statement that would improve student achievement. A second alternative was to grant all schools, regardless of their needs and circumstances, unregulated flexibility to implement the Regents Policy Statement. This was rejected because of a concern that it could be used to limit or eliminate instruction in learning standards areas rather than to strengthen program and student achievement.

In lieu of a single prescription or model for transforming middle-level schools or provide unregulated flexibility, the Regents determined that school districts should be provided opportunities, based upon their needs and circumstances, to develop programs that address their students' academic and personal needs and thereby ensure that all students in State public schools are provided instruction in the learning standards areas and have the skills, knowledge, and understanding necessary for success. The proposed amendment will allow districts to conduct their middle-level education programs in accordance with three models, which taken collectively, constitute a continuum of options based upon a district's or school's needs and capacity to change:

Model A: the district would continue to comply with the current regulations, making full use of the existing flexibility provisions in the regulations;

Model B: the district would be able to propose a program for approval by the commissioner that strengthens core academic subjects and effective academic intervention services, and provide all students with exploratory subjects that address the State learning standards, are of high interest to students and further reinforce academic learning;

Model C: the district would be able to propose new ideas for structuring the full educational program (Model C#1) or specific program refinements (Model C#2) and be granted relief by the commissioner from programmatic regulatory requirements, while ensuring that all students receive opportunities to achieve all of the State learning standards.

FEDERAL STANDARDS:

There are no related federal standards.

COMPLIANCE SCHEDULE:

It is anticipated that school districts will be able to implement the middle-level education model programs by the beginning of the 2005-2006 school year. Applications will be available on May 20, 2005. Completed applications for Model B, C#1 and C#2 programs beginning in the 2005-06 school year will be accepted for review and action by the Department through June 17, 2005. In subsequent years, applications for Model B, C#1

and C#2 must be received by the Department by January 15 for implementation beginning in the following school year.

Regulatory Flexibility Analysis

Small Businesses:

The proposed amendment relates to implementation of the Regents Policy Statement on Middle-Level Education in grades five through eight, and will not impose any adverse economic impact, reporting, record keeping or any other compliance requirements on small businesses. Because it is evident from the nature of the proposed amendment that it does not affect small businesses, no further measures were needed to ascertain that fact and none were taken. Accordingly, a regulatory flexibility analysis for small businesses is not required and one has not been prepared.

Local Governments:

The proposed amendment applies to all public school districts in the State.

COMPLIANCE REQUIREMENTS:

The proposed amendment does not impose any additional compliance requirements on school districts but instead aligns the Commissioner's Regulations with policy enacted by the New York State Board of Regents to provide districts with low-performing schools and high-performing schools additional flexibility to develop programs that address their students' academic and personal needs.

The proposed amendment will allow school districts under certain circumstances to:

(a) apply for relief from specific regulatory requirements related to the amount of instructional time devoted to specific standards areas if such instruction provides for excellence in education and is in the best interests of students;

(b) begin to meet the unit of study requirements for technology education and home and career skills in grade 5;

(c) apply for approval to implement an "Experiment in Organization" that provides for the flexible assign of certified staff.

Under the proposed amendment, districts with low-performing schools may propose a program that strengthens core academic subjects and effective academic intervention services, and provides all students with exploratory subjects that address the learning standards, are of high interest to students, and further reinforce core academic learning (Model B). The low-performing schools would receive regulatory relief from the prescribed time requirements for units of study in the exploratory courses in order to implement their proposed program. Districts with new or high-performing schools may propose new ideas for restructuring the full educational program (Model C#1) or specific program refinements (Model C#2) and be granted relief from programmatic regulatory requirements. In the alternative, a district may choose to continue to comply with all applicable regulations (Model A).

School districts must conduct annual testing in English language arts and mathematics in grades 3, 5, 6, and 7 (in addition to grades 4 and 8) as is now required by the No Child Left Behind Act of 2001 [Pub. L. 107-110, (NCLB)].

PROFESSIONAL SERVICES:

The proposed amendment does not impose additional professional services requirements on school districts.

COMPLIANCE COSTS:

School districts will be required to assume the cost burden of scoring the new assessments in grades 3, 5, 6 and 7. Such testing is required by the accountability provisions of the federal No Child Left Behind Act of 2001 [Pub. L. 107-110, (NCLB)]. School districts and other local educational agencies (LEAs) are required to comply with the NCLB as a condition to their receipt of federal funding under Title I of the ESEA, as amended. The proposed amendment will not impose any costs on these entities beyond those imposed by State and Federal law. Costs to implement the other provisions of the proposed amendment, including those related to implementation of the Models for Middle-Level Education programs and Experiments in Organizational Change, will not place an additional cost burden on LEAs and may, in fact, result in cost savings due to the increased flexibility provided by the proposed amendment.

ECONOMIC AND TECHNOLOGICAL FEASIBILITY:

The proposed amendment will not require any new technological requirements. Economic feasibility is addressed above under compliance costs.

MINIMIZING ADVERSE IMPACT:

The proposed amendment is necessary to implement policy enacted by the Board of Regents and to comply with the federal testing requirements associated with the No Child Left Behind Act. The proposed amendment has been carefully drafted to meet statutory requirements, federal legisla-

tion, and Regents policy while minimizing the impact on school districts. Where possible, the proposed amendment incorporates existing requirements and eliminates redundant requirements to minimize work at the local level. The proposed amendment emphasizes local flexibility in meeting the regulatory requirements.

Since February 2004, the Board of Regents has discussed several possible strategies for implementing the Regents Policy Statement on Middle-Level Education. One alternative was to require all schools to continue to comply with the existing regulations. This approach was rejected because it did not allow sufficient flexibility, based upon local needs and circumstances, for schools to develop programs consistent with the Regents Policy Statement that would improve student achievement. A second alternative was to grant all schools, regardless of their needs and circumstances, unregulated flexibility to implement the Regents Policy Statement on Middle-Level Education. This was rejected because of a concern that it could be used to limit or eliminate instruction in learning standards areas rather than to strengthen program and student achievement.

In lieu of a single prescription or model for transforming middle-level schools or provide unregulated flexibility, the Regents determined that school districts should be provided opportunities, based upon their needs and circumstances, to develop programs that address their students' academic and personal needs and thereby ensure that all students in New York State public schools are provided instruction in the seven learning standards areas and have the skills, knowledge, and understanding they will need to succeed.

LOCAL GOVERNMENT PARTICIPATION:

The Board of Regents and the State Education Department engaged the educational community (including teachers, administrators, members of boards of education, community members) in the development of the policy and the drafting of the amended regulations from the beginning. Since 2000, members of the Board of Regents and representatives of the State Education Department have conducted numerous (more than 100) informational hearings around the State explaining and discussing Regents policy and the regulatory implications and gathering input on possible draft language. Written comments were also solicited throughout the process. The results of the informational hearings and the comments received were considered during the drafting of the proposed regulations.

Rural Area Flexibility Analysis

TYPES AND ESTIMATED NUMBER OF RURAL AREAS:

The proposed amendment applies to all school districts in the State, including the 44 rural counties with less than 200,000 inhabitants and the 71 towns in urban counties with a population density of 150 per square mile or less.

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

The proposed amendment does not impose any additional compliance requirements on school districts but instead aligns the Commissioner's Regulations with policy enacted by the New York State Board of Regents to provide districts with low-performing schools and high-performing schools additional flexibility to develop programs that address their students' academic and personal needs.

The proposed amendment will allow school districts under certain circumstances to:

- (a) apply for relief from specific regulatory requirements related to the amount of instructional time devoted to specific standards areas if such instruction provides for excellence in education and is in the best interests of students;
- (b) begin to meet the unit of study requirements for technology education and home and career skills in grade 5;
- (c) apply for approval to implement an "Experiment in Organization" that provides for the flexible assign of certified staff.

Under the proposed amendment, districts with low-performing schools may propose a program that strengthens core academic subjects and effective academic intervention services, and provides all students with exploratory subjects that address the learning standards, are of high interest to students, and further reinforce core academic learning (Model B). The low-performing schools would receive regulatory relief from the prescribed time requirements for units of study in the exploratory courses in order to implement their proposed program. Districts with new or high-performing schools may propose new ideas for restructuring the full educational program (Model C#1) or specific program refinements (Model C#2) and be granted relief from programmatic regulatory requirements. In the alternative, a district may choose to continue to comply with all applicable regulations (Model A).

School districts must conduct annual testing in English language arts and mathematics in grades 3, 5, 6, and 7 (in addition to grades 4 and 8) as is now required by the No Child Left Behind Act of 2001 [Pub. L. 107-110, (NCLB)].

The proposed amendment does not impose additional professional services requirements on school districts.

COSTS:

School districts will be required to assume the cost burden of scoring the new assessments in grades 3, 5, 6 and 7. Such testing is required by the accountability provisions of the federal No Child Left Behind Act of 2001 [Pub. L. 107-110, (NCLB)]. School districts and other local educational agencies (LEAs) are required to comply with the NCLB as a condition to their receipt of federal funding under Title I of the ESEA, as amended. The proposed amendment will not impose any costs on these entities beyond those imposed by State and Federal law. Costs to implement the other provisions of the proposed amendment, including those related to implementation of the Models for Middle-Level Education programs and Experiments in Organizational Change, will not place an additional cost burden on LEAs and may, in fact, result in cost savings due to the increased flexibility provided by the proposed amendment.

MINIMIZING ADVERSE IMPACT:

The proposed amendment is necessary to implement policy enacted by the Board of Regents and to comply with the federal testing requirements associated with the No Child Left Behind Act. The proposed amendment has been carefully drafted to meet statutory requirements, federal legislation, and Regents policy while minimizing the impact on school districts. Where possible, the proposed amendment incorporates existing requirements and eliminates redundant requirements to minimize work at the local level. The proposed amendment emphasizes local flexibility in meeting the regulatory requirements. The Regents policy upon which the proposed amendment is based applies to all schools. Therefore, it was not possible to establish different compliance and reporting requirements for school districts in rural areas, or exempt them from the provisions.

Since February 2004, the Board of Regents has discussed several possible strategies for implementing the Regents Policy Statement on Middle-Level Education. One alternative was to require all schools to continue to comply with the existing regulations. This approach was rejected because it did not allow sufficient flexibility, based upon local needs and circumstances, for schools to develop programs consistent with the Regents Policy Statement that would improve student achievement. A second alternative was to grant all schools, regardless of their needs and circumstances, unregulated flexibility to implement the Regents Policy Statement on Middle-Level Education. This was rejected because of a concern that it could be used to limit or eliminate instruction in learning standards areas rather than to strengthen program and student achievement.

In lieu of a single prescription or model for transforming middle-level schools or provide unregulated flexibility, the Regents determined that school districts should be provided opportunities, based upon their needs and circumstances, to develop programs that address their students' academic and personal needs and thereby ensure that all students in New York State public schools are provided instruction in the seven learning standards areas and have the skills, knowledge, and understanding they will need to succeed.

RURAL AREA PARTICIPATION:

The Board of Regents and the State Education Department engaged the educational community (including teachers, administrators, members of boards of education, and community members, from rural areas) in the development of the policy and the drafting of the amended regulations from the beginning. Since 2000, members of the Board of Regents and representatives of the State Education Department have conducted numerous (more than 100) informational hearings around the State explaining and discussing Regents policy and the regulatory implications and gathering input on possible draft language. Written comments were also solicited throughout the process. The results of the informational hearings and the comments received were considered during the drafting of the proposed regulations.

Job Impact Statement

The proposed amendment relates to implementation of the Regents Policy Statement on Middle-Level Education in grades five through eight, and will not have an adverse impact on jobs or employment opportunities. The proposed amendment provides increased flexibility to school districts to structure their middle-level education instructional programs. Because it is evident from the nature of the rule that it will have a positive impact, or no impact, on jobs or employment opportunities, no further steps were needed

to ascertain those facts and none were taken. Accordingly, a job impact statement is not required and one has not been prepared.

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

State Assessments and Graduation and Diploma Requirements

I.D. No. EDU-32-05-00015-EP

Filing No. 824

Filing date: July 26, 2005

Effective date: July 26, 2005

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

Action taken: Amendment of section 100.5 of Title 8 NYCRR.

Statutory authority: Education Law, sections 101 (not subdivided), 207 (not subdivided), 208 (not subdivided), 209 (not subdivided), 305(1) and (2), 308 (not subdivided), 309 (not subdivided), 3204(3)

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

Specific reasons underlying the finding of necessity: The proposed amendment is necessary to implement revisions to policy adopted by the Board of Regents in June 2005.

Under current regulations, the minimum passing score on five required Regents examinations rises from 55 to 65 for those students who enter grade 9 in the 2005-2006 school year and thereafter. The revised policy phases in the 65 passing score on the five required Regents examinations to meet graduation requirements by requiring students who enter grade 9 in the 2005-06 school year to achieve 65 or higher on two required Regents examinations, by requiring students who enter grade 9 in the 2006-07 school year to achieve 65 or higher on three required Regents examinations, by requiring students who enter grade 9 in the 2007-08 school year to achieve 65 or higher on four required Regents examinations, and by requiring students who enter grade 9 in the 2008-09 school year to achieve 65 on the five required Regents examinations. The phase-in will give students and schools more time to improve achievement while keeping the educational system moving forward toward the goal of higher achievement for all students.

The proposed amendment will also allow students with disabilities entering grade 9 in September 2005 and thereafter to earn a local diploma if they take and pass the five required Regents examinations with a score of 55-64.

The proposed amendment also establishes an appeals process for students who score within three points of 65 on a required Regents examination for graduation and have a 65 or above course average. Students seeking an appeal must meet the following criteria to demonstrate that they meet the State learning standards: take the Regents examination under appeal at least two times; have a score on the Regents exam under appeal within three points of the 65 passing score on that examination; present evidence that they have received academic intervention services by the school in the subject area of the Regents examination under appeal; have an attendance rate of at least 95 percent for the school year during which they last took the Regents examination under appeal; have a course average in the subject under appeal that meets or exceeds the required passing grade by the school; and be recommended for an exemption to the graduation requirement by their teacher or Department chairperson in the subject of the Regents examination under appeal. A standing committee chaired by the school principal would review all appeals within 10 days of submission and make a recommendation to the superintendent of the school district or, in the case of New York City, the Chancellor or his/her designee. Students who are granted an appeal on one examination, and who have attained a passing score of 65 or above on each of the four remaining required Regents examinations, will be determined to have met all graduation requirements and earn a Regents diploma. Students who are granted an appeal on two examinations, and who have attained a passing score of 65 or above on each of the three remaining required Regents examinations, will receive a local diploma. A school will make a record of all appeals received and granted and report the information to the State Education Department. The record of appeals will appear on the New York State School Report Card.

Emergency action to adopt the proposed amendment is necessary for the preservation of the general welfare in order to ensure that students who will enter grade 9 in September 2005 are informed of the revision to the revised diploma and graduation requirements, and to otherwise ensure that

schools and school districts are able to make any necessary adjustments in students' class schedules to ensure their timely graduation pursuant to such requirements.

It is anticipated that the proposed amendment will be presented to the Board of Regents for adoption as a permanent rule at the October 2005 meeting of the Board of Regents, which is the first scheduled meeting after expiration of the 45-day public comment period mandated by the State Administrative Procedure Act.

Subject: State assessments and graduation and diploma requirements.

Purpose: To revise requirements for obtaining a Regents high school diploma, a Regents diploma with advanced designation, and a local high school diploma.

Substance of emergency/proposed rule (Full text is posted at the following State website: www.emsc.nysed.gov): The Commissioner of Education proposes to amend section 100.5 of the Regulations of the Commissioner of Education, effective July 26, 2005, relating to school health services. The following is a summary of the substance of the proposed amendment:

The proposed amendment implements policy adopted by the Board of Regents at their June 2005 meeting concerning the phase-in of the graduation standard of 65 on required Regents exams. Under current regulations, the minimum passing score on the five required Regents examinations rises from 55 to 65 for those students who first enter grade 9 in the 2005-2006 school year and thereafter. The proposed amendment phases in the 65 passing score on the five required Regents examinations to meet graduation requirements, by requiring students who first enter grade 9 in the 2005-06 school year to achieve 65 or above on two required Regents examinations and a score of 55 or above on the remaining three required Regents examinations, by requiring students who first enter grade 9 in the 2006-07 school year to achieve 65 or above on three required Regents examinations and a score of 55 or above on the remaining two required Regents examinations, by requiring students who enter grade 9 in the 2007-08 school year to achieve 65 or higher on four required Regents examinations and a score of 55 on the one remaining required Regents examination, and by requiring students who enter grade 9 in the 2008-09 school year to achieve 65 on all five required Regents examinations.

The proposed amendment will provide an additional safety net for all students with disabilities entering grade 9 in the 2005-06 school year, by providing that students with disabilities may achieve a passing score of 55-64 on the five required Regents examinations to meet local diploma requirements.

The proposed amendment also establishes an appeal process for students who first enter grade 9 in September 2005 or thereafter and who fail, after at least two attempts, to attain a score of 65 or above on a required Regents examination for graduation. Students seeking an appeal must meet the following criteria to demonstrate that they meet the State learning standards: have a score on the Regents exam under appeal that is within three points of the 65 passing score; present evidence that they have received academic intervention services by the school in the subject area of the Regents examination under appeal; have an attendance rate of at least 95 percent for the school year during which they last took the Regents examination under appeal; have a course average in the subject area of the Regents examination under appeal that meets or exceeds the required passing grade by the school; and be recommended for an exemption to the passing score on the required Regents examination under appeal by their teacher or Department chairperson in the subject area of the Regents examination under appeal. No student may appeal his or her score on more than two of the five required Regents examinations. A standing committee chaired by the school principal would review all appeals within 10 days of submission and make a recommendation to the superintendent of the school district or, in the case of New York City, the Chancellor or his/her designee. Students who are granted an appeal on one examination, and who have attained a passing score of 65 or above on each of the four remaining required Regents examinations, will be determined to have met all graduation requirements and earn a Regents diploma. Students who are granted an appeal on two examinations, and who have attained a passing score of 65 or above on each of the three remaining Regents examinations, will receive a local diploma. A school will make a record of all appeals received and granted, report the information to the State Education Department, and make the records available for the inspection by the Department.

