

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

PROPOSED RULE MAKING NO HEARING(S) SCHEDULED

Implementation of the K kosher Law Protection Act of 2004

I.D. No. AAM-19-05-00008-P

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

Proposed action: This is a consensus rule making to add Part 254 to Title 1 NYCRR.

Statutory authority: Agriculture and Markets Law, sections 18 subd. 6 and 201-c subds. 1 and 2

Subject: Implementation of the K kosher Law Protection Act of 2004.

Purpose: To implement legislative directive to adopt a rule regarding the filing by persons certifying food as kosher of qualifications to provide kosher certification.

Text of proposed rule: A new Part 254 of Title 1 of the Official Compilation of Codes, Rules and Regulations of the State of New York is adopted to read as follows:

PART 254

254.1 Statement of Qualifications of Persons Certifying Food as Kosher. Every person (including an individual, partnership, corporation, and association) who certifies non-prepackaged food as kosher or kosher-for-

Passover shall file with the Department of Agriculture and Markets a statement, upon a form provided by the Department, of that person's qualifications to certify food as kosher. Such statement may include the certifier's background, training, education, experience and any other information that shows the certifier's qualifications. The form may be filed electronically on the Department's website at <http://www.agmkt.state.ny.us/> or by mail or fax to the New York State Department of Agriculture and Markets, Division of Kosher Law Enforcement, 55 Hanson Place, Brooklyn, New York 11217.

254.2 Registration of Persons Certifying Non-Prepackaged Food as Kosher. Every person (including an individual, partnership, corporation and association) who manufactures, produces, processes, packs or sells non-prepackaged food represented or branded as kosher shall file with the Department of Agriculture and Markets, upon a form provided by the Department, the name, address and telephone number of the person certifying the food as kosher. The form may be filed electronically on the Department's website at <http://www.agmkt.state.ny.us/> or by mail or fax to the New York State Department of Agriculture and Markets, Division of Kosher Law Enforcement, 55 Hanson Place, Brooklyn, New York 11217.

Text of proposed rule and any required statements and analyses may be obtained from: Michael McCormick, Counsel's Office, Department of Agriculture and Markets, 10B Airline Dr., Albany, NY 12235, (518) 457-2449

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

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

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

Consensus Rule Making Determination

The Department has considered the proposed adoption of Part 254 of 1 NYCRR.

The K kosher Law Protection Act of 2004 (L. 2004, C. 151), effective July 13, 2004, directs that the Department make and complete on an emergency basis, a rule for the timely implementation of the Act. The rule is in place as an emergency measure. The proposed adoption of the rule on a permanent basis implements legislative directives by requiring that persons certifying non-prepackaged food as kosher file with the Department a statement of their qualifications to provide such certification and by requiring persons who manufacture, process, sell or offer for sale non-prepackaged food represented as kosher to file with the Department, the name, address and telephone number of the person certifying such food as kosher (subdivisions (1) and (2) of section 201-c of the Agriculture and Markets Law).

In light of the foregoing, the Department has determined that the proposed adoption of Part 254 of 1 NYCRR is a consensus rule within the meaning of section 102(11)(b) of the State Administrative Procedure Act, in that no person is likely to object to the rule as written because it merely implements or conforms to non-discretionary statutory provisions.

Job Impact Statement

1. Nature of Impact:

The proposed rule will not adversely impact any existing or prospective employment opportunity because the rule only requires the filing with the Department of Agriculture and Markets of qualifications of persons certifying non-prepackaged food as kosher and the identification of persons certifying such food as kosher. The rule does not establish minimum standards, nor require specific qualifications.

2. Categories and Numbers Affected:

Persons providing such certification of non-prepackaged food as kosher and persons manufacturing, producing, processing, packing and selling such food will be affected. The number is unknown.

3. Regions of Adverse Impact:

The proposed rule has uniform statewide impact.

4. Minimizing Adverse Impact:

There is no identifiable adverse impact.

Banking Department

REVISED CONSENSUS STATEMENT

Streamlined Forms and Procedures for Certain Branch, Public Accommodation Office and Electronic Facilities Applications

I.D. No. BNK-17-05-00005-P

This revised consensus statement pertains to a notice of proposed rule making, I.D. No. BNK-17-05-00005-P, printed in the *State Register* on April 27, 2005.

Revised Consensus Statement

No one is likely to object to the proposed amendments, which make technical changes or are otherwise non-controversial. The proposed amendments to Supervisory Policy G 4 reduce the required notice period for adjacent facilities. The amendments to this regulation and to Supervisory Policy G 6 also make minor technical changes. The amendments to Supervisory Procedure G 104 reduce the amount of information required in public accommodation office applications. The amendments to Supervisory Procedure G 105 reduce the information required in change of location applications and codify the Department's longstanding policy regarding relocations to a different market area. The amendment to Supervisory Procedure G 108 conforms the regulation to a change in the law effected by Chapter 360 of the Laws of 1984 which, among other things, eliminated the requirement that the findings described in section 1 of Supervisory Procedure G 108 be made in connection with approval of a new branch or public accommodation office.

The amendments to Supervisory Procedures CB 103, SB 101 and SL 101 reduce the amount of information required in all branch applications, as well as making minor technical amendments. The expedited process established by the amendments should not be controversial, especially since the overwhelming majority of institutions will qualify for this process. The criteria for determining which banks qualify are virtually identical to those used by the Federal bank regulatory agencies, and the CAM-ELS rating system is the long-standing, standardized system used by Federal and state bank regulators for measuring the health of banking organizations and describing the results of the bank examination process.

The amendments to Part 73 reduce the informational requirements for all banking institutions establishing electronic facilities. In addition, institutions with CRA ratings of "Satisfactory" or better will no longer be required to give prior notice of the establishment of electronic facilities. Virtually all institutions will qualify for the new after-the-fact notice procedure.

Office of Children and Family Services

NOTICE OF ADOPTION

Approval or Certification of a Foster Home on an Emergency Basis

I.D. No. CFS-09-05-00010-A

Filing No. 443

Filing date: April 26, 2005

Effective date: May 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 443.1 and 443.7 of Title 18 NYCRR.

Statutory authority: Social Services Law, sections 20(3)(d), 34(3)(f) and 378(5)

Subject: Approval or certification of a foster home on an emergency basis.

Purpose: To expand the circumstances in which an authorized agency may approve or certify a foster home on an emergency basis. Previously, foster homes could only be approved or certified on an emergency basis if a child was being removed from the child's home of origin as a result of abuse or neglect. These regulations allow authorized agencies to certify and approve foster homes on an emergency basis if a child needs to be placed voluntarily by his/her family of origin or as a result of a person in need of supervision (PINS) or juvenile delinquency proceeding. The regulations also allow for a local social services district to move a foster child to a foster home approved or certified on an emergency basis, in exceptional circumstances when there is a compelling reason.

Text of final rule: Subdivisions (g) and (h) of section 443.1 are amended to read as follows:

(g) Approved emergency relative foster home. An approved emergency relative foster home is a home in which foster care is provided to a child placed with an authorized agency [pursuant to the provisions of article 10 of the Family Court Act and] who is cared for 24 hours-a-day in a family home with a foster parent who is a relative within the second or third degree to the parent(s) or stepparent(s) of the child and which is duly approved by an authorized agency in accordance with section 443.7 of this Part.

(h) Certified emergency foster home. A certified emergency foster home is a home in which foster care is provided to a child placed with an authorized agency [pursuant to the provisions of Article 10 of the Family Court Act and] who is cared for 24 hours-a-day in a family home with a foster parent who is either a relative other than one who is within the second or third degree to the parent(s) or stepparent(s) of the child or is a nonrelative with a significant prior relationship with the child's family and which is duly certified by an authorized agency in accordance with section 443.7 of this Part.

Subdivision (a) of section 443.7 is amended to read as follows:

443.7 Agency procedures for certifying or approving potential emergency foster homes and emergency relative foster homes.

(a) A potential foster home or the home of a relative of a foster child may be certified or approved as an emergency foster home under the following *allowable* circumstances:

(1) *Allowable circumstances.*

(i) a child is removed from his or her own home pursuant to section 1021, 1022, [or] 1024, or 1027 of the Family Court Act or a child is [remanded to] *removed and placed into* foster care pursuant to article 3, 7 or 10 of the Family Court Act or section 384-a of the Social Services Law; or

(ii) a child currently placed in a foster care setting needs to be placed in a foster home and the social services district documents within the uniform case record a compelling reason why such home needs to be certified or approved on an emergency basis; and

(2) an eligible relative or non-relative, identified in subdivisions (g) and (h) of section 443.1 of this Part, is [acknowledged] *identified* by the child, child's parent(s) or stepparent(s), the court, a representative of the local district or other interested party, as potentially appropriate to provide foster care to the child or such person or relative volunteers to provide

foster care to the child. For the purposes of this section, an eligible non-relative may include, but is not limited to, a child's godparent, neighbor, [or] family friend, or an adult with a positive relationship with the child.

Final rule as compared with last published rule: Nonsubstantive changes were made in section 443.7(a)(1)(i).

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

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

Although non-substantive changes were made to the proposed regulations concerning certification of foster homes on an emergency basis, those changes do not require changes to the Regulatory Impact Statement, Regulatory Flexibility Analysis, Rural Area Flexibility Analysis or Job Impact Statement as originally published.

Assessment of Public Comment

Comments were received from two organizations. A strong letter in support was received from a legal services organization that advocates for individual children. A large social services district also wrote strongly in support. However, the social services district recommended a technical change to clarify that removals under Section 1027 of the Family Court Act are included in removal situations where the emergency certification/approval process may be used under Section 443.7(a)(1)(i) of the proposed regulations. The final regulations will be revised to include this non-substantive change. In addition, the social services district inquired whether the proposed amendment to Section 443.7(a)(1)(i) of the regulations that changes the reference to "remanded to" to "removed and placed into" is intended to limit the social services district's ability to continue using the emergency certification/approval process for certain children placed pursuant to Article 10 of the Family Court Act. That is not the intent of the proposed amendment. Under the regulations, districts retain the existing flexibility to use the emergency certification/approval process. There will be no additional changes to the regulation as a result of this comment.

Department of Economic Development

EMERGENCY RULE MAKING

Empire State Film Production Tax Credit Program

I.D. No. EDV-19-05-00009-E

Filing No. 437

Filing date: April 25, 2005

Effective date: April 25, 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 L. 2004, ch. 60, sec. 7(c) mandates the department to promulgate regulations for the program to establish procedures for the allocation of tax credits and describing the application process, the due dates for the applications, the standards used to evaluate the applications and any other provisions deemed necessary and appropriate by Oct. 31, 2004. Such legislation provides that, notwithstanding any other provisions to the contrary in the State Administrative Procedure Act, the rules and regulations may be adopted on an emergency basis.

Subject: Empire State Film Production Tax Credit Program.

Purpose: To establish procedures for the allocation of tax credits and describe the application process, the due dates for the applications, the

standards used to evaluate the application and any other provisions deemed necessary and appropriate and clarify necessary and pertinent definitions to the program.

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

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

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

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

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

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

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

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

Fifth, within 60 days after the completion of production of their qualified film, the approved applicant must submit a final application to the Office. The final application is similar to the initial application, though it now contains actual expenditure data as opposed to expenditure projections. The Office then considers certain criteria in its review to determine

whether the final application should be approved. Much like the criteria used for the initial application, this includes analysis of whether the application is complete, whether applicant actually shot principal photography on stage at a qualified film production facility on a set or sets, whether a qualified film was completed, and whether the actual qualified production costs equal or exceed 75% of the actual production costs on the film, etc. The proposed rule allows the Office to request additional documentation, including receipts of qualified productions costs, to help the Office determine if the applicant meets the criteria. At this point, the applicant is either approved and issued a certificate of tax credit (stating the amount of tax credit they will be receiving) or provided a notice of disapproval.

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

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

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

This notice is intended to serve only as a notice of emergency adoption. This agency does not intend to adopt the provisions of this emergency rule as a permanent rule. The rule will expire July 23, 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 emergency rule is in accord with the public policy objectives the Legislature sought to advance by creating a tax credit program for the film industry. This program is an attempt to create an incentive for film industry to bring productions to New York State as opposed to other competitive markets, such as Toronto. It is the public policy of the State to offer a tax credit that will help provide incentive for the film industry to bring productions to the State. The proposed rule helps to further such objectives by establishing an application process for the program, clarifying portions of the Program through the creation of various definitions and describing the credit allocation process itself.