This notice is intended to serve as both a notice of emergency adoption and a notice of proposed rule making. The emergency rule will expire October 23, 2005.

Text of rule and any required statements and analyses may be obtained from: Anne Marie Koschnick, Legal Assistant, Office of Coun-

sel, Education Department, Albany, NY 12234, (518) 473-8296, e-mail: legal@mail.nysed.gov

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

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

Regulatory Impact Statement

STATUTORY AUTHORITY:

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

Education Law section 207 empowers the Board of Regents and the Commissioner to adopt rules and regulations to carry out laws of the State regarding education and the functions and duties conferred on the Department by law.

Education Law section 208 authorizes the Regents to establish examinations as to attainments in learning and to award and confer suitable certificates, diplomas and degrees on persons who satisfactorily meet the requirements prescribed.

Education Law section 209 authorizes the Regents to establish secondary school examinations in studies furnishing a suitable standard of graduation and of admission to colleges; to confer certificates or diplomas on students who satisfactorily pass such examinations; and requires the admission to these examinations of any person who shall conform to the rules and pay the fees prescribed by the Regents.

Education Law section 305(1) and (2) provide that the Commissioner, as chief executive officer of the State system of education and of the Board of Regents, shall have general supervision over all schools and institutions subject to the provisions of the Education Law, or of any statute relating to education, and shall execute all educational policies determined by the Board of Regents.

Education Law section 308 authorizes the Commissioner to enforce and give effect to any provision in the Education Law or in any other general or special law pertaining to the school system of the State or any rule or direction of the Regents.

Education Law section 309 charges the Commissioner with the general supervision of boards of education and their management and conduct of all departments of instruction.

Education Law section 3204(3) provides for required courses of study in the public schools and authorizes the State education department to alter the subjects of required instruction.

LEGISLATIVE OBJECTIVES:

The proposed amendment is consistent with the authority conferred by the above statutes and is necessary to implement policy enacted by the Board of Regents relating to the State learning standards, State assessments and graduation and diploma requirements.

NEEDS AND BENEFITS:

The proposed amendment will revise the graduation and diploma requirements first adopted by the Board of Regents in July 1999, and subsequently revised in November 2003, to help ensure that all students in the State's public schools have the skills, knowledge and understandings they need to succeed in the next century. The proposed changes are necessary to implement revisions to policy adopted by the Board of Regents in June 2005.

Under current regulations, the minimum passing score on five required Regents examinations rises from 55 to 65 for those students who entered grade 9 in the 2005-2006 school year and thereafter. The revised policy phases in the 65 passing score on the five required Regents examinations to meet graduation requirements by requiring students who enter grade 9 in the 2005-06 school year to achieve 65 or above on two required Regents examinations and a score of 55 or above on the remaining three required Regents examinations, by requiring students who enter grade 9 in the 2006-07 school year to achieve 65 or above on three required Regents examinations and a score of 55 or above on the remaining two required Regents examinations, by requiring students who enter grade 9 in the 2007-08 school year to achieve 65 or higher on four required Regents examinations and a score of 55 on the one remaining required Regents examination, and by requiring students who enter grade 9 in the 2008-09 school year to achieve 65 on all five required Regents examinations. The phase-in will give students and schools more time to improve achievement

while keeping the educational system moving forward toward the goal of higher achievement for all students.

Despite the significant increase in the number of students with disabilities taking Regents level courses and passing Regents examinations, there still is a significant gap between the performance of special education and general education students. Therefore, the proposed amendment will provide an additional safety net for all students with disabilities entering grade 9 in the 2005-06 school year. Under this safety net, students with disabilities may achieve a passing score of 55-64 on the five required Regents examinations to meet local diploma requirements.

The proposed amendment also establishes an appeal process for students who first enter grade 9 in September 2005 or thereafter and who fail, after at least two attempts, to attain a score of 65 or above on a required Regents examination for graduation. Students seeking an appeal must meet the following criteria to demonstrate that they meet the State learning standards: have a score on the Regents exam under appeal that is within three points of the 65 passing score; present evidence that they have received academic intervention services by the school in the subject area of the Regents examination under appeal; have an attendance rate of at least 95 percent for the school year during which they last took the Regents examination under appeal; have a course average in the subject area of the Regents examination under appeal that meets or exceeds the required passing grade by the school; and be recommended for an exemption to the passing score on the required Regents examination under appeal by their teacher or Department chairperson in the applicable subject area. No student may appeal his or her score on more than two of the five required Regents examinations. A standing committee chaired by the school principal would review all appeals within 10 days of submission and make a recommendation to the superintendent of the school district or, in the case of New York City, the Chancellor or his/her designee. Students who are granted an appeal on one examination, and who have attained a passing score of 65 or above on each of the four remaining required Regents examinations, will be determined to have met all graduation requirements and earn a Regents diploma. Students who are granted an appeal on two examinations, and who have attained a passing score of 65 or above on each of the three remaining Regents examinations, will receive a local diploma. A school will make a record of all appeals received and granted, report the information to the State Education Department, and make the records available for the inspection by the Department.

COSTS:

(a) Costs to State government: None.

(b) Costs to local government: Based on the distribution of scores on Regents examinations of the 2000 student cohort (students who entered grade 9 in 2000) reported to the State Education Department by school districts, approximately 2,000-3,000 students would be eligible to seek an appeal out of the total statewide student population of about 200,000 students. The standing committee formed to review and make a decision on an appeal is made up of salaried administrators and teachers. The committee is expected to meet during the school day to review existing student records and to interview school staff and/or the student if needed. It is anticipated that the cost to the school district would be minimal and would be absorbed using existing staff and resources. It is estimated that the cost of the time for the standing committee to meet would not exceed \$100 per student seeking an appeal.

(c) Costs to private regulated parties: None.

(d) Costs to regulating agency for implementation and continued administration of this rule: None.

LOCAL GOVERNMENT MANDATES:

The proposed amendment revises the current requirements for meeting diploma and graduation requirements to give students and schools more time to improve achievement and to ensure that all students have continued opportunities to complete requirements for a high school diploma.

In the event of a student's appeal of his or her score on a required Regents examination, the school principal shall chair a standing committee comprised of three teachers (not to include the student's teacher in the subject area of the Regents examination under appeal) and two school administrators (one of whom shall be the school principal). The standing committee shall review an appeal within ten school days of its receipt and make a recommendation to the school superintendent or, in New York City, to the Chancellor or his/her designee. The school superintendent or Chancellor or Chancellor's designee shall make a final determination to accept or deny the appeal.

PAPERWORK:

Each school shall keep a record of all appeals received and granted and report this information to the State Education Department on a form

prescribed by the Commissioner. All school records relating to appeals of scores shall be made available for inspection by the State Education Department.

DUPLICATION:

The proposed amendment does not duplicate existing State or federal regulations.

ALTERNATIVES:

As an alternative to a phase-in of the 65 passing score on Regents examinations, the Board of Regents considered permitting general education students entering grade 9 in the 2005-2006 school year to graduate with a local diploma if the average of the sum of their passing scores on the five required Regents exams was 65 or above. Students entering grade 9 in the 2006-2007 school year would be required to pass the five exams with a score of 65 on each exam. This proposal was rejected because data provided to the State Education Department by school districts on the test results for students who entered grade 9 in 2000 showed a minimal difference between averaging and requiring a score of 65 on a certain number of exams.

The Board of Regents then considered a three-year phase-in of the requirement that the students achieve a score of 65 or above on the five required Regents examinations. After further consideration, the Board of Regents decided to adopt a phase-in of the requirement, but over a four-year rather than three-year phase-in period, to allow more time for schools and students to adjust curriculum and schedules and to ensure that students entering grade 9 in 2008 will be prepared to achieve the 65 passing score on all required Regents exams.

FEDERAL STANDARDS:

There are no related federal standards.

COMPLIANCE SCHEDULE:

It is anticipated that schools and school districts will be able to achieve compliance with the proposed amendment by its effective date.

Regulatory Flexibility Analysis

Small Businesses:

The proposed amendment will revise graduation and diploma requirements for students attending the public schools, consistent with policy adopted by the Board of Regents in June 2005. The proposed amendment does not impose any adverse economic impact, reporting, recordkeeping or any other compliance requirements on small businesses. Because it is evident from the nature of the proposed amendment that it does not affect small businesses, no further measures were needed to ascertain that fact and none were taken. Accordingly, a regulatory flexibility analysis for small businesses is not required and one has not been prepared.

Local Government:

EFFECT OF RULE:

The proposed rule applies to each of the 708 public school districts in the State, and to charter schools that are authorized to issue local and Regents diplomas with respect to State assessments and high school graduation and diploma requirements. At present, there are 4 charter schools offering a full high school program, 2 charter schools offering only 9th grade instruction, and 4 charter schools offering only 9th and 10th grade instruction.

COMPLIANCE REQUIREMENTS:

The proposed amendment will revise the graduation and diploma requirements first adopted by the Board of Regents in July 1999, and subsequently revised in November 2003, to help ensure that all students in the State's public schools have the skills, knowledge and understandings they need to succeed in the next century. The proposed changes are necessary to implement revisions to policy adopted by the Board of Regents in June 2005.

Under current regulations, the minimum passing score on five required Regents examinations rises from 55 to 65 for those students who entered grade 9 in the 2005-2006 school year and thereafter. The revised policy phases in the 65 passing score on the five required Regents examinations to meet graduation requirements by requiring students who enter grade 9 in the 2005-06 school year to achieve 65 or above on two required Regents examinations and a score of 55 or above on the remaining three required Regents examinations, by requiring students who enter grade 9 in the 2006-07 school year to achieve 65 or above on three required Regents examinations and a score of 55 or above on the remaining two required Regents examinations, by requiring students who enter grade 9 in the 2007-08 school year to achieve 65 or higher on four required Regents examinations and a score of 55 on the one remaining required Regents examination, and by requiring students who enter grade 9 in the 2008-09 school year to achieve 65 on all five required Regents examinations. The phase-in will give students and schools more time to improve achievement

while keeping the educational system moving forward toward the goal of higher achievement for all students.

Despite the significant increase in the number of students with disabilities taking Regents level courses and passing Regents examinations, there still is a significant gap between the performance of special education and general education students. Therefore, the proposed amendment will provide an additional safety net for all students with disabilities entering grade 9 in the 2005-06 school year. Under this safety net, students with disabilities may achieve a passing score of 55-64 on the five required Regents examinations to meet local diploma requirements.

In the event of a student's appeal of his or her score on a required Regents examination, the school principal shall chair a standing committee comprised of three teachers (not to include the student's teacher in the subject area of the Regents examination under appeal) and two school administrators (one of whom shall be the school principal). The standing committee shall review an appeal within ten school days of its receipt and make a recommendation to the school superintendent or, in New York City, to the Chancellor or his/her designee. The school superintendent or Chancellor or Chancellor's designee shall make a final determination to accept or deny the appeal.

Each school shall keep a record of all appeals received and granted and report this information to the State Education Department on a form prescribed by the Commissioner. All school records relating to appeals of scores shall be made available for inspection by the State Education Department.

PROFESSIONAL SERVICES:

The proposed amendment does not impose any additional professional services requirements.

COMPLIANCE COSTS:

Based on the distribution of scores on Regents examinations of the 2000 student cohort (students who entered grade 9 in 2000) reported to the State Education Department by school districts, approximately 2,000-3,000 students would be eligible to seek an appeal out of the total statewide student population of about 200,000 students. The standing committee formed to review and make a decision on an appeal is made up of salaried administrators and teachers. The committee is expected to meet during the school day to review existing student records and to interview school staff and/or the student if needed. It is anticipated that the cost to the school district would be minimal and would be absorbed using existing staff and resources. It is estimated that the cost of the time for the standing committee to meet would not exceed \$100 per student seeking an appeal.

ECONOMIC AND TECHNOLOGICAL FEASIBILITY:

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

MINIMIZING ADVERSE IMPACT:

The proposed amendment is necessary to implement policy adopted by the Board of Regents. The proposed amendment has been carefully drafted to meet statutory requirements and Regents policy while minimizing the impact on school districts. Where possible, the regulations have incorporated existing requirements and eliminated redundant requirements to minimize work at the local level and have emphasized local flexibility in meeting the regulatory requirements.

LOCAL GOVERNMENT PARTICIPATION:

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

Rural Area Flexibility Analysis

TYPES AND ESTIMATED NUMBER OF RURAL AREAS:

The proposed amendment applies to all school districts in the State, including those located in the 44 rural counties with less than 200,000 inhabitants and the 71 towns in urban counties with a population density of 150 per square mile or less. The proposed amendment also applies to charter schools in such areas, to the extent they offer instruction in the high school grades and issue Regents diplomas and local diplomas. At present, there are no such charter schools located in rural areas.

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

The proposed amendment will revise the graduation and diploma requirements first adopted by the Board of Regents in July 1999, and subsequently revised in November 2003, to help ensure that all students in the State's public schools have the skills, knowledge and understandings they need to succeed in the next century. The proposed changes are necessary to implement revisions to policy adopted by the Board of Regents in June 2005.

Under current regulations, the minimum passing score on five required Regents examinations rises from 55 to 65 for those students who entered grade 9 in the 2005-2006 school year and thereafter. The revised policy phases in the 65 passing score on the five required Regents examinations to meet graduation requirements by requiring students who enter grade 9 in the 2005-06 school year to achieve 65 or above on two required Regents examinations and a score of 55 or above on the remaining three required Regents examinations, by requiring students who enter grade 9 in the 2006-07 school year to achieve 65 or above on three required Regents examinations and a score of 55 or above on the remaining two required Regents examinations, by requiring students who enter grade 9 in the 2007-08 school year to achieve 65 or higher on four required Regents examinations and a score of 55 on the one remaining required Regents examination, and by requiring students who enter grade 9 in the 2008-09 school year to achieve 65 on all five required Regents examinations. The phase-in will give students and schools more time to improve achievement while keeping the educational system moving forward toward the goal of higher achievement for all students.

Despite the significant increase in the number of students with disabilities taking Regents level courses and passing Regents examinations, there still is a significant gap between the performance of special education and general education students. Therefore, the proposed amendment will provide an additional safety net for all students with disabilities entering grade 9 in the 2005-06 school year. Under this safety net, students with disabilities may achieve a passing score of 55-64 on the five required Regents examinations to meet local diploma requirements.

In the event of a student's appeal of his or her score on a required Regents examination, the school principal shall chair a standing committee comprised of three teachers (not to include the student's teacher in the subject area of the Regents examination under appeal) and two school administrators (one of whom shall be the school principal). The standing committee shall review an appeal within ten school days of its receipt and make a recommendation to the school superintendent or, in New York City, to the Chancellor or his/her designee. The school superintendent or Chancellor or Chancellor's designee shall make a final determination to accept or deny the appeal.

Each school shall keep a record of all appeals received and granted and report this information to the State Education Department on a form prescribed by the Commissioner. All school records relating to appeals of scores shall be made available for inspection by the State Education Department.

The proposed amendment does not impose any additional professional services requirements.

COMPLIANCE COSTS:

Based on the distribution of scores on Regents examinations of the 2000 student cohort (students who entered grade 9 in 2000) reported to the State Education Department by school districts, approximately 2,000-3,000 students would be eligible to seek an appeal out of the total statewide student population of about 200,000 students. The standing committee formed to review and make a decision on an appeal is made up of salaried administrators and teachers. The committee is expected to meet during the school day to review existing student records and to interview school staff and/or the student if needed. It is anticipated that the cost to the school district would be minimal and would be absorbed using existing staff and resources. It is estimated that the cost of the time for the standing committee to meet would not exceed \$100 per student seeking an appeal.

MINIMIZING ADVERSE IMPACT:

The proposed amendment is necessary to implement policy adopted by the Board of Regents, and has been carefully drafted to meet statutory requirements and Regents policy while minimizing the impact on school districts and boards of cooperative educational services in rural areas. Where possible, the regulations have incorporated existing requirements and eliminated redundant requirements to minimize work at the local level and have emphasized local flexibility in meeting the regulatory requirements. The Regents policy upon which the proposed amendment is based applies to all schools. Therefore, it was not possible to establish different compliance and reporting requirements entities in rural areas, or to exempt them from the provisions of the proposed amendment.

RURAL AREA PARTICIPATION:

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

Job Impact Statement

The proposed amendment revises graduation and diploma requirements consistent with policy adopted by the New York State Board of Regents.

The assessments and graduation requirements will help ensure that all students in New York State public schools have the skills, knowledge, and understandings they will need to succeed. The proposed amendment will not have an adverse impact on jobs or employment opportunities. Because it is evident from the nature of the amendment that it will have a positive impact, or no impact, on jobs or employment opportunities, no further steps were needed to ascertain those facts and none were taken. Accordingly, a job impact statement is not required and one has not been prepared.

NOTICE OF ADOPTION

Provisional Certification in School Psychology

I.D. No. EDU-18-05-00016-A

Filing No. 822

Filing date: July 26, 2005

Effective date: August 11, 2005

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

Action taken: Amendment of sections 80-2.3(e)(1), 80-2.9(a)(5) and 80-4.3(a)(3) of Title 8 NYCRR.

Statutory authority: Education Law, sections 207 (not subdivided), 210 (not subdivided), 305(1), (2) and (7); 3001(2); 3004(1); 3006(1)(b); 3009(1); 3010 (not subdivided)

Subject: Requirements for provisional certification in school psychology by licensed psychologists and for the interim bilingual education extension for certificates in school psychology and speech and language disabilities.

Purpose: To increase the number of bilingual certified school psychologists and teachers of students with speech and language disabilities.

Text or summary was published in the notice of proposed rule making, I.D. No. EDU-18-05-00016-P, Issue of May 4, 2005.

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

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

Assessment of Public Comment

A Notice of Proposed Rule Making concerning the proposed amendment was published in the *State Register* on May 4, 2005. Below is a summary of the written comments received during the public comment period, and the State Education Department's response:

COMMENT: The proposed regulation would allow licensed psychologists to practice without the pre-requisite knowledge and skills necessary to assess and treat children in a school setting. This lack of preparation extends to the educational coursework associated with the bilingual extension, which focuses on educational foundations and pedagogy.