NEEDS AND BENEFITS:

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

COSTS:

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

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

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

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

LOCAL GOVERNMENT MANDATES:

None.

PAPERWORK:

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

DUPLICATION:

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

ALTERNATIVES:

No alternatives were considered in regard to creating a new regulation in response to the statutory requirement. The Department of Economic Development, through its Governor's Office for Motion Picture and Television Development, did an extraordinary amount of outreach to various interested parties before submitting this 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 emergency rule.

FEDERAL STANDARDS:

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

COMPLIANCE SCHEDULE:

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

Regulatory Flexibility Analysis

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

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

Rural Area Flexibility Analysis

This program is open to participation from all qualified film production companies, which is defined by statute to include a corporation, partnership or sole proprietorship making and controlling a qualified film in New

York. The location of the companies is irrelevant, so long as they meet the necessary qualifications of the definition. This program may impose responsibility on statewide businesses that are qualified film production companies, in that they must undertake an application process to receive the empire state film production tax credit. However, the proposed regulation will not have a substantial adverse economic impact on rural areas. Accordingly, a rural flexibility analysis is not required and one has not been prepared.

Job Impact Statement

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

Department of Environmental Conservation

ERRATUM

A Notice of Adoption, I.D. No. ENV-44-04-00013-A, pertaining to Regulating Sulfur Content of Motor Vehicle Diesel Fuel published in the April 27, 2005 issue of the *State Register* contained an error in section 200.9, Table 1 of the text. The correct text follows:

(Section 200.1 through 200.8 remains unchanged)

Section 200.9, Table 1 is amended to read as follows:

225-4.2(b)	40 CFR 80.2(z) (July 1, 2003) page 580 as amended by 68 FR pages 56776-56781 (October 2, 2003) 40 CFR 80.2(nn) (July 1, 2003) page 581 40 CFR 80.2(t) (July 1, 2003) pages 579-580 40 CFR 80.2(w) (July 1, 2003) page 580 40 CFR 80.2(x) (July 1, 2003) page 580 40 CFR 80.2(l) (July 1, 2003) page 579 40 CFR 80.2(r) (July 1, 2003) page 579 40 CFR 80.2(y) (July 1, 2003) page 580 40 CFR 80.2(xx) (July 1, 2003) page 581 40 CFR 80.2(i) (July 1, 2003) page 579 40 CFR 80.2(h) (July 1, 2003) page 579 40 CFR 80.2 (n) (July 1, 2003) page 579 40 CFR 80.2(k) (July 1, 2003) page 579 40 CFR 80.2(j) (July 1, 2003) page 579 40 CFR 80.2(bb) (July 1, 2003) page 580 40 CFR 80.2(ss) (July 1, 2003) page 581 40 CFR 80.2(o) (July 1, 2003) page 579	+++ *
225-4.3	40 CFR Part 80, Subpart I (July 1, 2003) pages 826-865	*

+++ Available from the U.S. Government Printing Office website, <http://www.gpoaccess.gov/fr/index.html>

NOTICE OF ADOPTION

National Emission Standards for Hazardous Air Pollutants (NESHAP) Regulations

I.D. No. ENV-44-04-00014-A
Filing No. 445
Filing date: April 21, 2005
Effective date: 30 days after filing

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following action:
Action taken: Amendment of sections 200.9, 200.10, 219-2.2 and 219-7.2 of Title 6 NYCRR.
Statutory authority: Environmental Conservation Law, sections 1-0101, 3-0301, 19-0103, 19-0105, 19-0107, 19-0301, 19-0302, 19-0303, 19-0305, 19-0311, 19-0319, 70-0109

Subject: National Emission Standards for Hazardous Air Pollutants (NESHAP) Regulations.

Purpose: To incorporate NESHAPS contained in the most recent Code of Federal Regulations and add a reference test method.

Substance of final rule: 6 NYCRR Part 200 (Part 200) is being amended in order to correct the tables referencing Federal New Source Performance Standards (40 CFR Part 60), National Emission Standards for Hazardous Air Pollutants (40 CFR Part 61), National Emission Standards for Hazardous Air Pollutants regulations (40 CFR Part 63), and other miscellaneous Federal regulations.

Table 2 of Part 200.10 lists the Federal New Source Performance Standards for which New York State has accepted delegation for implementing and enforcing. This rule making will clarify the table by removing repetitive symbols for footnotes and citing to the 2003 Code of Federal Regulations.

Table 3 lists the National Emission Standards for Hazardous Air Pollutants regulations found in 40 CFR Part 61. This rule making will update the Table to reference regulations found in the 2003 Code of Federal Regulations.

Table 4 lists the National Emission Standards for Hazardous Air Pollutants regulations found in 40 CFR Part 63. This rule making will add a number of recently promulgated NESHAP regulations to Table 4, clarify which 40 CFR Part 63 regulations the U.S. Environmental Protection Agency has delegated to the Department, and update the Table to reference the 2003 Code of Federal Regulations.

Table 5 lists miscellaneous Federal regulations. Where indicated, this rule making will update the Table to reference the 2003 Code of Federal Regulations.

6 NYCRR Part 200.9, Table 1 will be amended to reflect these updated references in Part 200.10.

This rule making also includes technical corrections to the recently adopted 6 NYCRR Part 219 Incinerators rule making. The incorporation of the mercury test method was omitted from Table 1 (Referenced Material) in 6 NYCRR Part 200.9 and a cross reference to this method was not included in the express terms of 219.2.2(f) and 219-7.2. The Department will correct these technical omissions in this proposed consensus rule making.

Final rule as compared with last published rule: Nonsubstantive changes were made in section 200.10, Table 2.

Text of rule and any required statements and analyses may be obtained from: Edward Pellegrini, Department of Environmental Conservation, Division of Air Resources, 625 Broadway, Albany, NY 12233, (518) 402-8403, e-mail: eappelleg@gw.dec.state.ny.us

Additional matter required by statute: Pursuant to art. 8 of the (State Environmental Quality Review Act), a short environmental assessment form, a negative declaration and a coastal assessment form have been prepared and are on file. This rule was approved by the Environmental Board.

Revised Job Impact Statement

The page heading was revised as follows:
 6 NYCRR Part 200, General Provisions
 Sections [Subdivisions] 200.9 and 200.10
 6 NYCRR Part 219, Incinerators
 Subparts [Subdivisions] 219-2 and 219-7
 The effect of the regulations remains the same.

Assessment of Public Comment

The agency received no public comment.

New York State Ethics Commission

PROPOSED RULE MAKING NO HEARING(S) SCHEDULED

Extension of Time for Filing a Financial Disclosure Statement
I.D. No. ETH-19-05-00005-P

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

Proposed action: This is a consensus rule making to amend section 936.2(f)(2)(i), (3)(i) of Title 19 NYCRR.

Statutory authority: Executive Law, section 94(9)(c)

Subject: Extension of time for filing a financial disclosure statement.

Purpose: To amend the term "annual compensation".

Text of proposed rule: Subparagraph (i) of paragraph (2) of subdivision (f) of section 936.2 is amended to read as follows:

(f) "State officer or employee" shall mean:

(2) officers and employees of statewide elected officials, officers and employees of State departments, boards, bureaus, divisions, commissions, councils or other State agencies, who:

(i) receive annual compensation [in excess of \$30,000, or who, on or after January 1, 1990, in annual compensation] in excess of the filing rate; and

Subparagraph (i) of paragraph (3) of subdivision (f) of section 936.2 is amended to read as follows:

(3) members or directors of public authorities, other than multi-state authorities, public benefit corporations and commissions at least one of whose members is appointed by the Governor, and those employees of such authorities, corporations and commissions who:

(i) receive annual compensation [in excess of \$30,000, or who, on or after January 1, 1990, receive annual compensation] in excess of the filing rate, and

Text of proposed rule and any required statements and analyses may be obtained from: Theresa A. Schillaci, Ethics Commission, 39 Columbia St., Albany, NY 12207-2717, (518) 432-8250, e-mail: tschilla@dos.state.ny.us

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

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

Consensus Rule Making Determination

This Notice of Proposed Rule Making is being submitted as a consensus rule in accordance with State Administrative Procedure Act Sec. 202(1)(b)(i). The proposed rule change to sec. 936.2 of Title 19 NYCRR seeks to amend the regulatory definition of the term "annual compensation" to conform with the existing definition found at Public Officers Law sec. 73-a(1). The current statutory definition was enacted in 1989 (Ch. 242 of the Laws of 1989). Accordingly, the proposed regulatory amendment will make a technical change to the regulation and have no impact on the State workforce and is unlikely to result in an objection by anyone.

Job Impact Statement

A Job Impact Statement is not submitted with this Notice because the proposed rule making will have no impact on jobs or employment opportunities. The State Ethics Commission makes this finding based on the fact that the proposed rule making is technical in nature and only serves to conform the current regulatory language to a statutory amendment enacted in 1989. In addition, the regulation applies to certain State officers and employees required to file a financial disclosure statement and does not apply, nor relate to small businesses, economic development or employment opportunities.

PROPOSED RULE MAKING NO HEARING(S) SCHEDULED

Public Inspection of Annual Statements of Financial Disclosure

I.D. No. ETH-19-05-00006-P

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

Proposed action: This is a consensus rule making to amend section 937.4(a) of Title 19 NYCRR.

Statutory authority: Executive Law, sections 94(9)(c), (17)(a)(1)

Subject: Public inspection of annual statements of financial disclosure.

Purpose: To amend the location where disclosure forms will be available for public inspection.

Text of proposed rule: Paragraph (a) of subdivision (4) of section 937 is amended to read as follows:

(a) A request for public inspection of annual statement(s) of financial disclosure within the possession of the State Ethics Commission shall be in writing on a form provided by the commission for such purpose and substantially identified as a request for public inspection under section 94(17) of the Executive Law. Such request shall be filed with the State-

ments Access Officer, *at the offices of the State Ethics Commission*, Suite 900, 11 North Pearl Street, Albany, New York 12207].

Text of proposed rule and any required statements and analyses may be obtained from: Theresa A. Schillaci, Ethics Commission, 39 Columbia St., Albany, NY 12207-2717, (518) 432-8250, e-mail: tschilla@dos.state.ny.us

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

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

Consensus Rule Making Determination

This Notice of Proposed Rule Making is being submitted as a consensus rule in accordance with State Administrative Procedure Act Sec. 202(1)(b)(i). The proposed amendment to sec. 937.4 of Title 19 NYCRR seeks to eliminate an obsolete address for the Commission's office. The Commission office was re-located in 1991. No person is likely to object to the adoption of the proposed rule as it serves to update the regulations to reflect the current situation, has no impact on the State workforce or general public and is otherwise non-controversial.

Job Impact Statement

A Job Impact Statement is not submitted with this Notice because the proposed rule making will have no impact on jobs or employment opportunities. The State Ethics Commission makes this finding based on the fact that the proposed rule making is technical in nature and only serves to eliminate an obsolete office address from Commission regulations. In addition, the regulation applies to the public inspection of financial disclosure statements and does not apply, nor relate to small businesses, economic development or employment opportunities.

PROPOSED RULE MAKING NO HEARING(S) SCHEDULED

Exemption From Filing a Financial Disclosure Statement

I.D. No. ETH-19-05-00007-P

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

Proposed action: This is a consensus rule making to amend section 935.1(h) of Title 19 NYCRR.

Statutory authority: Executive Law, section 94(9)(k)

Subject: Requesting exemptions from filing a financial disclosure statement.

Purpose: To amend the definition of "State agency."

Text of proposed rule: Subdivision (h) of section 935.1 is amended to read as follows:

(h) "State agency" shall mean any State department, or division, board, commission or bureau of any State department, any public benefit corporation, public authority or commission at least one of whose members is appointed by the Governor, or State University of New York or the City University of New York, including all their constituent units except community colleges *of the State University of New York* and the independent institutions operating statutory or contract colleges on behalf of the State.

Text of proposed rule and any required statements and analyses may be obtained from: Theresa A. Schillaci, Ethics Commission, 39 Columbia St., Albany, NY 12207-2717, (518) 432-8250, e-mail: tschilla@dos.state.ny.us

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

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

Consensus Rule Making Determination

This notice of Proposed Rule Making is being submitted in accordance with State Administrative Procedure Act Sec. 202(1)(b)(i). The proposed rule change to sec. 935.1 of Title 19 NYCRR seeks to amend the regulatory definition of the term "state agency" to conform with the existing definition found at Public Officers Law sec. 73(1)(g). The current statutory definition was enacted in 1996 (Ch. 283 of the Laws of 1996). Accordingly, the proposed regulatory amendment will make a technical change to the regulation and have no impact on the State workforce and is unlikely to result in an objection by anyone.