RESPONSE: School districts around the State, and most particularly the New York City School District, have experienced persistent, serious shortages of certified school psychologists with bilingual skills to meet the needs of students classified with disabilities whose principal language is not English. The purpose of the proposed amendment is to increase the number of certified school psychologists available to meet the needs of limited English speaking students with disabilities. Specifically, the proposal would establish an expedited pathway for licensed psychologists who have demonstrated proficiency in a language other than English to obtain the first level certificate necessary to work as a school psychologist without first completing a college supervised internship in school psychology. Such candidates will have completed a doctoral program in psychology for licensure. Among other requirements, candidates must maintain registration in a program leading to the bilingual education extension and receive mentoring by a certified school psychologist during the first year of his or her employment under the provisional certificate. The Department believes that these requirements, in combination with the considerable academic preparation necessary to qualify for the psychology license, are sufficient to ensure that all such candidates will have the baseline competencies necessary to meet the needs of this student population.

COMMENT: The proposal lacks detail about how a licensed psychologist and provisionally certified school psychologist will gain the necessary educational knowledge and skills to perform effectively once they are in the school setting. It is unlikely that a year of mentored employment can replace the rigor and depth of graduate preparation in school psychology.

RESPONSE: The Department believes that a well crafted mentoring plan for candidates obtaining a provisional school psychologist certificate by the proposed route will be sufficient to convey the baseline knowledge and skills necessary for the provisional certificate holder to effectively

address the needs of the identified student population. Without this mechanism to increase the number of certified school psychologists with bilingual skills, the Department believes that the needs identified in the individualized education plans of many students with disabilities whose principal language is not English will not be adequately addressed consistent with the requirements of the IDEA, New York law or Part 200 of the Commissioner's regulations.

COMMENT: The responsibilities and expectations of the mentoring school psychologists are not included in the proposed regulation and are likely to be considerable.

RESPONSE: The Department anticipates providing guidance information and assistance to the field on the planning and implementation of effective mentoring programs to help address this need.

NOTICE OF ADOPTION

Photo Identification Cards

I.D. No. EDU-18-05-00017-A

Filing No. 820

Filing date: July 26, 2005

Effective date: August 11, 2005

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

Action taken: Repeal of section 50.2 and amendment of section 59.9 of Title 8 NYCRR.

Statutory authority: Education Law, sections 207 (not subdivided), 212 (not subdivided), 6502(1) and 6507(2)(a) and (4)(f)

Subject: A fee for photo identification cards for licensed professionals and repeal of an outdated fee provision.

Purpose: To establish a fee for a photo identification card to be issued to those professionals licensed and registered pursuant to Title VIII of the Education Law who elect to receive one and repeal an outdated fee provision in commissioner's regulations.

Text or summary was published in the notice of proposed rule making, I.D. No. EDU-18-05-00017-P, Issue of May 4, 2005.

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

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

Assessment of Public Comment

The agency received no public comment.

NOTICE OF ADOPTION

Extension in Gifted Education of a Teaching Certificate

I.D. No. EDU-21-05-00007-A

Filing No. 821

Filing date: July 26, 2005

Effective date: August 11, 2005

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

Action taken: Amendment of sections 52.21(b)(4)(v), 80-4.1(a)(2) and 80-4.3(d) of Title 8 NYCRR.

Statutory authority: Education Law, sections 207 (not subdivided); 210 (not subdivided); 305(1), (2) and (7); 3001(2); 3004(1); 3006(1)(b); 3009(1); 3010 (not subdivided)

Subject: Extension in gifted education of a teaching certificate.

Purpose: To clarify and strengthen the education requirements for the extension of a teaching certificate in gifted education to better align with the competencies tested in the teacher certification examination for this extension as articulated in the examination's framework, and defer the implementation of the requirement for the extension.

Text or summary was published in the notice of proposed rule making, I.D. No. EDU-21-05-00007-P, Issue of May 25, 2005.

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

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

Assessment of Public Comment

The agency received no public comment.

Department of Health

ERRATUM

A Notice of Proposed Rule Making, I.D. No. HLT-28-05-00004-P, pertaining to Treatment, Monitoring and Reporting of Radionuclides, published in the July 13, 2005 issue of the *State Register* contained a typo in Table 7 of the substance.

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

The corrected substance follows:

Substance of proposed rule (Full text is posted at the following State website: www.health.state.ny.us): The proposed code amendment incorporates the requirements of the Radionuclides Rule which was promulgated by the United States Environmental Protection Agency (EPA) on December 7, 2000. As a condition of primacy, New York State must promulgate a rule at least as stringent as the federal rule to assure that community water systems comply with the federal Radionuclides Rule. Initially the State was to establish primacy regulations by December 8, 2002. However, the New York State Department of Health (NYSDOH) received an extension from EPA to June 30, 2004 to adopt the required Code amendment. The Department entered into a Memorandum of Understanding with EPA regarding rule implementation while the Department pursues adopting the Code amendment.

The following is a summary of the proposed amendment to Subpart 5-1 of NYCRR Part 5:

Section 5-1.52 Tables

The following tables will be edited, or deleted and replaced to incorporate the requirements of the Radionuclides Rule into Subpart 5-1:

Table 7. Radiological Maximum Contaminant Level Determination: The revised Radionuclides Rule promulgates a new maximum contamination level (MCL) for uranium (30 µg/L) and retains the existing MCLs for combined radium 226 and 228 activity (5 pCi/L), gross alpha activity (15 pCi/L) and beta particle and photon radioactivity from manmade radionuclides (4 mrem/year).

Table 12. Radiological Monitoring Requirements: Monitoring requirements have been changed significantly and will now require an initial round of quarterly samples, followed by varying periodic monitoring depending on the initial sample results. Systems exceeding the MCL for gross alpha particle activity, combined radium activity or uranium concentration at any sampling point must conduct quarterly monitoring at that sampling point. For systems with multiple entry points, if a system exceeds the MCL at one entry point, the system is considered out of compliance. For systems that do not exceed the MCL, monitoring can be reduced as follows: one sample every 9 years at each entry point when monitoring results are less than the detection limit (DL); one sample every 6 years at each entry point when monitoring results are at or above the DL but below half of the MCL; one sample every 3 years at each entry point when monitoring results are above half of the MCL but at or below the MCL. Historical monitoring data can be used in lieu of the initial monitoring requirements for gross alpha, combined radium and uranium if such data are representative of all entry points.

Community water systems only have to monitor for beta particles or photon radioactivity if they are designated as either a vulnerable system or a system utilizing waters potentially contaminated by effluents from nuclear facilities. A vulnerable system is any system with a history of gross beta particle activity above 50 pCi/L. A contaminated system is any system potentially utilizing waters contaminated by effluents from nuclear facilities. Monitoring for these contaminants can also be reduced to once every three years if the monitoring results do not exceed a specified gross beta particle activity level.

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

The Best Available Technologies (BATs) table included in 5-1.91(e) has been amended to include additional information about BATs for achieving compliance with the radionuclide MCLs. Enhanced coagulation for uranium removal has been added.

EMERGENCY RULE MAKING

HIV Laboratory Test Reporting

I.D. No. HLT-32-05-00002-E

Filing No. 815

Filing date: July 21, 2005

Effective date: July 21, 2005

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

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

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

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

Specific reasons underlying the finding of necessity: The specific reasons underlying the finding of necessity to adopt as an emergency rule are as follows:

Section 63.4(a)(4)(i).

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

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

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

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

Section 63.11

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

based forms, which are current, clear and simplified, is necessary and urgent.

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

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

Subject: HIV laboratory test reporting.

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

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

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

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

This notice is intended to serve only as a notice of emergency adoption. This agency intends to adopt this emergency rule as a permanent rule and will publish a notice of proposed rule making in the *State Register* at some future date. The emergency rule will expire October 18, 2005.

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

Regulatory Impact Statement

Statutory Authority:

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

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

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

Legislative Objectives:

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

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

Needs and Benefits:

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

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

HIV viral load suppression is necessary to prevent the development of HIV drug resistance. Since June 2000, laboratories have reported detectable viral load test results to the Department. The inclusion of non-detectable viral loads in the surveillance system offers a valuable population-based assessment of the suppression of viral load and therefore the risk for the development of drug resistance. If the goal to avoid drug resistance is not being met at a population level, then viral load information will allow interventions to be designed that target the problems that are allowing resistant strains to proliferate (*i.e.*, direct transmission of resistant strains, lack of entry into medical care, and/or inadequate viral load suppression even with medical care).

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

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

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

Specifically, the need to repeal the existing HIV consent form results from the evolution of HIV testing technologies. Rapid HIV antibody tests now available can provide a negative or preliminary positive result during

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

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

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

Costs:

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

There will be no additional costs for the laboratories associated with the reporting of all HIV nucleic acid (RNA or DNA) detection test results and all CD4 lymphocyte test results, as this can easily be incorporated with the existing reporting of positive HIV nucleic acid (RNA and DNA) detection tests. Approximately 25 laboratories conduct HIV drug resistance testing. Laboratories already reporting test results to the NYSDOH via the NYS Electronic Clinical Laboratory Reporting System (ECLRS) may require some one-time programming costs to set up the extraction of data from their testing systems and incorporating it with the ECLRS transfers. Laboratories not reporting through ECLRS will require a minimum commitment of additional staff time to establish an account on the NYS Department of Health's (NYSDOH) Health Provider Network (HPN) for highly secured transfer of data directly to the NYSDOH.

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

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

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

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

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

of HIV-related information should decrease as a result of these amendments.

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

Local Government Mandates:

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

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

Paperwork:

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

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

Duplication:

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

Alternatives:

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

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

Federal Standards:

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

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

Compliance Schedule:

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

Regulatory Flexibility Analysis

Effect of Rule:

The proposed changes to the regulations will affect approximately 24 laboratories that conduct HIV drug resistance testing. Of these 24 laborato-

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

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

Compliance Requirements:

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

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

Professional Services:

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

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

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

Compliance Costs:

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

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

Economic and Technical Feasibility:

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

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

Minimizing Adverse Impact:

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

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

Small Business and Local Government Participation:

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

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

Rural Area Flexibility Analysis

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

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

Job Impact Statement

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

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

EMERGENCY RULE MAKING

Newborn Screening Panel

I.D. No. HLT-32-05-00003-E

Filing No. 816

Filing date: July 21, 2005

Effective date: July 21, 2005

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

Action taken: Amendment of sections 69-1.2 and 69-1.3 of Title 10 NYCRR.

Statutory authority: Public Health Law, section 2500-a

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

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

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

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

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

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

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

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

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

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

* * *

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

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

(n)(m) Specialized care center means a health care facility established under article 28 of the Public Health Law which is approved by the department and certified by the Wadsworth Center [for Laboratories and

Research] to provide treatment and/or services to children identified by the testing laboratory.

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

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

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

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

*argininemia (ARG);
argininosuccinic acidemia (ASA);
biotinidase deficiency;
branched-chain ketonuria, also known as maple syrup urine disease (MSUD);*

*carnitine palmitoyl transferase Ia deficiency (CPT-IA);
carnitine palmitoyl transferase II deficiency (CPT-II);
carnitine-acylcarnitine translocase deficiency (CAT);
carnitine uptake defect (CUD);*

*citrullinemia (CIT);
cobalamin A,B cofactor deficiency (Cbl A,B);
congenital adrenal hyperplasia (CAH);
cystic fibrosis (CF);*

*dienoyl-CoA reductase deficiency (DE REDUCT);
galactosemia;
glutaric acidemia type I (GA-I);
hemoglobinopathies, including homozygous sickle cell disease;
homocystinuria;*

*human immunodeficiency virus (HIV) exposure and infection;
3-hydroxy-3-methylglutaryl-CoA lyase deficiency (HMG);
hyperammonemia/ornithinemia/citrullinemia (HHH);
hypermethioninemia (HMET);*

*hypothyroidism;
isobutyryl-CoA dehydrogenase deficiency (IBG or IBCD);
isovaleric acidemia (IVA);
long-chain 3-hydroxyacyl-CoA dehydrogenase deficiency (LCHADD);*

*malonic aciduria (MAL);
medium-chain acyl-CoA dehydrogenase deficiency (MCADD);
medium-chain ketoacyl-CoA thiolase deficiency (MCKAT);
medium/short-chain hydroxyacyl-CoA dehydrogenase deficiency (M/*

*SCHAD);
2-methylbutyryl-CoA dehydrogenase deficiency (2MBG);
3-methylcrotonyl-CoA carboxylase deficiency (3-MCC);
3-methylglutaconic aciduria (3MGA);*

*2-methyl 3-hydroxy butyryl-CoA dehydrogenase deficiency (2M3HBA);
methylmalonic acidemia (Cbl C, D);
methylmalonyl-CoA mutase deficiency (MUT);*

*mitochondrial acetoacetyl-CoA thiolase deficiency (BKT);
mitochondrial trifunctional protein deficiency (TFP);
multiple acyl-CoA dehydrogenase deficiency (MADD, also known as GA-II);*

*multiple carboxylase deficiency (MCD);
phenylketonuria (PKU);
propionic acidemia (PA);
short-chain acyl-CoA dehydrogenase deficiency (SCADD);
tyrosinemia (TYR); and*

very long-chain acyl-CoA dehydrogenase deficiency (VLCADD).

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

Section 69-1.3 Responsibilities of the chief executive officer. The chief executive officer shall ensure that a satisfactory specimen is submitted to the testing laboratory for each newborn born in the hospital, or admitted to the hospital within the first twenty-eight (28) days of life [with] *from whom*

no specimen [having] *has* been previously collected, and that the following procedures are carried out:

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

* * *

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

This notice is intended to serve only as a notice of emergency adoption. This agency intends to adopt 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 October 18, 2005.

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

Summary of Regulatory Impact Statement

Statutory Authority:

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

Legislative Objectives:

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

Needs and Benefits:

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

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

Overall, the potential positive effect on public health of the proposed screening panel is significant. It is best illustrated by considering that many of the conditions in the expanded screening panel proposed by this amendment carry several variants or subtypes, each with a different clinical presentation, which, if viewed as separate disorders, would translate into

the Newborn Screening Program's ability to detect more than 71 serious but treatable neonatal conditions.

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

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

Costs:

Costs to Private Regulated Parties:

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

The Program estimates that, following implementation of this proposal, 2,700 newborns will screen positive for one or more of the new conditions annually, and will require either repeat screening or referral to facilities and practitioners, depending on whether the value of the initial screening result for the condition's marker is close to the empirically determined cutoff point for positive, or significantly above that point. Cost figures that follow are based on this high-end estimate for presumptive positives and an estimated maximum number of infants needing immediate referral. The Department has revised its estimate of the number of infants expected to screen positive annually based on the results of a two-pronged approach: the Program's four months' experience with screening approximately 85,000 specimens for the 20-test panel mandated by the emergency rulemaking effective October 28, 2004; and a shorter-term, parallel study on 2,000 residual newborn specimens stripped of all identifiers and analyzed for any one of the 13 conditions added by emergency rulemaking effective April 25, 2005. Both undertakings used preliminary values for the cutoff point (marker level) for considering a specimen positive, values that intentionally maximize the number of presumptive positives. As the Program gains experience testing and verifies clinical outcomes, it is reasonable to expect that cutoff points will be adjusted to reduce the number of false positives to as few as possible, while retaining the capability to capture all true positives and eliminate false negatives.

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

Birthing facilities would likely incur minimal additional costs related to fulfilling their responsibilities for ensuring collection of a repeat specimen and referral of identified infants. Such costs would be limited to human resources costs of approximately 2.0 person-hours for arranging collection of a second specimen and its forwarding to the Department. On average, each birthing facility can expect to handle 4.5 additional infants in need of referral to a metabolic center per year as a result of screening tests conducted pursuant to this proposal. This increase is expected to have little

effect on the facility's workload since currently the number of infants referred to all facilities annually ranges from 350 to 500; therefore, no additional staff would be required at these institutions to comply with this proposal. Any facility can calculate its specific cost impact based on its annual number of births and expenses applying the following factors: an estimated rate of ten screen-positive infants per 1,000 births; and a referral rate of 3.5 infants per 1,000 births.

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

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

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

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

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

Costs for Implementation and Administration of the Rule:

Costs to State Government:

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

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

Costs to the Department:

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

A system for follow-up and assurance of access to necessary treatment for identified infants is fully established. In order to accommodate testing panel expansions effective October 28, 2004, the Department bolstered staffing in the Program's follow-up unit to handle the increased number of screen-positive results and interface with medical practitioners and facili-

ties, by redeploying staff and filling three positions with an annual value of \$138,381. The Department has requested permission to fill one clerical and eight scientific/clinical positions with a total annual value of \$565,365. The requested positions would allow the Department to meet public demands for a reduction in both the time required to generate screening test results and the number of infants with false positive screen test results, by conducting testing and data entry during weekday evening hours and on weekends and by assisting in development of molecular tests to better differentiate infants in need of immediate referral from infants whose marker levels may have been temporarily elevated or otherwise falsely positive. The Department also expects that staffing costs attributable to hiring a physician, which are included in the cost figures identified above, would translate to long-term cost savings across all affected parties. The physician would provide review of screen test results, thereby potentially reducing both the number of infants requiring testing of a second specimen and the number of infants requiring referral to metabolic centers for medical evaluation and testing.

Costs to Local Government:

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

Local Government Mandates:

The proposed regulations impose no new mandates on any county, city, town or village government; or school, fire or other special district, unless a county, city, town or village government; or school, fire or other special district operates a facility, such as a hospital, caring for infants 28 days of age or under and, therefore, is subject to these regulations to the same extent as a private regulated party.

Paperwork:

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

Duplication:

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

Alternative Approaches:

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

Federal Standards:

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

Compliance Schedule:

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

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

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

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

Regulatory Flexibility Analysis

Effect on Small Businesses and Local Governments:

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

Compliance Requirements:

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

Professional Services:

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

Compliance Costs:

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 following up infants screening positive for one or more of the 33 disorders proposed for addition to the newborn screening panel, primarily because testing proposed under this regulation is expected to result in, on average, fewer than one screen-positive infant per week at each of the 11 birthing facilities that are small businesses. Communicating the need and/or arranging referral for medical evaluation of one additional identified infant would take 1.0 person-hour, and is expected to be able to be accomplished with existing staff.