Job Impact Statement

A Job Impact Statement is not submitted with this Notice because the proposed rule making will have no impact on jobs or employment opportunities. The State Ethics Commission makes this finding based on the fact that the proposed rule making is technical in nature and only serves to conform the current regulatory language to a statutory amendment enacted

in 1996. In addition, the regulation applies to certain State officers and employees required to file a financial disclosure statement and does not apply, nor relate to small businesses, economic development or employment opportunities.

Department of Health

EMERGENCY RULE MAKING

Enactment of a Serialized Official New York State Prescription Form

I.D. No. HLT-19-05-00003-E

Filing No. 435

Filing date: April 21, 2005

Effective date: April 21, 2005

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

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

Statutory authority: Public Health Law, section 21

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

Specific reasons underlying the finding of necessity: We are proposing that these regulations be adopted on an emergency basis because immediate adoption is necessary to protect the public health and safety and to meet statutory requirements. The budget proposal enacting Section 21 contains explicit authority for the Commissioner to promulgate emergency regulations. This was done recognizing the need to provide for a proper transition period for the use of statewide forged proof prescriptions, which under the regulations will be for a period of 18 months. Without the regulations the program is required to be enacted in 60 days which would be detrimental to both practitioners and the public.

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

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

Subject: Serialized official New York State prescription form.

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

Substance of emergency rule: Part 910 (10 NYCRR)

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

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

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

Section 505.3 (18 NYCRR)

- Language included to reflect use of facsimile prescriptions
- Language included to allow electronically transmitted prescriptions
- Language included to mandate that all claims for payments of drugs or supplies under the MA program shall contain the serial number of the Official NYS Prescription Form
- Delete language prohibiting telephone orders for OTCs
- Language amended—telephone prescriptions for non-controlled substances WILL NOT require a follow-up hard copy prescription (even with refills)
- Delete Estimated Acquisition Cost—defined in Social Services Law 367-a(9)(b)(ii)
- Delete language referencing triplicate prescriptions and update to language consistent with Official NYS Prescription Form and Article 33 of the Public Health Law
- Delete language referencing other Sections that have been deleted (i.e. 10 NYCRR 85.25)
- Delete language referencing dispensing fees—in Social Services Law 367-a(9)(d)
- Language is added to reference prescription drugs filled in compliance with 6810 of the Education Law and the Article 33 of the Public Health Law and new 10 NYCRR Part 910.

Part 528 (18 NYCRR)

- Section 528.1 is deleted—obsolete listing of non-prescription drugs covered under the MA program. Listing of reimbursable drugs and rate is available on-line at the NYS eMedNY website
- Section 528.2 is deleted—language regarding dispensing fees include routine delivery charges is moved to 18 NYCRR 505.3(f)(6). Compounding fee language in 18 NYCRR 505.3(6)(3)

Part 85 (10 NYCRR)

- Section 85.21 amended—OTC List—quantities and dosage forms have been deleted to allow greater flexibility in coverage. Remove OTC categories that are no longer marketed
- Section 85.22 amended—establishment of OTC prices amended to more accurately reflect OTC pricing (Ad Hoc Committee is obsolete) and removal of references to deleted Sections (i.e., 18 NYCRR 528.2 and 10 NYCRR 85.25)
- Section 85.23 deleted—Revisions to list of OTCs and Maximum Reimbursable Prices—in Social Services Law 365-a(4)(a)
- Section 85.25 deleted—Prescription drug list covered under MA—obsolete. Drug list available on line at NYS eMedNY website.

This notice is intended to serve only as a notice of emergency adoption. This agency intends to adopt this emergency rule as a permanent rule and will publish a notice of proposed rule making in the *State Register* at some future date. The emergency rule will expire July 19, 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

Regulatory Impact Statement

Statutory Authority:

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

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

Legislative Objectives:

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

Needs and Benefits:

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

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

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

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

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

Costs:

Costs to Regulated Parties:

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

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

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

Costs to State and Local Government:

There will be no costs to state or local government.

Costs to the Department of Health:

There will be no additional costs to the Department.

Local Government Mandates:

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

Paperwork:

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

Duplication:

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

Alternatives:

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

Federal Standards:

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

Compliance Schedule:

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

Regulatory Flexibility Analysis

Effect of Rule on Small Business and Local Government:

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

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

Compliance Requirements:

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

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

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

Professional Services:

No additional professional services are necessary.

Compliance Costs:

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

Economic and Technological Feasibility:

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

Minimize Adverse Impact:

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

Small Business and Local Government Participation:

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

Rural Area Flexibility Analysis

Types and Estimated Numbers of Rural Areas:

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

Compliance Requirements:

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

Professional Services:

None necessary.

Compliance Costs:

None.

Economic and Technological Feasibility:

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

Minimize Adverse Impact:

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

Rural Area Participation:

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

Job Impact Statement

Nature of Impact:

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

EMERGENCY RULE MAKING

HIV Laboratory Test Reporting

I.D. No. HLT-19-05-00010-E

Filing No. 438

Filing date: April 25, 2005

Effective date: June 1, 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 Com-

missioner. 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 July 23, 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 and. 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 June 1, 2005.

Regulatory Flexibility Analysis

Effect of Rule:

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

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

Compliance Requirements:

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

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

Professional Services:

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

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

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

Compliance Costs:

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

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

Economic and 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

I.D. No. HLT-19-05-00011-E

Filing No. 439

Filing date: April 25, 2005

Effective date: April 25, 2005

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

Action taken: Amendment of sections 69-1.1—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 rule making 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: The New York State newborn screening panel.

Purpose: To add 33 disorders.

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 July 23, 2005.

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

Summary of Regulatory Impact Statement

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

Legislative Objectives:
 In enacting PHL Section 2500-a, the Legislature intended to promote public health through mandatory screening of New York State newborns to detect those with serious but treatable neonatal conditions and to ensure their referral for medical intervention. This proposal, which would add 33 conditions – all inherited metabolic disorders – to the list of ten genetic/

congenital disorders and one infectious disease currently in regulation, is in keeping with the Legislature's public health aims of early identification and timely medical intervention for all the State's youngest citizens.