Providers, such as clinical specialists (*i.e.*, medical geneticists), and primary and ancillary care providers (*i.e.*, pediatricians, nutritionists and physical therapists), some of whom operate small businesses, would incur costs for first response and ongoing care of affected infants, as well as treatment supplies and dietary supplements. Specifically, such providers would incur human resources costs of approximately \$300 for an initial

comprehensive medical evaluation of one infant with an abnormal screening test result. However, given the low specificity of screening tests to ensure no false-negative test results, the Department anticipates that as many as 98 percent of infants will be found to not have the target condition, based on clinical assessment and relatively simple confirmatory tests.

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

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

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

Economic and Technological Feasibility:

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

Minimizing Adverse Impact:

The Department did not consider alternate, less stringent compliance requirements, or regulatory exceptions for facilities operated as small businesses or by local government, because of the importance of the proposed testing to statewide public health and welfare. These amendments will not have an adverse impact on the ability of small businesses or local governments to comply with Department requirements for mandatory newborn screening, as full compliance would require minimal enhancements to present collection, reporting, follow-up and recordkeeping practices.

Small Business and Local Government Participation

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

Rural Area Flexibility Analysis

Types of Estimated Numbers of Rural Areas:

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

This proposed amendment to add 33 conditions – all inherited metabolic disorders – to the list of ten genetic/congenital disorders and one infectious disease for which every newborn in the State must be tested will affect hospitals, alternative birthing centers, and physician and midwifery practices located in rural areas, provided such facilities care for infants 28 days of age or under, or are required to register the birth of a child. The

Department estimates that 54 hospitals and birthing centers operate in rural areas, and another 30 birthing facilities are located in counties with low-population density townships. Although they are well distributed throughout the State, no specialized care center operates in a rural area. New York State licenses 67,790 physicians and certifies 350 licensed midwives, some of whom are engaged in private practice in areas designated as rural; however, the number of professionals practicing in rural areas cannot be estimated because licensing agencies do not maintain records of licensees' employment addresses.

Reporting, Recordkeeping and other Compliance Requirements:

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

Professional Services:

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

Compliance Costs:

Birthing facilities operating in rural areas and practitioners in private practice in rural areas (*i.e.*, licensed midwives who assist with at-home births) will incur no new costs related to collection and submission of blood specimens to the State's Newborn Screening Program, since the dried blood spot specimens now collected and mailed to the program for other currently available testing would also be used for the additional tests proposed by this amendment. However, such facilities and, to a lesser extent, at-home birth attendants would likely incur minimal costs related to follow-up of infants screening positive for one of the metabolic disorders, since the proposed added testing is expected to result in no more than one more referral per week. Communicating the need and/or arranging referral for medical evaluation of one additional identified infant would take 1.0 person-hour, and is expected to be able to be accomplished with existing staff.

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

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

The Department expects that costs of medical services and supplies will be reimbursed by all payor mechanisms now covering the care of

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

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

Minimizing Adverse Impact:

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

Rural Area Participation:

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

Job Impact Statement

A Job Impact Statement is not required because it is apparent, from the nature and purpose of the proposed rule, that it will not have a substantial adverse impact on jobs and employment opportunities. The amendment proposes the addition of 33 conditions – all inherited metabolic disorders – to the scope of newborn screening services already provided by the Department. It is expected that, of the small number of regulated parties that will experience moderate rather than minimal impact on their workload, few, if any, will need to hire new personnel. Therefore, this proposed amendment carries no adverse implications for job opportunities.

EMERGENCY RULE MAKING

Serialized Official New York State Prescription Form

I.D. No. HLT-32-05-00004-E

Filing No. 817

Filing date: July 21, 2005

Effective date: July 21, 2005

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

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

Statutory authority: Public Health Law, section 21

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

Specific reasons underlying the finding of necessity: We are proposing that these regulations be adopted on an emergency basis because immediate adoption is necessary to protect the public health and safety and to meet statutory requirements. The budget proposal enacting Section 21 contains explicit authority for the Commissioner to promulgate emergency regulations. This was done recognizing the need to provide for a proper transition period for the use of statewide forge proof prescriptions, which under the regulations will be for a period of 18 months. Without the regulations the

program is required to be enacted in 60 days which would be detrimental to both practitioners and the public.

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

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

Subject: Serialized official New York State prescription form.

Purpose: To enact the form.

Text of emergency rule: The existing Chapter VIII (Physician Profiling) of Title 10 NYCRR is hereby renumbered Chapter IX and the new Chapter VIII renamed (Official New York State Prescription Forms).

A new Part 910 is added to Chapter VIII to Title 10 NYCRR to read as follows:

Part 910

Official New York State Prescription Forms

(Statutory Authority: Public Health Law, Section 21)

Section 910.1 Definitions

(a) For the purpose of this section, the following terms have the following meanings:

(1) "Prescription" means:

(i) a prescription pursuant to Section 6810 of the New York State Education Law and Section 21 and Article 33 of the New York State Public Health Law; or

(ii) an out-of-state prescription, which means a prescription issued by a practitioner in another state who is licensed by that state to prescribe; or

(iii) a prescription issued for other than a drug as defined by this section.

(2) "Drug" means an article or substance for which a prescription is required by the Federal Food, Drug and Cosmetic Act or the Commissioner of Health.

(3) "Practitioner" means a person licensed, authorized, or otherwise permitted in this state to issue a prescription.

(4) "Registered practitioner" means a practitioner duly registered with the department to be issued official New York State prescription forms.

(5) "Facility" means a hospital, veterinary hospital, clinic, dispensary, maternity home, nursing home, mental hospital, or other facility licensed or authorized by a state agency and approved by the department as authorized to be issued official New York State prescription forms.

(6) "Registered facility" means a facility duly registered with the department to be issued official New York State prescription forms.

(7) "Primary address" means the address of a registered practitioner's or registered facility's Federal Drug Enforcement Administration (DEA) registration or, if such practitioner or facility is not registered with the DEA, an address designated as the primary address in the practitioner's or facility's registration with the department.

(8) "Staff practitioner" means a practitioner who is employed by, has admission privileges with or is otherwise affiliated with a registered facility.

(9) "Diversion of drugs" means possession, delivery or use of a drug or a prescription by a person in a manner not specifically authorized by law.

(10) "Prescription issued for other than a drug" means a prescription for an item for which a prescription is not required under Section 6810 of the New York State Education Law, and any item for which a written order or fiscal order is required under the requirements of the New York Medical Assistance Program.

Section 910.2 Prescribing

(a) All prescriptions written in this state shall be issued on an official New York State prescription form provided by the department or a prescription form of a practitioner or institution in conformity with Section 6810 of the New York State Education Law and Section 21 and Article 33 of the New York State Public Health Law; except that prescriptions written for schedule II controlled substances and other controlled substances listed under section 80.67 of the New York Compilation of Codes, Rules and Regulations (10 NYCRR) shall continue to be issued only upon an official New York State prescription.

(b) Effective April 19, 2006, upon which date the eighteen-month period stipulated in Section 21 of the New York State Public Health Law

expires, all prescriptions written in this state shall be issued only upon an official New York State prescription form.

(c) A prescription shall be issued by a practitioner for legitimate medical purposes in good faith and in the course of his or her professional practice only. An order purporting to be a prescription that is not issued for legitimate medical purposes is not a prescription within the meaning of the New York State Education Law and the New York State Public Health Law and the person knowingly dispensing such an order, as well as the person issuing such order, shall be subject to all penalties provided in law or regulations.

Section 910.3 Registration

(a) Registration of practitioners and facilities.

(1) Effective April 19, 2006, upon which date the eighteen-month period stipulated in Section 21 of the New York State Public Health Law expires, practitioners and facilities shall register with the department in order to be issued official New York State prescription forms. Such registration shall include, but not be limited to, the primary address and the address of each place of business to be imprinted on official New York State prescription forms. Any change to a practitioner's or a facility's registered address shall be promptly reported to the department by the practitioner or facility in a manner approved by the department.

(2) A practitioner's or a facility's registration shall be without fee and subject to approval by the department. Such registration shall be valid for a period of two years and may be denied, suspended or revoked upon a finding by the department that the registered practitioner or registered facility has had any license to practice a medical profession or certification to operate a facility terminated, revoked or suspended by any state or Federal agency.

(3) A registered practitioner or registered facility whose registration is revoked or suspended shall be notified in writing setting forth the reasons and basis for the Department's action. The effective date of the action shall be at a minimum of 5 days after the date of the written notification. The registered practitioner or registered facility shall have the right to submit written arguments within 30 days of the date of written notification that the department's decision was based on mistake of fact. Such submission shall not stay the department's action and the department shall review any such submission and notify the registered facility or registered practitioner of its decision within 60 days of the date of submission of any written arguments.

(4) Where the department has revoked the registration of a registered facility or registered practitioner, it may revoke or cancel any official New York State prescription forms in the possession of the registered facility or registered practitioner. Any revocation or any suspension shall require the practitioner to return all unused official New York State prescription forms, within 15 days after the date of the written notification.

(5) A facility or practitioner that has had any license to practice or certification to operate a facility terminated, revoked, or suspended by an state or Federal agency may, upon restoration of such license or certification, register to be issued official New York State prescription forms.

Section 910.4 Issuance of Official New York State Prescription Forms

(a) Issuance of official New York State prescription forms to registered practitioners and registered facilities.

(1) The department will issue official New York State prescription forms free of charge only to registered practitioners and registered facilities in this state; provided, however, for the period until April 19, 2006, upon which date the eighteen-month period stipulated in Section 21 of the New York State Public Health Law expires, practitioners and facilities not registered shall continue to be issued official prescriptions pursuant to Article 33 of the New York State Public Health Law for prescribing schedule II controlled substances and other controlled substances listed under 10 NYCRR 80.67. Such forms shall not be transferable. The number of official prescription forms issued to a registered practitioner or registered facility at any time shall be a reasonable quantity and at the discretion of the department.

(2) Official New York State prescription forms shall be imprinted only with the primary address and other addresses listed on the registration of the facility or practitioner. Such prescriptions shall be sent only to the primary address of the registered practitioner or registered facility.

(3) Official New York State prescription forms shall, at the option of a registered practitioner or group practice of registered practitioners, be imprinted with the names of registered practitioners in such group practice.

(4) Official New York State prescription forms issued to a practitioner may be used only by the practitioner(s) to whom they are issued.

Official prescriptions issued to a facility may be used by staff practitioners only for patients of the registered facility.

(5) The department may determine that certain official New York State prescription forms shall be valid for a limited period of time.

(6) The department may revoke or cancel official New York State prescription forms in possession of registered practitioners or registered facilities when the license of such practitioner or facility is suspended, terminated, or revoked.

(7) Official New York State prescription forms of registered facilities that are no longer operating or of registered practitioners who are deceased or who no longer prescribe shall be returned to the Bureau of Narcotic Enforcement, NYS Department of Health or its designee, at a designated address. If the registered practitioner is deceased, it is the responsibility of the registered practitioner's estate or lawful designee to return such forms.

Section 910.5 Safeguarding of prescriptions

(a) Safeguarding of official New York State prescription forms by registered practitioners and registered facilities.

(1) Adequate safeguards and security measures shall be undertaken by registered practitioners holding official New York State prescription forms to assure against the loss, destruction, theft, or unauthorized use of the forms. Registered practitioners shall maintain a sufficient but not excessive supply of such forms in reserve.

(2) Registered practitioners and registered facilities shall immediately notify the department, in a manner designated by the department, upon their knowledge of the loss, destruction, theft or unauthorized use of any official New York State prescription forms issued to them, as well as the failure to receive official New York State prescription forms within a reasonable time after ordering them from the department.

(3) Registered practitioners and registered facilities shall immediately notify the department upon their knowledge of any diversion or suspected diversion of drugs pursuant to the loss, theft, or unauthorized use of prescriptions.

(4) It is the responsibility of a registered facility to obtain all official prescription forms for use, to assign such forms to its staff practitioners and to ensure the security of all such forms. Registered facilities obtaining official New York State prescription forms shall establish a system of control and security which will include at a minimum, the following:

(i) A record of all such forms received;

(ii) A record of all such forms assigned to its staff practitioners;

(iii) A system requiring that such forms be secure when not in use;

(iv) A system whereby such forms are surrendered to the registered facility by the staff practitioner if the staff practitioner to whom they were assigned terminates his affiliation with the registered facility;

(v) A system whereby the registered facility has a sufficient but not excessive number of such forms in reserve for use by the registered facility.

Section 910.6 Dispensing

Dispensing.

(1) A licensed, registered pharmacist, or a pharmacy intern acting in conformity with the provisions of Section 6806 of the Education Law and regulations thereunder in a registered pharmacy may, in good faith and in the course of his or her professional practice, sell and dispense a drug pursuant to a prescription, including an official New York State prescription. Schedule II controlled substances or other controlled substances listed in section 80.67 of 10 NYCRR may be dispensed only pursuant to an official New York State prescription or an out-of-state prescription. Effective April 19, 2006, upon which date the eighteen-month period stipulated in Section 21 of the New York State Public Health Law expires, all written prescriptions may be dispensed only pursuant to an official New York State prescription or an out-of-state prescription, which does not require an official New York State prescription. Such dispensing shall be in conformity with Section 6810 of the New York State Education Law and Section 21 and Article 33 of the New York State Public Health Law.

(2) A prescription for a schedule II controlled substance or other controlled substances listed in section 80.67 of 10 NYCRR may not be refilled.

(3) A pharmacy shall continue to file with the department information in accordance with section 80.73(c)(2) of 10 NYCRR for prescriptions, including out-of-state prescriptions, dispensed for schedule II controlled substances and other controlled substances listed in section 80.67 of 10 NYCRR and may also file such information for original fillings for prescriptions dispensed for all controlled substances.

(4) Effective June 1, 2005, a pharmacy shall file with the department information in accordance with section 80.73(c)(2) of 10 NYCRR for the original fillings of prescriptions, including out-of-state prescriptions, dis-

dispensed for all controlled substances. Such information shall be submitted only electronically to the department utilizing a transmission format acceptable to the department.

(5) A practitioner dispensing schedule II controlled substances or other controlled substances listed in section 80.67 of 10 NYCRR shall continue to file with the department information pursuant to such dispensing in the manner approved by the department. Effective June 1, 2005, such information shall be submitted only utilizing an electronic transmission format acceptable to the department.

(6) A pharmacy shall make a good faith effort to verify the identity of any person accepting delivery of a dispensed prescription for a controlled substance by requiring such person, if unknown to the pharmacy, to present appropriate identification.

Section 85.21 of Title 10 NYCRR is amended to read as follows:

Section 85.21 Establishment of list of reimbursable, nonprescription drugs.

Pursuant to section 365-a of the Social Services Law nonprescription drugs included in the therapeutic categories listed in this section may be reimbursed in the New York State Medical Assistance Program.

Product [Quantity]

(a) Analgesic and Antipyretic

(1) Acetaminophen [Tablets 80 mg 30's

325 mg 100's

500mg 100's

Liquid 120 ml

Drops 15 ml

Suppositories 12.0-125 mg .12's

300-325 mg 12's

600-650 mg 12's]

(2) Acetylsalicylic Acid

[Tablets 81 mg 36's

325 mg 100's

Tablets, Buffered 100's

Tablets, Enteric Coated 325 mg 1.00's

Suppositories 300-325 mg 12's

650 mg 12's]

(3) Ibuprofen [Tablets 200 mg 100's]

(b) Antacid

[(1) Aluminum Hydroxide Gel Suspension 355 ml Tablets 100's

(2) Aluminum Hydroxide with Magnesium Hydroxide or Magnesium Trisilicate and/or Simethicone and/or other antacid preparations

Suspension 355 ml

Tablets 40's-60's

100's

(3) Aluminum Hydroxide, Magnesium

Trisilicate, Alginate Acid and

Sodium Bicarbonate

Tablets 100's]

(c) Antivertigo

Dimenhydrinate [Tablets. 50 mg 12's

100's]

(d) Cough and Cold

(1) Phenylephrine Hydrochloride

[Nasal Solution 1/8% 20/30 ml

1/4% 30 ml

1/2% 30 ml]

(2) Guaifenesin and/or

[Syrup 120 ml

237 ml]

[with] Decongestant and/or

Antitussive [Drops 30 ml]

(3) Non-Narcotic Antitussants and/or Antihistamine

[Syrup 120 ml

237 ml]

(4) Antihistamine and Decongestant [Syrup 120 ml]

(5) Nonnarcotic Antitussants and/or

Upper Respiratory Combinations of

Antihistamines and Decongestants [Tablets or Capsules 10's-24's]

(6) Decongestant [Syrup 120 ml Decongestant Tablets 30 mg 24's]

(7) Sodium Chloride nasal

drops/spray [0.4 - 0.9% 15-50 ml]

(e) Dermatological

(1) Bacitracin [Ointment 30 G]

(2) Neomycin [Ointment 15 G

30G]

- (3) Tolnaftate
[Cream or Gel 1% 15 G
Powder 1% 45 G
Cream 5% 30 G
Cream 10% 30G
Gel 5% 45 G
Gel 10% 45 G
Lotion 5% 30 ml
60 ml
Lotion 10% 30 ml
60 ml]
[(5)] (4) Aluminum Acetate [Solution 473 ml]
[(6)] (5) Hydrocortisone
[Cream 0.5% 30 G
Ointment 05% 30 G
Lotion 0.5% 60 ml]
[(7) Iodochlorhydroxyquin (clioquinol)
Crema 3% 300
Ointment 3% 30 G]
(f) Family Planning
(1) Contraceptive [Cream Small
Large
Kit, with applicator
(2) Contraceptive Jelly Small
Large
Kit, with applicator
Disposable applicator 10's
(3) Contraceptive Suppositories 12's
(4) Contraceptive Foam Small
(5) Contraceptive. Sponge
(nonoxynol 9) 1 03's
6's
12's
Large]
(g) Fecal Softener and Laxatives
(1) Milk of Magnesia [Suspension 473 ml
Milk of Magnesia Tablets 100's]
(2) Heavy Mineral Oil [473 ml]
(3) Docusate, Calcium, Potassium or Sodium
[(i) Capsules 100 mg 100's
(ii) Solution 10 mg/ml 30 ml
(iii) Syrup 20 mg/5 ml 473 ml]
(4) Bisacodyl
[(i) Suppositories 10 mg 4's
12's
50's
(ii) Tablets, enteric coated 5 mg 100's]
(5) Bulk Laxatives
[(i) Psyllium and/or methyl cellulose, karaya gum, combinations,
etc. 10 or 16 oz
(ii) Sugar free Psyllium powder 250-399 G
(iii) Polycarbofil Tablets 500 mg 60's
100's]
(6) Barium Enema PrepKit
(7) Senna [Tablets 100's]
(h) Hematinic
(1) Ferrous Sulfate
[Tablets 300-325 mg 100's
Tablets, Enteric Coated 300-325 mg 100's
Liquid 473 ml
Drops 50 ml]
(2) Ferrous Gluconate [Tablets 300-325 mg 100's]
(i) Insulin
[(1) Insulin Injection USP
Insulin Inj. Beef & Pork U-40 10 ml
Insulin Inj. Beef & Pork U-100 10 ml
Insulin Inj. Pork U-i 00 10 ml
Insulin Inj. Pork
Ultra Purified U-i00 10 ml
Insulin Inj. Beef U-100 10 ml
(2) Insulin Suspension,
Protamine Zinc USP:
Protamine Zinc Beef & Pork U-40 10 ml
Protamine Zinc Beef & Pork U-100 10 ml
Protamine Zinc Pork U-100 10 ml
Protamine Zinc Beef U-100 10 ml
(3) Insulin Suspension,
Isophane...USP:
Isophane Beef & Pork U-40 10 ml
Isophane Beef & Pork U-100 10 ml
Isophane Pork Ultra Purified U-100 10 ml
Isophane PorkU-100 10 ml
Isophane Beef U-100 10 mi
70% Isophane Pork Susp./30% Insulin
Pork Inj U-100 10 ml.
(4) Insulin Zinc Suspension USP: ALL
(Prompt, Extended, Intermediate)
Zinc Susp. Beef & Pork U-40 10 ml.
Zinc: Susp. Beef & Pork U-.100 -10 ml
Zinc Susp. Pork Ultra Purified U-100.10 ml
Zinc Susp. Beef U-100 10 ml
Zinc Susp. Beef. Ultra.Purified U-100 10 ml
(5) Insulin, Biosynthetic Human
Insulin Injection U-100 10 ml
U-100 1.5 ml
Insulin Susp. Isophane U-100 10 ml
U-100 1.5 ml
Insulin Zinc Susp. U-100 10 ml
70% Isophane Susp./30%
Insulin Inj. U-100 10 ml
U-100 1.5 ml]
(j) Vitamin/Mineral
(1) ACD *with or without iron* [Solution 50 ml
ACD, Solution w/iron 50 ml]
(2) Multi-vitamin with or without iron [Solution 30 ml 50ml
Multi-vitamin Solution
w/iron 50 ml
(3) Multi-vitamin Capsules or
Tablets 100's
Multi-vitamin with minerals 100's
Multi-vitamin with or
without minerals 237 ml
473 ml]
[(4)](3) Therapeutic Vitamins with or
without Minerals
[Capsules or Tablets 100's]
[(5)] (4) Prenatal Vitamins,
[Capsules or Tablets 100's]
[(6)] (5) Ascorbic Acid [100 mg 100's
250 mg 100's
500 mg 100's]
[(7)] (6) Calcium [500 mg 100's
600-650 mg 100's
For persons with diagnosis of chronic
renal disease only:
Calcium .1 .25G:(500 mg
elemental Ca) 60's]
[(8)] (7) Pyridoxine Hydrochloride
[Tablets 25 mg 100's 50 mg 100's
100 mg 100's]
[(9)] (8) Vitamin D [8000 I/ml
2]
[(10)] (9) Thiamine Hydrochloride
[Tablets 50 mg 100's
100 mg 100's]
[(11)] (10) Magnesium [Gluconate
Tablets 500 mg 100's]
(11) Nicotinic Acid
(k) Basic Aluminum Carbonate Products (only for persons with diag-
nosis of chronic renal disease)
(1) Capsules 400-600 mg 100's
(2) Tablets 300-600 mg 100's 250's
(3) Suspension 400-600 mg/5ml 355 ml]
(l) Ocular/Oral Lubricants
(1) Lubricant Ophthalmic [Ointment 3.5 G]
(2) Sodium Chloride Ophthalmic [Ointment 3.5 G]
(3) Artificial Tears [15 ml]
[(4) Sodium Chloride
Ophthalmic Sol'n 2% 15 ml
5% 15 ml]

- [(5)] (4) Saliva Substitute
[(squeeze or spray solution) 120-180 ml]
- (m) Anti-Diarrheal Product
(1) Kaolin-Pectin Combination [237 ml
355 ml]
- [(1)] (2) Attapulgite Suspension [237 ml
355 ml]
- [(2)] (3) Loperamide HCl [Liquid 1 mg/5 ml 120 ml]
- [(3)] (4) Polycarbophil [Tablets 500 mg 100's]
- (n) Antihistamine(s)
[(1) Brompheniramine Tablets 4 mg 24's
100's
(2) Chlorpheniramine Tablets 4 mg 24's
100's
(3) Diphenhydramine Capsules 25 mg 100's
Liquid 12.5 mg/5 ml 120 ml]
- (o) Enzyme
Pancreatic Tablets [300-325 mg .100's]
- [(p) Anti-Malarial
Quinine Sulfate 300 mg 100's]
- (q) Cardiovascular
(1) Ephedrine Sulfate Capsules 25 mg 100's
(2) Nicotinic Acid Tablets 50 mg 100's
100 mg 100's
500 mg 100's]
- [(r)] (p) Pediculicide
[Pyrethrins 0.17-0.33%:60ml
with piperonyl butoxide 2-4% Liquid 120 ml]
- [(s)] (q) Emetic
Ipecac Syrup [30 ml]
- [(t)] (r) Smoking cessation.

Section 85.22 of Title 10 NYCRR is amended to read as follows:

Section 85.22 Maximum reimbursable price and limitations on reimbursement for nonprescription drugs. Pursuant to section 365-a of the Social Services Law, the amount which may be reimbursed for those nonprescription drugs specified in this Part by the commissioner as a reimbursable item of medical assistance shall be the lower of:

(a) the provider's usual and customary price to the general public on the date of provision of service, but not to exceed the lower sale price, if any, in effect on that date; or

(b) the maximum reimbursable price established and maintained by the commissioner. [Such maximum price is defined as the lower of:

(1) the price recommended by the New York State Department of Health ad hoc technical pharmacy advisory committee which reflects the realities of the consumer-oriented non-prescription drug market place; or

(2) the average wholesale price for each drug product plus an amount equal to the current pharmacy dispensing fee as approved by the Director of the Budget and maintained in 18 NYCRR 528.2(a).]

(c) Reimbursement shall not be available under the medical assistance program for any nonprescription drug in the following categories:

(1) A drug regularly supplied as an integral part of a medical care program activity to a Medicaid recipient by private, voluntary or public agency such as the Veterans Administration, Department of Health and Human Services, State Department of Health or other funded programs.

(2) Any drug for which there are low-cost alternatives if purchased by a Medicaid recipient, either non-prescription or [those] prescription drugs. [specified in section 85.25 of this Part.]

(3) Any drug considered ineffective in accordance with standards developed by the Food and Drug Administration.

(4) Any drug sold after the expiration date printed on the container label.

(5) Any drug in a container whose expiration date has been altered, mutilated, destroyed, obliterated or removed by means of an affixed price sticker or other change.

Sections 85.23 and 85.25 of Title 10 NYCRR are hereby deleted.

Section 505.3 of Title 18 NYCRR is amended to read as follows:

Section 505.3 Drugs. (a) Definitions.

(1) Compounded prescription means one in which two or more ingredients are mixed by the dispensing pharmacist. Medical assistance reimbursement for compounding is limited to the following:

(i) a combination of any two or more legend drugs found on the list of Medicaid reimbursable prescription drugs; or

(ii) a combination of any legend drugs included on the list of Medicaid reimbursable prescription drugs and any other item(s) not commercially available as an ethical or proprietary product(s); or

(iii) a combination of two or more products which are labeled "Caution: For Manufacturing Purposes only." The reconstitution of a commercially available drug is not a compounded prescription.

(2) Drug means both prescription and nonprescription drugs.

(3) Nonprescription drug means any drug for which a prescription is not required under section 6810 of the Education Law, including over the counter, prepackaged items.

(4) Practitioner means a [physician, physician's assistant, dentist, podiatrist or nurse practitioner.] *person licensed, authorized or otherwise permitted to write a prescription.*

(5) Prescription drug means any drug for which a prescription is required under section 6810 of the Education Law.

(6) Written order or fiscal order are terms which are used interchangeably in this section and refer to any original, signed written order of a practitioner *including any faxed transmitted order* which requests a pharmacy to provide a drug to a medical assistance recipient. *All written orders and fiscal orders shall comply with the provisions of Section 21 of the Public Health Law and regulations promulgated thereunder or contained in this section including but not limited to requirements for prescribing brand necessary drugs.*

[(7) Estimated acquisition cost means the average wholesale price of a prescription drug, as reported by the prescription drug price update service used by the department, less 10 percent thereof. The department currently contracts with Medi-Span, Inc., 8425 Woodfield Crossing Rd. P.O. Box 40930, Indianapolis, IN 46240-0930 for prescription drug price updates.

(8) The department will adjust the payment levels for prescription drugs monthly, if possible, but in no event less often than quarterly, unless otherwise required by federal law or federal regulation.]

(b) Written order required. (1) Drugs may be obtained only upon the written order of a practitioner, except for telephone *and electronic* orders for [prescription] drugs filled in compliance with this section and *10 NYCRR Part 910.*

(i) The ordering/prescribing of drugs is limited to the practitioner's scope of practice.

(ii) The ordering/prescribing of drugs is limited to practitioners not excluded from participating in the medical assistance program.

(2) All orders for drugs must show the ordering practitioner's name, address, telephone number, United States Drug Enforcement Agency (DEA) number (if applicable), and either the practitioner's MMIS provider identification number, the practitioner's license number or the certification number of the facility in which the drugs were ordered. All orders must also contain the name [and identification number] of the recipient for whom ordered.

(3) When used in the context of an order for a prescription drug, the order must also meet the requirements for a prescription under section 6810 of the Education Law *and 10 NYCRR Part 910.* When used in the context of a nonprescription drug, the order must also contain the following information: name of the drug; quantity ordered; strength or dosage; ingredient information, as necessary; directions for use; date ordered; and number of refills, if any.

(4) Telephone orders and for prescription drugs permitted to be filled by subdivision (4) of section 6810 of the Education Law *and non-prescription drugs* are permitted [however, refills of telephone orders are not permitted unless supported by written order].

(5) A telephone order must be recorded by the pharmacy in the format required by subdivision [(6)] (4) of Section 6810 of the Education Law, recording the time of the call and the initials of the person taking the call and the dispenser, prior to dispensing the drug. The pharmacist must label the drug as he/she would a written prescription, and make a good faith effort to verify the practitioner's identity, *and validity of the prescription* if the practitioner is unknown to the pharmacist. The practitioner must expressly state whether substitution is permitted or prohibited.

[(6) Telephone orders are not permitted for nonprescription drugs nor for prescription drugs not permitted to be filled by subdivision (4) of section 6810 of the Education Law.]

(6) *Effective April 1, 2005 an order which requests a pharmacy to provide a drug to a Medical Assistance recipient may be electronically transmitted unless otherwise prohibited by law or regulation. All written orders and all orders which are electronically transmitted must comply with the relevant provision of the state education law and all regulations promulgated thereunder. It is the responsibility of the pharmacist to make a good faith effort to verify the practitioner's identity and validity of the prescription if the practitioner is unknown to the pharmacist.*

(7) On or after June 1, 2005 and after the Department has provided advance written notice to appropriate providers, all claims for payment of drugs or supplies provided under this section and submitted to the medical assistance program shall contain the serial number of the official New York State prescription form.

(c) Where obtained. Drugs may be obtained only from pharmacies which are properly registered by the State in which the pharmacy is located, or from the ordering practitioner. A pharmacy must keep on file the signed written order of the practitioner for audit by the department, or other authorized agency, for six years from the date of payment for any drug dispensed. A practitioner must annotate the patient record to reflect the dispensing of the drug and the quantity, dose, directions for use and number of refills, if any.

(d) Prescription refills. (1) A written order may not be refilled unless the practitioner has indicated the number of allowable refills on the order.

(2) No written order for drugs may be refilled more than six months after the date of issuance, nor more than five times within a six month period.

(3) Refills must bear the prescription number of the original written order.

(e) Prescribed quantities. (1) Drugs must be ordered in a quantity consistent with the health needs of the patient and sound medical practice.

(2) Dispensing limits for drugs. (i) Except as provided in subparagraph (ii) of this paragraph, the maximum quantity of drugs dispensed is limited to the larger of:

(a) a 30 day supply; or

(b) 100 doses. One hundred doses is 100 units of a solid formulation.

(ii) The dispensing limit does not apply to long-term maintenance drugs. Long-term maintenance drugs are:

(a) drugs ordered or prescribed with one or more refills in quantities of a 30-day supply or greater. The quantity ordered or prescribed must be based on generally accepted medical practice. The ordering practitioner must be contacted if dispensing the supply specified in the prescription would result in the medical assistance recipient receiving a quantity of drugs which exceeds the manufacturer's labeling indications; or

(b) drugs ordered or prescribed without refills in quantities of a 60-day supply or greater. The quantity ordered or prescribed must be based on generally accepted medical practice. The ordering practitioner must be contacted if dispensing the supply specified in the prescription would result in the medical assistance recipient receiving a quantity of drugs which exceeds the manufacturer's labeling indications; or

(c) drugs ordered or prescribed for family planning purposes. The quantity ordered or prescribed must be based on generally accepted medical practice; or

(d) prescriptions written and dispensed on the official New York State [Triplicate] Prescription form for up to a three-month supply when written in conformity with the Controlled Substance Act (Title IV of Article 33 of the Public Health Law).

(f) Payment for drugs. (1) The reimbursement amounts are payment in full.

(2) Payment for drugs will only be made for prescription drugs listed in 10 NYCRR 85.25.

(3) Payment will only be made for nonprescription drugs listed in 10 NYCRR section 85.21. Payment must not exceed the maximum reimbursable price for the package size listed in the fee schedule for pharmacy services. The fee schedule for pharmacy services is available from the department and is also contained in the department's Medicaid Management Information System (MMIS) Provider Manual (Pharmacy). Copies of the manual may be obtained by writing Computer Sciences Corporation, Health and Administrative Services Division, 800 North Pearl St., Albany, New York 12204. Copies may also be obtained from the Department of Social Services, 40 North Pearl St., Albany, New York 12243. The manuals are provided free of charge to every pharmacy at the time of enrollment in the MA program. If a lesser amount than the package size listed in the fee schedule is dispensed, the amount charged is determined by multiplying the unit price by the number of units dispensed. The unit price is the listed maximum reimbursable price of the drug divided by the listed package size.]

[(4)] (2) Drugs provided by a practitioner and billed separately will be paid for at the actual cost to the practitioner.

[(5)] The ingredient cost of drugs dispensed by a pharmacy will be paid for as follows:

(i) The maximum payment for a multiple source prescription drug for which an upper payment limit has been set by the Federal Health Care Financing Administration (HCFA) must be the specified upper limit set by HCFA for the particular multiple source prescription drug, plus a dispensing fee.

(ii) The maximum payment for multiple source prescription drugs and brand name prescription drugs for which no upper limit has been set by HCFA is the lower of the estimated acquisition cost to the pharmacy plus a dispensing fee or the provider's usual and customary price charged to the general public.

(iii) The maximum payment for nonprescription drugs is the lowest of the usual and customary charge to the general public, not exceeding the lowest sale price on the date of service, or the price established under Part 528 of this Title.

(iv) The upper limit for payment of a multiple source drug for which a specific upper limit of reimbursement has been established does not apply if a prescriber certifies "brand medically necessary" or "brand necessary" in his or her own handwriting directly on the face of the prescription in addition to writing "d a w" in the box provided for such purpose on the prescription form. A handwritten statement that is transferred to a rubber stamp or other mechanical device and then stamped onto the prescription form is not acceptable. Reimbursement for these drugs will be made under the provision of subparagraph (ii) of this paragraph. In order to be reimbursed under subparagraph (iv) of this paragraph, a prescription ordered by telephone must be followed within five business days by a written prescription containing the information required by this subparagraph.]

[(6)] (3) The Department will pay each pharmacy enrolled in the MA program a [\$2.60] dispensing fee for each prescription drug claim. *Dispensing fees include routine delivery charges.* The Department will pay an additional compounding fee of \$.75 for each compounded prescription drug claim. The additional dispensing fee for a compounded prescription drug claim will not be paid when a manufacturer's specialty drug is reconstituted or when a non-medical or non-therapeutic agent is added to the prescription drug.

(g) Limitations. (1) The department will pay for therapeutic vitamins and specific vitamin preparations only when ordered by a physician for the treatment of deficiency states or pathological conditions requiring increased vitamins.

(2) The department will pay for amphetamine and amphetamine-like substances (congeners) only when used in outpatient treatment of conditions other than obesity or weight reduction.

(3) No payment will be made for any drug which has weight reduction as its sole clinical use, or for any drug when used to promote fertility.

(4) From time to time the department may limit the frequency or the amount of drugs which may be ordered. The department may require prior approval or prior authorization of drugs. The department may allow for exceptions to prior approval or prior authorization requirements in emergency circumstances. Emergency circumstances for purposes of this paragraph means any condition requiring alleviation of severe pain or which threatens to cause disability or take life if not promptly treated. The department will advise practitioners and pharmacies in writing before any reduction in frequency or amount, prior authorization or prior approval is imposed on any drug.

(h) Utilization threshold. (1) This subdivision describes the utilization threshold that the department has established for pharmacy services. Part 503 of this Title authorizes the department to establish a utilization threshold for specific provider service types, including pharmacy services. Part 503 also describes the application of the utilization threshold, services and procedures excluded from the utilization threshold for all provider service types subject to a threshold, the method for obtaining an exemption from or increase in the utilization threshold, notices, and the right to a fair hearing in certain situations.

(2) General rules. (i) Federally nonparticipating persons. Payment will be made for up to 43 pharmacy service formulary codes in a benefit year for persons who belong to a group listed in section 360-3.3(a)(1) or 360-3.3(b) (7) of this Title.