Needs and Benefits:

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

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

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

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

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

Costs:

Costs to Private Regulated Parties:

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

The Program estimates that, following implementation of this proposal, 2,700 newborns will screen positive for one or more of the new conditions annually, and will require either repeat screening or referral to facilities and practitioners, depending on whether the value of the initial screening result for the condition's marker is close to the empirically determined cutoff point for positive, or significantly above that point. Cost figures that follow are based on this high-end estimate for presumptive positives and an estimated maximum number of infants needing immediate referral. The Department has revised its estimate of the number of infants expected to screen positive annually based on the results of a two-pronged approach: the Program's four months' experience with screening approximately 85,000 specimens for the 20-test panel mandated by the emergency rule making 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 now being added by this emergency rule as the second phase of panel expansion. 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.

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

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

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

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

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

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

Costs for Implementation and Administration of the Rule:

Costs to State Government:

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

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

Costs to the Department:

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

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

Costs to Local Government:

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

Local Government Mandates:

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

Paperwork:

No increase in paperwork would be attributable to activities related to specimen collection, and reporting and filing of test results, as the number and type of forms now used for these purposes will not change. Facilities that submit newborn specimens will sustain minimal to no increases in

paperwork, specifically, only that necessary to conduct and document follow-up and/or referral.

Duplication:

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

Alternative Approaches:

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

Federal Standards:

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

Compliance Schedule:

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

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

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

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

Regulatory Flexibility Analysis

Effect on Small Businesses and Local Governments:

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

Compliance Requirements:

The Department expects that affected facilities, and medical practices operated as small businesses or by local governments, will experience minimal additional regulatory burdens in complying with the amendment's requirements, as functions related to mandatory newborn screening are already embedded in established policies and practices of affected institutions and individuals. Activities related to collection and submission of blood specimens to the State's Newborn Screening Program will not change, since newborn dried blood spot specimens now collected and mailed to the Program for other currently performed testing would also be used for the additional tests proposed by this amendment. However, birthing facilities and at-home birth attendants (*i.e.*, licensed midwives) would be required to follow up infants screening positive for any one or more of the conditions proposed for addition to the State's panel, and assume responsibility for referral for medical evaluation and additional testing as

appropriate for each infant's medical status. The anticipated increased burden is expected to have minimal effect on the ability of small businesses or local government-operated facilities to comply, as no such facility would experience an increase of more than two per week in the number of infants requiring referral. Therefore, the Department expects that regulated parties will be able to comply with these regulations as of their effective date, upon filing with the Secretary of State.

Professional Services:

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

Compliance Costs:

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 record keeping practices.

Small Business and Local Government Participation:

This amendment is being proposed as an emergency rule, and ensuring notification of its provisions and requirements in accordance with the SAPA process to affected parties that are either small businesses or local governments would cause unnecessary and potentially detrimental delay in full implementation of the expanded screening profile proposed by this regulation. Notification 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 fore-

seen, 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 mini-

mal changes to present collection, reporting, follow-up and recordkeeping practices.

Rural Area Participation:

This amendment is being proposed as an emergency rule, and ensuring notification of its provisions and requirements in accordance with the SAPA process to affected parties located in rural areas would cause unnecessary and potentially detrimental delay in full implementation of the expanded screening profile proposed by this regulation. 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.

Insurance Department

EMERGENCY RULE MAKING

Rules Governing Individual and Group Accident and Health Insurance Reserves

I.D. No. INS-19-05-00004-E

Filing No. 436

Filing date: April 21, 2005

Effective date: April 21, 2005

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

Action taken: Repeal of Part 94 and addition of new Part 94 (Regulation 56) to Title 11 NYCRR.

Statutory authority: Insurance Law, sections 201, 301, 1304, 1308, 4217 and 4517

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

Specific reasons underlying the finding of necessity: Regulation No. 56 was originally effective August 18, 1971 in its present form and has not been substantively amended since that time. In the intervening 31 years, the National Association of Insurance Commissioners has adopted new reserving tables for individual and group disability income insurance policies, popularly referred to as the Commissioners' Disability Tables ("CDT"). The current CDT was adopted in 1986 and is used widely across the country as the standard for holding reserves for individual and group disability insurance policies. It reflects both modern morbidity and claims experience and the judgement of actuaries and regulators who are knowledgeable about the current state of the disability insurance market.

However, New York authorized insurers are required to use the 1964 CDT because it was required by Regulation No. 56 (see, e.g., 11 NYCRR Part 94.1(a)(4)(iii)(A)). Also, Regulation No. 56 did not apply to group insurance, providing little or no guidance to New York insurers that write this important form of protection. The effect of the application of this outdated regulation is that New York authorized insurers are required to hold reserves far in excess of the national standard for disability insurance active lives reserves, but below the prevailing standard for claims reserves. Most New York authorized insurers hold reserves in excess of the amount needed to pay claims due to the required use of the outdated tables. For these insurers, the adoption of the more recent tables will significantly reduce the cost of doing business and allow them to compete more effectively with insurers that are not subject to New York standards and to pass the cost savings on to consumers. For some insurers, this regulation may require an increase in reserves especially for coverages such as group health insurance for which there had been no standards previously. The

adoption of these standards will help to ensure that such insurers remain financially capable of paying claims as they come due.

New York authorized insurers must file quarterly financial statements based upon minimum reserve standards in effect on December 31, 2004. The filing date for the June 30, 2005 quarterly statement is August 15, 2005. The insurers must be given advance notice of the applicable standards in order to file their reports in an accurate and timely manner.

For all of the reasons stated above, an emergency adoption of this new Regulation No. 56 is necessary for the general welfare.

Subject: Rules governing individual and group accident and health insurance reserves.

Purpose: To prescribe rules and regulations for valuation of minimum individual and group accident and health insurance reserves including standards for valuing certain accident and health benefits in life insurance policies and annuity contracts.

Substance of emergency rule: Section 94.1 lists the main purposes of the regulation including implementation of sections 4217(d), 4517(d) and 4517(f) of the Insurance Law and prescribing rules for valuing certain accident and health benefits in the life insurance policies.