(ii) Federally participating persons. Payment will be made for up to 60 pharmacy service formulary codes in a benefit year for persons who belong to a group listed in section 360-3.3(a)(2)-(6), 360-3.3(b)(1)-(6) or 360-3.3(b) (3) of this Title.

(3) Formulary codes. As used in this subdivision, a formulary code is defined as follows:

(i) for prescription drugs, the first time a prescription is filled is one formulary code; each refill of the original prescription is also one formulary code; and

(ii) for nonprescription drugs and medical and surgical supplies, each initial fiscal order for the drug or supply is one formulary code; each refill of the fiscal order is also one formulary code.

(i) The Department may, after completing a competitive request for proposal (RFP) process, contract with mail-order pharmacies or their corporate owners to supply prescription and nonprescription drugs and medical/surgical supplies by mail to medical assistance (MA) recipients. The department may elect to offer mail-order pharmacy services in one or more social services districts through a contractor selected after completion of the RFP process. Individuals who are furnished MA by such districts who are not restricted in their access to drugs or medical/surgical supplies and who are not patients in residential health care facilities or any other facilities which have pharmaceuticals included in their medical assistance payments may choose to receive long-term maintenance drugs, excepting drugs [written and dispensed on official New York State triplicate prescription forms,] *prohibited pursuant to Article 33 of the Public Health Law*, nonprescription drugs and medical/surgical supplies by mail from contractors selected through the RFP process to provide such drugs and supplies.

Sections 528.1 and 528.2 of Title 18 NYCRR are hereby deleted.

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 October 18, 2005.

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

Regulatory Impact Statement

Statutory Authority:

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

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

Legislative Objectives:

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

Needs and Benefits:

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

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

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

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

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

Costs:

Costs to Regulated Parties:

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

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

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

Costs to State and Local Government:

There will be no costs to state or local government.

Costs to the Department of Health:

There will be no additional costs to the Department.

Local Government Mandates:

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

Paperwork:

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

Duplication:

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

Alternatives:

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

Federal Standards:

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

Compliance Schedule:

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

Regulatory Flexibility Analysis

Effect of Rule on Small Business and Local Government:

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

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

Compliance Requirements:

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

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

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

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

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

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

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

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

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

Professional Services:

No additional professional services are necessary.

Compliance Costs:

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

Economic and Technological Feasibility:

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

Minimizing Adverse Impact:

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

Small Business and Local Government Participation:

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

Rural Area Flexibility Analysis

Types and Estimated Numbers of Rural Areas:

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

Compliance Requirements:

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

Professional Services:

None necessary.

Compliance Costs:

None.

Economic and Technological Feasibility:

The proposed rule is both economically and technologically feasible. The process will utilize existing electronic systems for reporting of dispensing information by pharmacies. The regulations encourage the use of electronic prescribing, which is more efficient and more secure than a

paper process. Electronic prescribing will also enhance patient safety through a reduction in medication error due to legibility issues.

Minimizing Adverse Impact:

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

Rural Area Participation:

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

Job Impact Statement

Nature of Impact:

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

Metropolitan Transportation Authority

PROPOSED RULE MAKING NO HEARING(S) SCHEDULED

Unauthorized Sale of Transportation Services

I.D. No. MTA-32-05-00016-P

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

Proposed action: Addition of sections 1040.13, 1050.13, 1085.16 and 1097.16 to Title 21 NYCRR.

Statutory authority: Public Authorities Law, sections 1203-a, 1204 and 1266

Subject: Penalties for the new crime of unauthorized sale of transportation services.

Purpose: To provide additional public notice.

Text of proposed rule: Section 1050.13 is added to read as follows:

Public Notice of the Provisions of New York Penal Law § 165.16 (as added by Chapter 57 of the Laws of 2005).

The following notice of the provisions of New York Penal Law § 165.16 is provided pursuant to Section 2, part T, Chapter 57 of the Laws of 2005. New York Penal Law § 165.16 states:

§ 165.16 Unauthorized sale of certain transportation services.

1. A person is guilty of unauthorized sale of certain transportation services when, with intent to avoid payment by another person to the metropolitan transportation Authority, New York city transit authority or a subsidiary or affiliate of either such authority of the lawful charge for transportation services on a railroad, subway, bus or mass transit service operated by either such authority or a subsidiary or affiliate thereof, he or she, in exchange for value, sells access to such transportation services to such person, without authorization, through the use of an unlimited fare-card or doctored farecard. This section shall apply only to such sales that occur in a transportation facility, as such term is defined in subdivision two of section 240.00 of this chapter, operated by such metropolitan transportation authority, New York city transit authority or subsidiary or affiliate of such authority, when public notice of the prohibitions of its section and the exemptions thereto appears on the face of the farecard or is conspicuously posted in transportation facilities operated by such metropolitan transportation authority, New York city transit authority or such subsidiary or affiliate of such authority.

2. It shall be a defense to a prosecution under this section that a person, firm, partnership, corporation, or association: (a) selling a fare-card containing value, other than a doctored farecard, relinquished all rights and privileges thereto upon consummation of the sale; or (b) sold access to transportation services through the use of a farecard, other than a doctored farecard, when such sale was made at the request of the purchaser as an accommodation to the purchaser at a time when a fare-card was not immediately available to the purchaser, provided, however, that the seller lawfully acquired the farecard and did not, by means of an unlawful act, contribute to the circumstances that caused the purchaser to make such request.

3. For purposes of this section:

(a) "farecard" means a value-based, magnetically encoded card contain-ing stored monetary value from which a specified amount of value is deducted as payment of a fare;

(b) "unlimited farecard" means a farecard that is time-based, magnetically encoded and which permits entrance an unlimited number of times into facilities and conveyances for a specified period of time; and

(c) "doctored farecard" means a farecard that has been bent or manipulated or altered so as to facilitate a person's access to transportation services without paying the lawful charge.

Unauthorized sale of transportation service is a class B misdemeanor.

Section 1040.13 is added to read as follows:

Public Notice of the Provisions of New York Penal Law § 165.16 (as added by Chapter 57 of the Laws of 2005).

The following notice of the provisions of New York Penal Law is provided pursuant to Part T, Section 2 of Chapter 57 of the Laws of 2005. New York Penal Law § 165.16 states:

Unauthorized sale of certain transportation services.

1. A person is guilty of unauthorized sale of certain transportation services when, with intent to avoid payment by another person to the metropolitan transportation Authority, New York city transit authority or a subsidiary or affiliate of either such authority of the lawful charge for transportation services on a railroad, subway, bus or mass transit service operated by either such authority or a subsidiary or affiliate thereof, he or she, in exchange for value, sells access to such transportation services to such person, without authorization, through the use of an unlimited fare-card or doctored farecard. This section shall apply only to such sales that occur in a transportation facility, as such term is defined in subdivision two of section 240.00 of this chapter, operated by such metropolitan transportation authority, New York city transit authority or subsidiary or affiliate of such authority, when public notice of the prohibitions of its section and the exemptions thereto appears on the face of the farecard or is conspicuously posted in transportation facilities operated by such metropolitan transportation authority, New York city transit authority or such subsidiary or affiliate of such authority.

2. It shall be a defense to a prosecution under this section that a person, firm, partnership, corporation, or association: (a) selling a fare-card containing value, other than a doctored farecard, relinquished all rights and privileges thereto upon consummation of the sale; or (b) sold access to transportation services through the use of a farecard, other than a doctored farecard, when such sale was made at the request of the purchaser as an accommodation to the purchaser at a time when a fare-card was not immediately available to the purchaser, provided, however, that the seller lawfully acquired the farecard and did not, by means of an unlawful act, contribute to the circumstances that caused the purchaser to make such request.

3. For purposes of this section:

(a) "farecard" means a value-based, magnetically encoded card contain-ing stored monetary value from which a specified amount of value is deducted as payment of a fare;

(b) "unlimited farecard" means a farecard that is time-based, magnetically encoded and which permits entrance an unlimited number of times into facilities and conveyances for a specified period of time; and

(c) "doctored farecard" means a farecard that has been bent or manipulated or altered so as to facilitate a person's access to transportation services without paying the lawful charge.

Unauthorized sale of transportation service is a class B misdemeanor.

Section 1085.16 is added to read as follows:

Public Notice of the Provisions of New York Penal Law § 165.16 (as added by Chapter 57 of the Laws of 2005).

The following notice of the provisions of New York Penal Law § 165.16 is provided pursuant to Part T, Section 2 of Chapter 57 of the Laws of 2005. New York Penal Law § 165.16 states:

Unauthorized sale of certain transportation services.

1. A person is guilty of unauthorized sale of certain transportation services when, with intent to avoid payment by another person to the metropolitan transportation Authority, New York city transit authority or a subsidiary or affiliate of either such authority of the lawful charge for transportation services on a railroad, subway, bus or mass transit service operated by either such authority or a subsidiary or affiliate thereof, he or she, in exchange for value, sells access to such transportation services to such person, without authorization, through the use of an unlimited fare-card or doctored farecard. This section shall apply only to such sales that occur in a transportation facility, as such term is defined in subdivision two of section 240.00 of this chapter, operated by such metropolitan transportation authority, New York city transit authority or subsidiary or affiliate of such authority, when public notice of the prohibitions of its section and the exemptions thereto appears on the face of the farecard or is conspicuously posted in transportation facilities operated by such metropolitan transportation authority, New York city transit authority or such subsidiary or affiliate of such authority.

2. It shall be a defense to a prosecution under this section that a person, firm, partnership, corporation, or association: (a) selling a fare-card containing value, other than a doctored farecard, relinquished all rights and privileges thereto upon consummation of the sale; or (b) sold access to transportation services through the use of a farecard, other than a doctored farecard, when such sale was made at the request of the purchaser as an accommodation to the purchaser at a time when a fare-card was not immediately available to the purchaser, provided, however, that the seller lawfully acquired the farecard and did not, by means of an unlawful act, contribute to the circumstances that caused the purchaser to make such request.

3. For purposes of this section:

(a) "farecard" means a value-based, magnetically encoded card contain-ing stored monetary value from which a specified amount of value is deducted as payment of a fare;

(b) "unlimited farecard" means a farecard that is time-based, magnetically encoded and which permits entrance an unlimited number of times into facilities and conveyances for a specified period of time; and

(c) "doctored farecard" means a farecard that has been bent or manipulated or altered so as to facilitate a person's access to transportation services without paying the lawful charge.

Unauthorized sale of transportation service is a class B misdemeanor.

Section 1097.16 is added to read as follows:

Public Notice of the Provisions of New York Penal Law § 165.16 (as added by Chapter 57 of the Laws of 2005).

The following notice of the provisions of New York Penal Law § 165.16 is provided pursuant to Part T, Section 2 of Chapter 57 of the Laws of 2005. New York Penal Law § 165.16 states:

Unauthorized sale of certain transportation services.

1. A person is guilty of unauthorized sale of certain transportation services when, with intent to avoid payment by another person to the metropolitan transportation Authority, New York city transit authority or a subsidiary or affiliate of either such authority of the lawful charge for transportation services on a railroad, subway, bus or mass transit service operated by either such authority or a subsidiary or affiliate thereof, he or she, in exchange for value, sells access to such transportation services to such person, without authorization, through the use of an unlimited fare-card or doctored farecard. This section shall apply only to such sales that occur in a transportation facility, as such term is defined in subdivision two of section 240.00 of this chapter, operated by such metropolitan transportation authority, New York city transit authority or subsidiary or affiliate of such authority, when public notice of the prohibitions of its section and the exemptions thereto appears on the face of the farecard or is conspicuously posted in transportation facilities operated by such metropolitan transportation authority, New York city transit authority or such subsidiary or affiliate of such authority.

2. It shall be a defense to a prosecution under this section that a person, firm, partnership, corporation, or association: (a) selling a fare-card containing value, other than a doctored farecard, relinquished all rights and privileges thereto upon consummation of the sale; or (b) sold access to transportation services through the use of a farecard, other than a doctored farecard, when such sale was made at the request of the purchaser as an accommodation to the purchaser at a time when a fare-card was not immediately available to the purchaser, provided, however, that the seller lawfully acquired the farecard and did not, by means of an unlawful act, contribute to the circumstances that caused the purchaser to make such request.

3. For purposes of this section:

(a) "farecard" means a value-based, magnetically encoded card containing stored monetary value from which a specified amount of value is deducted as payment of a fare;

(b) "unlimited farecard" means a farecard that is time-based, magnetically encoded and which permits entrance an unlimited number of times into facilities and conveyances for a specified period of time; and

(c) "doctored farecard" means a farecard that has been bent or manipulated or altered so as to facilitate a person's access to transportation services without paying the lawful charge.

Unauthorized sale of transportation service is a class B misdemeanor.

Text of proposed rule and any required statements and analyses may be obtained from: Robin Bergstrom, Metropolitan Transportation Authority, 347 Madison Ave., 9th Fl., New York, NY 10017, (212) 878-7317, e-mail: E-mails may be sent by accessing www.mta.info

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

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

Regulatory Impact Statement

1. Statutory authority: Public Authorities Law sections 1203-a, 1204 and 1266 authorize the New York City Transit Authority (NYCTA), the Manhattan and Bronx Surface Transit Operating Authority (MaBSTOA), the Staten Island Rapid Transit System Operating Authority (SIRTOA), the Metro-North Commuter Railroad company (MNR), and the Long Island Rail Road Company (LIRR) to promulgate rules pertaining to the conduct and safety of persons using their transportation facilities.

2. Legislative objectives: NYCTA, MaBSTOA, SIRTOA, MNR and LIRR have each been given statutory authority to adopt rules as deemed necessary, convenient or desirable for the use and operation of transportation facilities and services, including rules relating to the protection and maintenance of facilities under its jurisdiction, the conduct and safety of the public, the payment of fares for the use of such facilities, full fare passage and the protection of revenues. Part T of Chapter 57 of the Laws of 2005 amended the New York State Penal Law by adding a new section, § 165.16. This section established a new crime: "Unauthorized Sale of Certain Transportation Services" to address the practice whereby "swipers" tamper with expired MetroCards, adding ride swipes to the expired cards and then loiter near subway turnstiles to sell the "swipes" to prospective passengers. Section 2 of new act requires that MTA, NYCTA and any subsidiary or affiliate selling fare cards shall promulgate and publish rules and regulations providing additional public notice of the manner of sales that are prohibited by the new law.

3. Needs and benefits:

a. To be in compliance with the express wording of Section 2 of the new act, NYCTA, MaBSTOA, SIRTOA, MNR and LIRR must "publish rules and regulations providing additional notice of the manner or sales that are prohibited by the new law."

b. The additional publication of the new crime in the NYCRR should serve to enhance deterrence of the crime which MTA estimates costs the authority as much as \$10 million per year in lost revenue and an additional \$6 million a year in repair costs for Metrocard Vending Machines.

4. Costs: The rule has no projected costs inasmuch as its focus is publication of a law concerning the conduct of members of the public in their use of the transportation facilities.

5. Local government mandates: No program, service duty or responsibility is imposed by the rule upon any county, city, town, village, school district, fire district or other special district.

6. Paperwork: The rule imposes no reporting requirements.

7. Duplication: The rule creates no conflict or overlap with or duplication of any other legal mandate.

8. Alternatives: None. The requirements of Section 2 of Part T of Ch. 57 of the Laws of 2005 are express.

9. Federal standards: The rule does not exceed any minimum standards of the federal government.

10. Compliance schedule: The dissemination of information to the public concerning modification to MTA rules is always widespread rendering a compliance schedule unnecessary. Moreover, police officers traditionally participate in efforts to educate the riding public when a new rule takes effect in lieu of formal enforcement.

Regulatory Flexibility Analysis

Inasmuch as this rule simply provides additional notice of the existence of a new section of the penal law which makes the Unauthorized Sale of Transportation Services a crime, it will not impose any adverse economic impact or reporting, recordkeeping or other compliance requirements on small businesses or local governments.

Rural Area Flexibility Analysis

Inasmuch as the purpose of the rule is to provide additional notice of a new crime of Unauthorized Sale of Transportation Services as described in the state penal law, the rule will not impose any adverse impacts or record-keeping compliance in rural areas.

Job Impact Statement

Inasmuch as this rule serves simply to provide additional public notice of the manner of sales that are prohibited by the new crime of Unauthorized Sale of Transportation Services, it will not impact on jobs or employment opportunities.

Power Authority of the State of New York

PROPOSED RULE MAKING HEARING(S) SCHEDULED

Rates for the Sale of Power and Energy

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

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

Proposed action: Amendment of service tariffs for the Power Authority's economic development power programs.

Statutory authority: Public Authorities Law, section 1005

Subject: Rates for the sale of power and energy.

Purpose: To recover the cost of providing firm power and energy services and implement chapter of Laws of 2005 regarding sale of power to various Economic Development Power Program customers.

Public hearing(s) will be held at: 10:30 a.m. on Sept. 13, 2005 at the Power Authority, 501 7th Ave., 9th Fl., New York, NY.

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

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

Substance of proposed rule: POWER AUTHORITY OF THE STATE OF NEW YORK

NOTICE OF PROPOSED RULE MAKING

Pursuant to the New York State Public Authorities Law, Section 1005, the Power Authority of the State of New York (the Authority) proposes to amend certain tariffs for business customers served under Economic Development Power programs formerly served by the Authority's former James A. FitzPatrick nuclear power plant in order to modify the rates for certain of these customers and to conform to revisions of the Public Authorities Law. The proposed revisions, among other conforming changes, will be made to the rate provisions of Service Tariff Nos. 1, 1S, 35 and 50.

Copies of the proposed amendments to Service Tariff Nos. 1, 1S, 35 and 50 may be inspected at the Authority's office at the address below and at other designated locations, or obtained from the address below.

Written comments on the proposed service tariff amendments will be accepted through Monday, September 26, 2005, at the address below. In addition, a public forum will be held on Tuesday, September 13, 2005, at 10:30 a.m. at the Authority's New York office at 501 7th Avenue, 9th Floor. For further information, including the address of other Authority offices at which copies of the proposed service tariff amendments may be inspected, contact:

POWER AUTHORITY OF THE STATE OF NEW YORK

Angela D. Graves, Deputy Secretary

123 Main Street

White Plains, New York 10601

(914) 287-3092

(914) 681-6949 (fax)

angela.graves@nypa.gov

Text of proposed rule and any required statements and analyses may be obtained from: Angela D. Graves, Power Authority of the State of

New York, 123 Main St., 15-M, White Plains, NY 10601, (914) 287-3092, e-mail: angela.graves@nypa.gov

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

Statements and analyses are 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.

Public Service Commission

NOTICE OF ADOPTION

Redistribution of Funds by National Fuel Gas Distribution Corporation

I.D. No. PSC-32-04-00013-A

Filing date: July 22, 2005

Effective date: July 22, 2005

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

Action taken: The commission, on July 20, 2005, adopted an order in Case 04-G-1047 granting, in part, a request by National Fuel Gas Distribution Corporation (NFG) for a limited waiver of the terms and conditions governing the use of specific research and development funds.

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

Subject: Waiver request.

Purpose: To approve a limited waiver request.

Substance of final rule: The Commission granted, in part, a limited waiver request by National Fuel Gas Distribution Corporation (NFG) to the extent that NFG is permitted to use Millennium Funds for approved end-use energy efficiency programs, not including distributed generation projects, up to a total limit of \$500,000 annually, subject to the terms and conditions set forth in the order.

Final rule compared with proposed rule: No changes.

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

Assessment of Public Comment

An assessment of public comment is not submitted with this notice because the rule is within the definition contained in section 102(2)(a)(ii) of the State Administrative Procedure Act. (04-G-0837SA1)

NOTICE OF ADOPTION

Major Rate Increase by National Fuel Gas Distribution Corporation

I.D. No. PSC-06-05-00014-A

Filing date: July 22, 2005

Effective date: July 22, 2005

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

Action taken: The commission, on July 20, 2005, adopted an order in Case 04-G-1047 establishing a two-year rate plan for National Fuel Gas Distribution Corporation (NFG).

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

Subject: Major rate increase.

Purpose: To approve a two-year rate plan.

Substance of final rule: The Commission approved a two-year rate plan for National Fuel Gas Distribution 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. (04-G-1047SA1)

NOTICE OF ADOPTION

Electric Safety Standards

I.D. No. PSC-08-05-00009-A

Filing date: July 21, 2005

Effective date: July 21, 2005

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

Action taken: The commission, on June 15, 2005, adopted an order in Case 04-M-0159 granting, in part, petitions for rehearing by electric corporations in New York.

Statutory authority: Public Service Law, sections 2, 5, 65 and 66

Subject: Consideration of petitions for rehearing.

Purpose: To revise the electric safety standards applicable to all New York electric utilities.

Substance of final rule: The Commission granted, in part, petitions for rehearing filed jointly by Central Hudson Gas & Electric Corporation, New York State Electric and Gas Corporation (NYSEG), Niagara Mohawk Power Corporation and Rochester Gas and Electric Corporation (RG&E), a separate petition filed jointly by NYSEG and RG&E, and an individual petition by Orange and Rockland Utilities, Inc., and modified the electric safety standards adopted on January 5, 2005 to address implementation issues raised by the utilities, subject to the terms and conditions set forth in the order.

Final rule compared with proposed rule: No changes.

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

Assessment of Public Comment

An assessment of public comment is not submitted with this notice because the rule is within the definition contained in section 102(2)(a)(ii) of the State Administrative Procedure Act. (04-M-0159SA2)

NOTICE OF ADOPTION

Fixed Price Option by Central Hudson Gas & Electric Corporation

I.D. No. PSC-13-05-00012-A

Filing date: July 22, 2005

Effective date: July 22, 2005

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

Action taken: The commission, on July 20, 2005, adopted an order in Case 05-G-0311 approving in part, a request from the Small Customer Marketer Coalition that Central Hudson Gas & Electric Corporation (Central Hudson) be directed to terminate and cease offering a fixed price option for gas service to customers with annual consumption requirements greater than 500 Ccf operating under Service Classifications 1 and 2.

Statutory authority: Public Service Law, sections 65 and 66(12)

Subject: Fixed price option for gas service provided by Central Hudson.

Purpose: To approve a petition to terminate Central Hudson's fixed price option for gas service.

Substance of final rule: The Commission approved, in part, a request from the Small Customer Marketer Coalition, and directed Central Hudson Gas & Electric Corporation to cease offering its fixed price option for gas

service to customers with annual consumption requirements greater than 500 Ccf operating under Service Classifications 1 and 2, no later than the 2006-07 heating season, and to offer the option for the 2005-06 heating season only if other ratepayers do not subsidize the offer through the Gas Adjustment Clause, 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.

(05-G-0311SA1)

NOTICE OF ADOPTION

Provision of Water Service by Saratoga Water Services, Inc.

I.D. No. PSC-14-05-00011-A

Filing date: July 26, 2005

Effective date: July 26, 2005

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

Action taken: The commission, on June 15, 2005, adopted an order in Case 03-W-1736 approving a joint petition by Saratoga Water Services, Inc. (Saratoga Water) and Maldel, LLC (Maldel) concerning the provision of water service and granting a waiver request.

Statutory authority: Public Service Law, section 89-b

Subject: Provision of water service to a subdivision, and waiver of certain tariff provisions that relate to main extensions, referencing 16 NYCRR Parts 501 and 502.

Purpose: To approve the request of Saratoga Water and Maldel for the provision of water service and waiver of certain tariff provisions.

Substance of final rule: The Commission approved the joint petition of Saratoga Water Services, Inc. and Maldel, LLC for the provision of water service to a proposed real estate subdivision known as Travers Meadow PDD in the Town of Malta, Saratoga County and granted a waiver of certain tariff provisions that relate to main extensions, referencing 16 NYCRR, Parts 501 and 502.

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-1736SA1)

NOTICE OF ADOPTION

Submetering of Electricity by Strivers Gardens Realty, LLC

I.D. No. PSC-15-05-00018-A

Filing date: July 25, 2005

Effective date: July 25, 2005

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

Action taken: The commission, on June 15, 2005, adopted an order in Case 05-E-0095, approving the petition of Strivers Gardens Realty, LLC (Strivers Gardens) to submeter electricity at 300 W. 135th St., New York, NY.

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

Subject: Request to submeter electricity.

Purpose: To grant Strivers Gardens' authorization to submeter electricity at a new master-metered residential condominium.

Substance of final rule: The Commission approved a request by Strivers Gardens Realty LLC to submeter electricity at a new residential condominium, located at 300 West 135th Street, New York, New York, in the territory of Consolidated Edison Company of New York, 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.

(05-E-0095SA1)

NOTICE OF ADOPTION

Delivery and Storage Redelivery Service by Rochester Gas & Electric Corporation

I.D. No. PSC-17-05-00013-A

Filing date: July 20, 2005

Effective date: July 20, 2005

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

Action taken: The commission, on July 20, 2005, adopted an order in Case 05-G-0417 approving amendments to Rochester Gas and Electric Corporation's (RG&E) schedule for gas service—P.S.C. No. 16.

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

Subject: Tariff filing by RG&E.

Purpose: To approve the filing.

Substance of final rule: The Commission approved Rochester Gas and Electric Corporation's tariff revisions contained in its Service Classification Nos. 5, 7 and 9 to clarify the Delivery and Storage Redelivery Service (DSR) options available to energy service companies (ESCOs) when an ESCO takes over another ESCO's customers, or when a newly qualified ESCO needs to elect DSR service.

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.

(05-G-0417SA1)

NOTICE OF ADOPTION

Financing of a Gas-Fired Combined Cycle Generation Facility by Astoria Energy LLC

I.D. No. PSC-18-05-00008-A

Filing date: July 25, 2005

Effective date: July 25, 2005

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

Action taken: The commission, on July 20, 2005, adopted an order in Case 05-E-0457 approving a petition by Astoria Energy LLC approving a request to incur additional debt financing.

Statutory authority: Public Service Law, section 69

Subject: Financing of the construction of a gas-fired combined cycle generation facility.

Purpose: To approve additional debt financing.

Substance of final rule: The Commission authorized Astoria Energy LLC to incur an additional \$93.044 million in debt related to letters of

credit, and to secure an additional \$50 million in contingent debt, 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. (05-E-0457SA1)

NOTICE OF ADOPTION

Long Term Debt by Corning Natural Gas Corporation

I.D. No. PSC-18-05-00010-A

Filing date: July 21, 2005

Effective date: July 21, 2005

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

Action taken: The commission, on July 20, 2005, adopted an order in Case 05-G-0418 approving a petition by Corning Natural Gas Corporation (Corning) to enter into a loan agreement for an amount of up to \$1.9 million.

Statutory authority: Public Service Law, section 69

Subject: Issuance of long-term indebtedness.

Purpose: To allow Corning's request to issue long-term indebtedness.

Substance of final rule: The Commission approved Corning Natural Gas Corporation's (Corning) request to enter into a loan agreement with Community Bank, N.A. for an amount of up to \$1.9 million, to refinance a portion of Corning's existing line of credit, 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. (05-G-0418SA1)

NOTICE OF ADOPTION

Non-Residential Service Application Form by Niagara Mohawk Power Corporation

I.D. No. PSC-18-05-00011-A

Filing date: July 20, 2005

Effective date: July 20, 2005

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

Action taken: The commission, on July 20, 2005, adopted an order in Case 05-G-0458 approving amendments to Niagara Mohawk Power Corporation's (Niagara Mohawk) schedule for gas service—P.S.C. No. 219.

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

Subject: Tariff filing by Niagara Mohawk.

Purpose: To approve the filing.

Substance of final rule: The Commission approved Niagara Mohawk Power Corporation's (Niagara Mohawk) request to make modifications to its schedule for gas service, to revise the manner in which the information on the Non-Residential Service Application Form is displayed and organized, and recommended Niagara Mohawk file the same revision to its electric tariff schedule.

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. (05-G-0458SA1)

NOTICE OF ADOPTION

Authorization to Incur Indebtedness by the New York Independent System Operator, Inc.

I.D. No. PSC-20-05-00030-A

Filing date: July 21, 2005

Effective date: July 21, 2005

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

Action taken: The commission, on July 20, 2005, adopted an order in Case 05-E-0503, approving, with conditions, the request of New York Independent System Operator, Inc. (NYISO) for authority to enter into a revolving credit agreement.

Statutory authority: Public Service Law, section 69

Subject: Authorization to incur indebtedness.

Purpose: To allow NYISO to incur indebtedness.

Substance of final rule: The Commission approved, with conditions, the request of the New York Independent System Operator, Inc. for a \$50,000,000 Replacement Revolver for a five-year period, 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. (05-E-0503SA1)

NOTICE OF ADOPTION

Accounts Receivable Discount Factor by Central Hudson Gas & Electric Corporation

I.D. No. PSC-20-05-00031-A

Filing date: July 20, 2005

Effective date: July 20, 2005

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

Action taken: The commission, on July 20, 2005, adopted an order in Case 05-E-0506 approving an amendment to Central Hudson Gas & Electric Corporation's (Central Hudson) schedule for electric service—P.S.C. No. 15.

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

Subject: Tariff filing by Central Hudson.

Purpose: To approve the filing.

Substance of final rule: The Commission approved Central Hudson Gas & Electric Corporation's (Central Hudson) tariff filing to revise the effective date of the annual update of the discount factor for purchase of retail suppliers' accounts receivable under Central Hudson's Retail Access Program.

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.
(05-E-0506SA1)

NOTICE OF ADOPTION

Accounts Receivable Discount Factor by Central Hudson Gas & Electric Corporation

I.D. No. PSC-20-05-00033-A
Filing date: July 20, 2005
Effective date: July 20, 2005

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

Action taken: The commission, on July 20, 2005, adopted an order in Case 05-G-0508 approving an amendment to Central Hudson Gas & Electric Corporation's (Central Hudson) schedule for gas service—P.S.C. No. 12.

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

Subject: Tariff filing by Central Hudson.

Purpose: To approve the filing.

Substance of final rule: The Commission approved Central Hudson Gas & Electric Corporation's (Central Hudson) tariff filing to revise the effective date of the annual update of the discount factor for purchase of retail suppliers' accounts receivable under Central Hudson's Retail Access Program.

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.
(05-G-0508SA1)

NOTICE OF ADOPTION

Accounting Changes and Over Earnings by State Telephone Company

I.D. No. PSC-21-05-00010-A
Filing date: July 25, 2005
Effective date: July 25, 2005

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

Action taken: The commission, on July 20, 2005, adopted an order in Case 05-C-0509 approving the petition of State Telephone Company to implement certain accounting changes that address over earnings and waiver from the commission's policy statement on pensions and postretirement benefits other than pensions for 1995 through 2003.

Statutory authority: Public Service Law, sections 91, 94(2) and 95(2)

Subject: Certain accounting changes resulting from the Tax Reform Act of 1986 and other related actions.

Purpose: To reduce revenues and implement certain accounting changes to address over earnings.

Substance of final rule: The Commission authorized State Telephone Company (the company) to implement certain accounting changes to address over earnings and certain compliance issues resulting from the Tax Reform Act of 1986, over a ten-year period, and approved the company's request for waiver from the Commission's Policy Statement on Pensions and Postretirement Benefits Other Than Pensions for 1995 through 2003. The Commission further directed the company to file tariff amendments to implement the changes, effective August 1, 2005, 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.
(05-C-0509SA1)

NOTICE OF ADOPTION

Reconciliation of State Income Tax by Consolidated Edison Company of New York, Inc.

I.D. No. PSC-22-05-00008-A
Filing date: July 20, 2005
Effective date: July 20, 2005

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

Action taken: The commission, on July 20, 2005, adopted an order in Case 05-E-0575 approving amendments to Consolidated Edison Company of New York, Inc.'s (Con Edison) schedule for electric service, P.S.C. No. 9.

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

Subject: Tariff filing by Con Edison.

Purpose: To approve the filing.

Substance of final rule: The Commission approved Consolidated Edison Company of New York, Inc.'s tariff revisions to add an alternate method of reconciling the refund of state income tax on a customer's bill.

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.
(05-E-0575SA1)

NOTICE OF ADOPTION

Empire Zone Rider for Customers by Niagara Mohawk Power Corporation

I.D. No. PSC-22-05-00009-A
Filing date: July 20, 2005
Effective date: July 20, 2005

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

Action taken: The commission, on July 20, 2005, adopted an order in Case 05-E-0581 approving amendments to Niagara Mohawk Power Corporation's (Niagara Mohawk) schedule for electric service—P.S.C. No. 207.

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

Subject: Tariff filing by Niagara Mohawk.

Purpose: To approve the filing.

Substance of final rule: The Commission approved Niagara Mohawk Power Corporation's request to revise its Rule 34 – Program 2 – Empire Zone Rider (EZR) and Service Classification No. 7 (SC 7) – Sale of Standby Service to Customers with On-Site Generation to allow customers served under SC 7 to be able to retain or add an EZR to their billing under certain conditions.

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.
(05-E-0581SA1)

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

Billing Systems by New York State Electric and Gas Corporation

I.D. No. PSC-32-05-00006-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 accept, modify or reject, in whole or in part, a proposal filed by New York State Electric and Gas Corporation to make various changes in the rates, charges, rules and regulations contained in its schedules for electricity service—P.S.C. Nos. 119, 120 and 121 to become effective Jan. 1, 2006.

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

Subject: Billing systems.

Purpose: To establish an itemized (unbundled) list of electricity charges on bills and establish revised electricity billing procedures to conform to NYSEG's new billing system.

Substance of proposed rule: On July 20, 2005, New York State Electric and Gas Corporation (NYSEG) filed proposed tariff amendments to establish an itemized (unbundled) list of electricity charges on bills and establish revised electricity billing procedures to conform to the specifications on NYSEG's new billing system. The proposed effective date of NYSEG's filing is January 1, 2006. The Commissioner may approve, reject or modify, in whole or in part, NYSEG's proposed tariff revisions.

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

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

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

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

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

(05-E-0876SA1)

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

Retirement of Electric Generating Units

I.D. No. PSC-32-05-00007-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 the establishment of policies and procedures for addressing the retirement of electric generating units, and the resolution of related issues. The Commissioner may adopt, reject or modify the policies and procedures proposed.

Statutory authority: Public Service Law, sections 5(1)(b), 65(1), 66(1), (2), (5) and 70

Subject: Policies and procedures regarding retirement of electric generating units.

Purpose: To establish policies and procedures.

Substance of proposed rule: The Public Service Commission is considering the establishment of policies and procedures for addressing the retirement of electric generating units, and the resolution of related issues. The Commission may adopt, reject or modify the policies and procedures proposed.

Text of proposed rule and any required statements and analyses may be obtained by filing a Document Request Form (F-96) located on our website <http://www.dps.state.ny.us/f96dir.htm>. For questions, contact:

Central Operations, Public Service Commission, Bldg. 3, Empire State Plaza, Albany, NY 12223-1350, (518) 474-2500

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

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

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

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

(05-E-0889SA1)

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

Order Adopting Proposal to Amend the Gas Purchase of Receivables Program by Consolidated Edison Company of New York, Inc.

I.D. No. PSC-32-05-00008-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 for clarification of its order adopting proposal to amend the Gas Purchase of Receivables Program, issued May 19, 2005 in Case 03-G-1671, filed by Consolidated Edison Company of New York, Inc.

Statutory authority: Public Service Law, sections 2, 4, 5, 32, 65 and 66

Subject: Petition for clarification of its order adopting proposal to amend the Gas Purchase of Receivables Program.

Purpose: To approve the petition.

Substance of proposed rule: Consolidated Edison Company of New York, Inc. filed a petition for clarification of the Commission's Order Adopting Proposal to Amend the Gas Purchase of Receivables Program issued May 19, 2005 in Case 03-G-1671. It asks that the Commission clarify that no further petition is required for the Company to defer its gas customers' share of the gas purchase of receivables implementation costs.

The Commission may approve or reject the petition, in whole or in part. In addition, the Commission may decide to offer different or additional clarification of its May 19, 2005 Order.

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

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

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

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

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

(03-G-1671SA6)

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

Billing Systems by New York State Gas & Electric Corporation

I.D. No. PSC-32-05-00009-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 proposal filed by New York State Electric & Gas Corporation to make various changes in the rates, charges, rules and regulations contained in its schedules for gas service—P.S.C. Nos. 87, 88 and 90 to become effective Jan. 1, 2006.