Section 94.2 is the applicability section. This section applies to both individual policies and group certificates. The regulation applies to all life insurers, fraternal benefit societies, and accredited reinsurers doing business in the State of New York. It applies to all statutory financial statements filed after its effective date.

Section 94.3 is the definitions section.

Section 94.4 sets forth the general requirements and minimum standards for claim reserves, including claim expense reserves and the testing of prior year reserves for adequacy and reasonableness using claim runoff schedules and residual unpaid liability.

Section 94.5 sets forth the general requirements and minimum standards for unearned premium reserves.

Section 94.6 sets forth the general requirements and minimum standards for contract reserves.

Section 94.7 concerns increases to, or credits against reserves carried, arising from reinsurance agreements.

Section 94.8 prescribes the methodology of adequately calculating the reserves for waiver of premium benefit on accident and health policies.

Section 94.9 provides that a company shall maintain adequate reserves for all individual and group accident and health insurance policies that reflect a sound value being placed on its liabilities under those policies.

Section 94.10 provides the specific standards for morbidity, interest and mortality.

Section 94.11 allows for a four-year period for grading into the higher reserves beginning with year-end 2003 for insurers for which higher reserves are required because of this Part.

Section 94.12 establishes the severability provision of the regulation.

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 July 19, 2005.

Text of emergency rule and any required statements and analyses may be obtained from: Michael Barry, Insurance Department, 25 Beaver St., New York, NY 10004, (212) 480-5265, e-mail: mbarry@ins.state.ny.us

Regulatory Impact Statement

1. Statutory authority:

The superintendent's authority for the adoption of Regulation No. 56 (11 NYCRR 94) is derived from sections 201, 301, 1304, 1308, 4217, and 4517 of the Insurance Law.

These sections establish the superintendent's authority to promulgate regulations governing reserve requirements for life insurers. Sections 201 and 301 of the Insurance Law authorize the superintendent to prescribe regulations accomplishing, among other concerns, interpretation of the provisions of the Insurance Law, as well as effectuating any power given to him under the provisions of the Insurance Law to prescribe forms or otherwise to make regulations.

Section 1304 of the Insurance Law enables the superintendent to require any additional reserves as necessary on account of life insurers' policies, certificates and contracts.

Section 1308 of the Insurance Law describes when reinsurance is permitted and the effect that reinsurance will have on reserves. Section 4217(d) provides that reserves for all individual and group accident and health policies shall reflect a sound value placed on the liabilities of such policies and permits the superintendent to issue, by regulation, guidelines for the application of reserve valuation provisions for these types of policies.

For fraternal benefit societies, section 4517(d) provides that reserves for all individual accident and health certificates shall reflect a sound value placed on the liabilities of such certificates and permits the superintendent to issue, by regulation, standards for minimum reserve requirements on these types of certificates. Additionally, section 4517(f) provides that reserves for unearned premiums and disabled lives be held in accordance with standards prescribed by the superintendent for certificates or other obligations which provide for benefits in case of death or disability resulting solely from accident, or temporary disability resulting from sickness, or hospital expense or surgical and medical expense benefits.

2. Legislative objectives:

One major area of focus of the Insurance Law is solvency of insurers doing business in New York. One way the Insurance Law seeks to ensure solvency is through requiring all insurers licensed to do business in New York State to hold reserve funds necessary in relation to the obligations made to policyholders.

3. Needs and benefits:

The regulation is necessary to help ensure the solvency of life insurers doing business in New York. The Insurance Law does not specify mortality, morbidity, and interest standards used to value individual and group accident and health insurance policies and relies on the superintendent to specify the method. Without this regulation, there would be no standard method for valuing such products and, in fact, the current regulation, absent the emergency regulation, provides no guidance related to certain coverages such as group accident and health policies. This could result in inadequate reserves for some insurers, which would jeopardize the security of policyholder funds.

Additionally, the current regulation, absent the emergency regulation, requires higher reserves than necessary for certain individual accident and health insurance policies. This emergency regulation, by lowering such reserves for individual policies, will result in a lower cost of doing business in New York.

4. Costs:

Costs to most insurers licensed to do business in New York State will be minimal, including the cost to develop computer programs which calculate reserves for accident and health insurance due to several changes in the underlying reserve methodology and new morbidity tables. Companies that are domiciled in New York and are not licensed to do business in other states will be impacted the most by this adoption. Most insurers that are domiciled in New York and licensed to do business in other states already have in place identical or similar procedures for reserve requirements and morbidity tables due to adoption by many states of the Health Insurance Reserves Model Regulation of the National Association of Insurance Commissioners (NAIC). The adoption of this regulation by New York State improves reserve uniformity throughout the insurance industry. Therefore, minimal additional costs will be incurred in most cases. For some insurers doing business only in New York or in other states that have not adopted the NAIC model regulation, the adoption for the first time of standards for certain coverages such as group health insurance may require an increase in reserves and would therefore increase the insurer's cost of capital. In addition, an insurer that needs to modify its current systems could produce modifications internally or purchase software from a consultant, who would typically charge \$5,000 to \$10,000. Once the program has been developed, no additional systems costs should be incurred due to those requirements.

Costs to the Insurance Department will be minimal. There are no costs to other government agencies or local governments.

5. Local government mandates:

The regulation imposes no new programs, services, duties or responsibilities on any county, city, town, village, school district, fire district or other special district.

6. Paperwork:

The regulation imposes no new reporting requirements.

7. Duplication:

The regulation does not duplicate any existing law or regulation.

8. Alternatives:

The only significant alternative to be considered was to keep the current version of Regulation No. 56, without adopting this emergency regulation, which would result in different reserve requirements for those life insurers licensed in New York.

9. Federal standards:

There are no federal standards in the subject area.

10. Compliance schedule:

Beginning with year-end 2003, where the requirements of this regulation produce reserves higher than those calculated at year-end 2002, the

insurer may linearly interpolate, over a four year period, between the higher reserves and those calculated based on the year-end 2002 standards. Insurers must be in full compliance with this Part by year-end 2006. This allows insurers subject to the regulation ample time to achieve full compliance, since this regulation has been adopted on an emergency basis since December 31, 2002.