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

Subject: Billing systems.

Purpose: To establish revised gas billing procedures to conform to NYSEG's new billing system.

Substance of proposed rule: On July 20, 2005, New York State Electric & Gas Corporation (NYSEG) filed proposed tariff amendments to establish revised gas billing procedures to conform to the specifications on NYSEG's new billing system. NYSEG also requests a waiver of Section 720-6.5(c) of 16 NYCRR to permit proration of the Gas Supply Charge for the heating load of gas heating customers based on degree days rather than the calendar day proration method as set forth in 16 NYCRR. The proposed effective date of NYSEG's filing is January 1, 2006. The Commission may approve, reject or modify, in whole or in part, NYSEG's proposed tariff revisions.

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

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

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

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

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

(05-G-0878SA1)

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

Gas Portfolios by The Brooklyn Union Gas Company and KeySpan Gas East Corporation

I.D. No. PSC-32-05-00010-P

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

Proposed action: The Public Service Commission is considering whether to approve or reject, in whole or in part, a petition filed by The Brooklyn Union Gas Company and KeySpan Gas East Corporation (the companies) to combine their gas resource portfolios and to allocate gas costs for commodity and capacity between the companies.

Statutory authority: Public Service Law, sections 65(1), (2), 66(5), (6), (8), (12), 66-e(1), (2) and (3)

Subject: Gas portfolios and the method of allocating gas commodity and capacity costs.

Purpose: To approve the combination of the companies' gas portfolios and establish a methodology to allocate gas commodity and capacity costs between the companies.

Substance of proposed rule: The Public Service Commission is considering to accept, modify, or reject, in whole or part, a petition filed by The Brooklyn Union Gas Company and KeySpan Gas East Corporation to combine their gas resource portfolios and allocate purchased gas costs for commodity and capacity between the companies.

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

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

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

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

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

(05-G-0903SA1)

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

Energy Services Company Referral Programs

I.D. No. PSC-32-05-00011-P

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

Proposed action: The Public Service Commission is considering whether to approve, modify or reject, in whole or in part, proposed statewide attributes, and a standard-form customer agreement, for Energy Services Company referral programs, and other related matters.

Statutory authority: Public Service Law, section 5

Subject: Proposed statewide attributes, and standard-form customer agreement for Energy Services Company referral programs, and consideration of related matters.

Purpose: To establish a standardized set of program attributes and guidelines, and a standard-form customer agreement.

Substance of proposed rule: The Public Service Commission is considering whether to approve, modify or reject, in whole or in part, a Staff proposal for a statewide Energy Services Company (ESCO) Referral Program, and a standard-form customer agreement for such program. Staff's proposal is intended to promote customer awareness of competitive energy alternatives, encourage greater customer participation in energy competition, help customers make informed decisions when choosing an energy supplier, protect consumer interests, ensure compliance with the Commission's Uniform Business Practices, encourage ESCOs to both actively market their services and offer value-added services (such as "green" power and energy conservation measures), and promote administrative efficiency and minimize implementation costs. The Commission will also consider other related matters, the making of other related findings, and granting of other regulatory authorizations.

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

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

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

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

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

(05-M-0858SA1)

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

Capital Reserve Fee by Emerald Green Lake Louise Marie Water Company

I.D. No. PSC-32-05-00012-P

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

Proposed action: The Public Service Commission is considering whether to modify, in whole or in part, Emerald Green Lake Louise Marie Water Company, Inc.'s (Emerald Green) capital reserve fee (CRF) to reflect its need for capital contributions.

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

Subject: Emerald Green's capital reserve fee.

Purpose: To modify Emerald Green's capital reserve fee.

Substance of proposed rule: On March 31, 2005, the Commission approved Emerald Green Lake Louise Marie Water Company, Inc.'s (Emerald Green) request for a \$4,000 Capital Reserve Fee (CRF), to be collected from developers or individuals building homes in Emerald Green's service territory. The \$4,000 CRF is based on the projected number of new homes and estimated construction costs of needed improvements provided by Emerald Green's engineer. The Order provides that the Commission may adjust the CRF based upon data provided by Emerald Green. Accordingly,

the Commission is considering whether modification of the CRF is necessary.

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

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

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

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

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

(04-W-0349SA4)

Workers' Compensation Board

EMERGENCY RULE MAKING

Waiver Agreements

I.D. No. WCB-32-05-00001-E

Filing No. 814

Filing date: July 20, 2005

Effective date: July 20, 2005

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

Action taken: Amendment of section 300.36 of Title 12 NYCRR.

Statutory authority: Workers' Compensation Law, sections 117, 141 and 32

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

Specific reasons underlying the finding of necessity: WCL § 32, as amended Chapter 635 of the Laws of 1996, permits the parties to a workers' compensation claim to enter into an agreement settling upon and determining the compensation and other benefits due to the claimant or the claimant's dependents, subject to approval by the Board. At first, few waiver agreements were submitted to the Board, and a meeting was held before a Board Commissioner in all cases to question the parties about the agreement. However, in the late 1990's, the number of waiver agreement submitted to the Board increased so dramatically that it was not feasible to hold a meeting in every case in which an agreement was filed. Moreover, most agreements submitted to the Board were routine. Beginning in 2000, Board Commissioners began reviewing routine agreements administratively, without holding a meeting to discuss the agreement with the parties. The majority of settlement agreements are reviewed and approved by the Board without the need for a meeting with the parties. On April 22, 2004, the Appellate Division, Third Department rendered a Memorandum and Order in *Matter of Hart v. Pageprint/Dekalb*, 6 A.D.3d 947, 775 N.Y.S.2d 195 (3rd Dept., Slip Op. No. 94339, 2004), finding that the administrative review of waiver agreements was invalid insofar as it conflicted with the terms of 12 NYCRR 300.36. The purpose of this amendment is to amend 12 NYCRR 300.36, consistent with WCL § 32, to permit the Board to review and approve or disapprove routine waiver agreements administratively, without the need for a meeting with the parties, which benefits everyone. Requiring meetings for all waiver agreements would greatly increase the time it takes for such an agreement to be approved as the Board has limited calendar time. Additionally, the Board has numerous agreements which have been processed administratively and are ready for approval, but cannot be approved due to the above referenced decision. If the Board is to continue to efficiently and timely review and issue decisions regarding waiver agreements, it must process the routine agreements administratively.

Subject: Waiver agreements pursuant to section 32.

Purpose: To provide for the administrative review of waiver agreements.

Text of emergency rule: Subdivision (b) of section 300.36 of Title 12 NYCRR is amended to read as follows:

(b) Any agreement submitted to the board for approval shall be on a form prescribed by the chair or, alternatively, contain the information prescribed by the chair. [For the purposes of section 32 of the Workers' Compensation Law and this section, an agreement shall be deemed submitted when it is received by the board at the time a hearing is conducted to question the parties about the agreement. No agreement shall be approved for a period of 10 calendar days after submission to the board.]

Subdivision (c) of section 300.36 of Title 12 NYCRR is amended to read as follows:

(c) The [submission] receipt of an agreement [to] by the board for approval shall act as a stay on all related proceedings before the board.

Subdivision (e) is renumbered (f), a new subdivision (e) is added and renumbered (f) is amended to read as follows:

(e) *The agreement shall be reviewed by the chair, a designee of the chair, a member of the board, or a Workers' Compensation Law Judge, who will make a determination whether to approve or disapprove the agreement. The chair, designee of the chair, member of the board, or Workers' Compensation Law Judge reviewing the agreement may approve or disapprove the agreement administratively, based on a review of the record before the board, or may choose to schedule a meeting to question the parties about the agreement. If the agreement is reviewed administratively, the Board shall advise the parties in writing of the date the agreement shall be deemed submitted for the purposes of Section 32 of the Workers' Compensation Law and this section. If a meeting is scheduled to question the parties about the agreement, the agreement will be deemed submitted for the purposes of Section 32 of the Workers' Compensation Law and this section at such meeting. No agreement shall be approved for a period of 10 calendar days after submission to the board.*

([e]/f) The board will advise the parties of the approval or disapproval of all agreements by duly filing and serving a notice of [decision] approval or disapproval.

Subdivisions (f), (g), (h) and (i) of Section 300.36 of 12 NYCRR are renumbered (g), (h), (i) and (j).

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 October 17, 2005.

Text of emergency rule and any required statements and analyses may be obtained from: Cheryl M. Wood, Workers' Compensation Board, 20 Park St., Rm. 401, Albany, NY 12207, (518) 486-9564, e-mail:Office ofGeneralCounsel@wcb.state.ny.us

Regulatory Impact Statement

1. Statutory authority:

The Workers' Compensation Board (hereinafter referred to as Board) is clearly authorized to amend 12 NYCRR 300.36. Workers' Compensation Law Section 117(1) authorizes the Chair to make reasonable regulations consistent with the provisions of the Workers' Compensation Law and the Labor Law. Worker's Compensation Law Section 117 (1) further authorizes the Board to adopt reasonable the provisions of the Workers' Compensation Law and the Labor Law.

Section 141 of the Workers' Compensation Law provides that the Chair shall be the administrative head of the Board and authorizes the Chair, in the name of the Board, to enforce all the provisions of the WCL and to make administrative regulations and orders providing, in part, for the receipt, indexing and examining of all notices, claims and reports. Section 142 of the Workers' Compensation Law confers upon the Board the power to hear and determine all claims for compensation or benefits and to approve agreements.

Section 32 of the Workers' Compensation Law provides that whenever a claim for workers' compensation has been filed, the claimant or the deceased claimant's dependents and the employer or its insurance carrier may enter into a written agreement settling upon and determining the compensation and other benefits due to the claimant or the claimant's dependents. Such agreement shall not be binding unless approved by the Board. Once approved by the Board, the agreement shall be final and conclusive upon the parties. An agreement may be modified at any time by written agreement of all the interested parties provided it is approved by the Board.

2. Legislative objectives:

Section 73 of Chapter 635 of the Laws of 1996 amended Section 32 of the Workers' Compensation Law to permit the parties to a workers' compensation claim to enter into an agreement settling upon and determining

the compensation and other benefits due to the claimant or the claimant's dependents. This rule would amend the regulations adopted in 1997 implementing Section 73 of Chapter 635 of the Laws of 1996 to provide for the administrative review of waiver agreements.

3. Needs and benefits:

Prior to the enactment of Section 73 of Chapter 635 of the Laws of 1996, a workers' compensation claimant was not permitted to permanently waive his or her right to benefits under the Workers' Compensation Law (hereinafter "WCL"). The 1996 amendment to WCL § 32 permits the parties to a workers' compensation claim to enter into an agreement settling upon and determining the compensation and other benefits due to the claimant or the claimant's dependents, subject to approval by the Board. At first, few waiver agreements were submitted to the Board, and a meeting was held before a Board Commissioner in all cases to question the parties about the agreement. However, in the late 1990's, the number of waiver agreement submitted to the Board increased so dramatically that it was not feasible to hold a meeting in every case in which an agreement was filed. Moreover, most agreements submitted to the Board were routine. Beginning in 2000, Board Commissioners began reviewing routine agreements administratively, without holding a meeting to discuss the agreement with the parties. The majority of settlement agreements are reviewed and approved by the Board without the need for a meeting with the parties. On April 22, 2004, the Appellate Division, Third Department rendered a Memorandum and Order in *Matter of Hart v. Pageprint/Dekalb*, 6 A.D.3d 947, 775 N.Y.S.2d 195 (3rd Dept. 2004), finding that the administrative review of waiver agreements was invalid insofar as it conflicted with the terms of 12 NYCRR 300.36. On April 29, 2004, the Board filed an emergency regulation with the Department of State, effective immediately, to amend 300.36 to permit the Board to review waiver agreements submitted pursuant to Workers' Compensation Law § 32 administratively.

The purpose of this amendment is to permanently amend 12 NYCRR 300.36, consistent with WCL § 2, to permit the Board to review and approve or disapprove routine waiver agreements administratively, without the need for a meeting with the parties.

Permitting the Board to review and approve or disapprove routine waiver agreements administratively, without the need for a meeting benefits all participants to the workers' compensation system. The Board receives approximately 1,000 new waiver agreements each month. Requiring meetings for all waiver agreements would greatly increase the length of time it would take to review each agreement, as the Board has limited calendar time and only a small number of Board Commissioners. Additionally, claimants would be required to take time during the work day to appear at a Board district office for the meeting. The waiver agreements that are reviewed administratively are routine and the claimants represented. The Board is working to ensure that the parties who have entered into a routine waiver agreement have that agreement reviewed and a decision issued without delay. By redirecting the simple or routine cases from the meeting calendar and processing them administratively, the complex cases that remain on the meeting calendar will progress more quickly.

In addition, this proposed amendment makes two minor changes to 12 NYCRR 300.36 which reflect the current practice of the Board, and have minimal impact on regulated parties. These changes (1) require the Board to stay all proceedings in a case upon the receipt by the Board of a waiver agreement and (2) reflect that the written approval or disapproval by the Board of a waiver agreement is a "notice of approval" or "notice of disapproval," rather than a "notice of decision."

In essence this rule conforms the regulations to practices and procedures that have been in effect since 2000.

4. Costs:

The proposed amendment will not result in any new or additional costs to private regulated parties, State, local governments or the Workers' Compensation Board. This proposal merely adds a second process for the review and approval or disapproval of waiver agreements, which does not require personal appearances before the Board by the parties. By eliminating the need for personal appearances before the Board for all waiver agreements, parties will experience savings in travel costs, appearance costs and claimants will not have to take time away from work to attend.

5. Local government mandates:

Approximately 2511 political subdivisions currently participate as municipal employers in self-insured programs for workers' compensation coverage in New York State. These self-insured municipal employers will be affected by the proposed rule in the same manner as all other employers who are self-insured for workers' compensation coverage. As with all other participants in the workers' compensation system, this proposal merely adds a second process for the review and approval or disapproval of

waiver agreements, which does not require personal appearances before the Board by the parties.

6. Paperwork:

The proposed amendment does not add any reporting requirements.

7. Duplication:

This amendment will not duplicate any existing Federal or State requirements.

8. Alternatives:

One alternative discussed was to hold a meeting in every case to question the parties about the agreement submitted. However, in most instances, waiver agreements submitted to the Board are routine, questioning of the parties concerning the agreement is not necessary, and a meeting would result in a delay in the processing of such agreements. Pursuant to the proposed amendment, the Board could schedule a meeting to discuss the agreement with the parties when circumstances so warrant.

Representatives of the Board have been meeting with different constituent groups across the State at which this topic is discussed. At a meeting with representatives of both carriers and claimants, it was suggested, to improve the administrative process and alleviate concerns expressed, that the Board modify its internal processing when reviewing waiver agreements administratively. The Board is currently reviewing this suggestion to determine impact and feasibility of implementation.

9. Federal standards:

There are no federal standards applicable to this proposed amendment.

10. Compliance schedule:

It is expected that the affected parties will be able to comply with this change immediately.

Regulatory Flexibility Analysis

1. Effect of rule:

Approximately 2,511 political subdivisions currently participate as municipal employers in self-insured programs for workers' compensation coverage in New York State. These self-insured municipal employers will be affected by the proposed rule in the same manner as all other employers who are self-insured for workers' compensation coverage.

Small businesses that are self-insured will also be affected by the proposed rule in the same manner as all other employers who are self-insured for workers' compensation coverage.

Small businesses which are self-insured employers and self-insured local governments may voluntarily enter into waiver agreements settling upon and determining claims for compensation. This amendment will speed the processing and approval of such agreements.

2. Compliance requirements:

The amendment will not require any additional reporting or record-keeping by small businesses or local governments.

3. Professional services:

It is believed that no professional services will be needed to comply with this rule.

4. Compliance costs:

This proposal will not impose any compliance costs on small business or local governments. This amendment is intended simply to speed the processing and approval of waiver agreements submitted pursuant to Workers' Compensation Law § 32.

5. Economic and technological feasibility:

No implementation or technology costs are anticipated for small businesses and local governments for compliance with the proposed amendment. Therefore, it will be economically and technologically feasible for small businesses and local governments affected by the proposed amendment to comply.

6. Minimizing adverse impact:

This proposed amendment is designed to minimize adverse impacts due to the current regulations for small businesses and local governments. This rule provides only a benefit to small businesses and local governments.

7. Small business participation and local government participation:

On April 29, 2004, the Board filed an emergency regulation with the Department of State to amend 300.36 to permit the Board to review routine waiver agreements administratively. After the adoption of the emergency amendment to 300.36, the Board received comments from members of the regulated community, including third-party administrators and insurance carriers who represent and insure small business and local government entities. While some members of the regulated community have indicated a preference that a meeting be held in every case to question the parties about the agreement submitted, the majority of comments received support the amendment allowing the Board to review and approve routine agreements administratively.

Rural Area Flexibility Analysis

1. Types and estimated numbers of rural areas:

The rule applies to all claimants, insurance carriers and self-insured employers in all rural areas of the state which are subject to the provisions of the Workers' Compensation Law.

2. Reporting, recordkeeping and other compliance requirements:

The amendment will not impose any additional reporting, recordkeeping or compliance requirements on regulated parties in rural areas.

3. Costs:

This proposal will not impose any compliance costs on rural areas. This amendment is intended simply to speed the processing and approval of waiver agreements submitted pursuant to Workers Compensation Law § 32.

4. Minimizing adverse impact:

This proposed amendment is designed to minimize adverse impact for regulated parties in rural areas. This proposed amendment provides only a benefit to regulated parties in rural areas.

5. Rural area participation:

On April 29, 2004, the Board filed an emergency regulation with the Department of State to amend 300.36 to permit the Board to review routine waiver agreements administratively. After the adoption of the emergency amendment to 300.36, the Board received comments from members of the regulated community, including third-party administrators and insurance carriers who represent and insure employers in rural areas. While some members of the regulated community have indicated a preference that a meeting be held in every case to question the parties about the agreement, the majority of comments received supported the amendment allowing the Board to review and approve routine agreements administratively.

Job Impact Statement

The proposed amendment will not have an adverse impact on jobs. This amendment is intended simply to speed the processing and approval of waiver agreements submitted pursuant to WCL § 32 and will therefore ultimately benefit the participants to the workers' compensation system.