Regulatory Flexibility Analysis

1. Small Businesses:

The Insurance Department finds that this rule will not impose any adverse economic impact on small businesses and will not impose any reporting, recordkeeping or other compliance requirements on small businesses. The basis for this finding is that this rule is directed at all life insurance companies licensed to do business in New York State, none of which fall within the definition of "small business" as found in Section 102(8) of the State Administrative Procedure Act. The Insurance Department has reviewed filed Reports on Examination and Annual Statements of authorized insurers and believes that none of them fall within the definition of "small business", because there are none which are both independently owned and have under one hundred employees.

2. Local Governments:

The regulation does not impose any impacts, including any adverse impacts, or reporting, recordkeeping, or other compliance requirements on any local governments.

Rural Area Flexibility Analysis

1. Types and estimated number of rural areas:

Insurance companies covered by the regulation do business in every county in this state, including rural areas as defined under SAPA 102(10).

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

The regulation establishes reserve requirements for individual and group accident and health policies and establishes standards for valuing certain accident and health benefits in life insurance policies and annuity contracts.

3. Costs:

Costs to most insurers licensed to do business in New York State will be minimal, including the cost to develop computer programs which calculate reserves for accident and health insurance due to several changes in the underlying reserve methodology and new morbidity tables. Companies that are domiciled in New York and are not licensed to do business in other states will be impacted the most by this adoption. Most insurers that are domiciled in New York and licensed to do business in other states already have in place identical or similar procedures for reserve requirements and morbidity tables due to adoption by many states of the Health Insurance Reserves Model Regulation of the National Association of Insurance Commissioners (NAIC). The adoption of this regulation by New York State improves reserve uniformity throughout the insurance industry. Therefore, minimal additional costs will be incurred in most cases. For some insurers doing business only in New York or in other states that have not adopted the NAIC model regulation, the adoption for the first time of standards for certain coverages such as group health insurance may require an increase in reserves and would therefore increase the insurer's cost of capital. In addition, an insurer that needs to modify its current systems could produce modifications internally or purchase software from a consultant, who would typically charge \$5,000 to \$10,000. Once the program has been developed, no additional systems costs should be incurred due to those requirements.

4. Minimizing adverse impact:

The regulation does not impose any adverse impact on rural areas.

5. Rural area participation:

The regulation was drafted after consultation with member companies of the Life Insurance Council of New York (LICONY). A copy of the draft was distributed to LICONY in November 2002. Additional changes were made to the text of the regulation based on changes made to the NAIC's Health Insurance Reserves Model Regulation in December 2003 and a revised draft of the regulation was distributed to LICONY in January 2004. In addition, a discussion of the proposed rule making was included in the Insurance Department's regulatory agenda which was published in the January 5, 2005 issue of the *State Register*.

Job Impact Statement

Nature of impact:

The Insurance Department finds that this rule will have little or no impact on jobs and employment opportunities. This regulation sets standards for setting reserves for insurers. Most insurers will be able to reduce reserves and a few may need to increase reserves but this is unlikely to impact jobs and employment opportunities.

Categories and number affected:
 No categories of jobs or number of jobs will be affected.
 Regions of adverse impact:
 This rule applies to all insurers licensed to do business in New York State. There would be no region in New York which would experience an adverse impact on jobs and employment opportunities.
 Minimizing adverse impact:
 No measures would need to be taken by the Department to minimize adverse impacts.
 Self-employment opportunities:
 This rule would not have a measurable impact on self-employment opportunities.

behalf of KeySpan Energy Services to use the FOCUS watt-hour meter line.

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

Subject: New types of electronic meters.

Purpose: To allow electric utilities in New York State to use the FOCUS solid-state residential meter line.

Substance of final rule: The Commission approved a request by Landis+Gyr Incorporated on behalf of KeySpan Energy Services to use the FOCUS meter line for revenue metering and billing applications for residential service in New York State.

Final rule compared with proposed rule: No changes.

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

Assessment of Public Comment

An assessment of public comment is not submitted with this notice because the rule is within the definition contained in section 102(2)(a)(ii) of the State Administrative Procedure Act. (04-E-0732SA1)

Public Service Commission

NOTICE OF WITHDRAWAL

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

The following rule making has been withdrawn from consideration:

I.D. No.	Publication Date of Proposal
PSC-07-05-00020-P	February 16, 2005

NOTICE OF ADOPTION

Water Rates and Charges by New York Water Service Corporation

I.D. No. PSC-43-04-00023-A
Filing date: April 26, 2005
Effective date: April 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 April 13, 2005, adopted an order in Case 04-W-0665 establishing a three-year rate plan for New York Water Service Corporation (NYWS).

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

Subject: Joint proposal by NYWS and the Department of Public Service.

Purpose: To approve the revenue requirement and rate design.

Substance of final rule: The Commission adopted the proposed terms of a Joint Proposal allowing New York Water Service Corporation three annual rate increases of \$0.7 million, \$0.3 million and \$0.3 million (3.2%, 1.4% and 1.4%) for the years ending April 30 of 2006, 2007 and 2008, subject to the terms and conditions set forth in the order.

Final rule compared with proposed rule: No changes.

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

Assessment of Public Comment

An assessment of public comment is not submitted with this notice because the rule is within the definition contained in section 102(2)(a)(ii) of the State Administrative Procedure Act. (04-W-0665SA1)

NOTICE OF ADOPTION

New Types of Electricity Meters, Transformers and Auxiliary Devices by Landis + Gyr Incorporated

I.D. No. PSC-03-05-00021-A
Filing date: April 21, 2005
Effective date: April 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 April 13, 2005, adopted an order in Case 04-E-0732 approving Landis + Gyr Incorporated's (L+G) petition on

NOTICE OF ADOPTION

Affiliated Exempt Telecommunications Company by Waverly Electric Light & Power Company

I.D. No. PSC-06-05-00015-A
Filing date: April 21, 2005
Effective date: April 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 April 13, 2005, adopted an order in Case 05-M-0080 approving Waverly Electric Light & Power Company's (Waverly) request for a waiver under section 34(i) of the Public Utility Holding Company Act of 1935.

Statutory authority: Public Service Law, sections 65(1), (2), (3), 66(1) and 110

Subject: Contracts between affiliates regarding an affiliated exempt telecommunications company.

Purpose: To waive the review of or approval of contracts between affiliates.

Substance of final rule: The Commission waived its authority under § 34(i) of the Public Utility Holding Company Act to review contracts between FirstEnergy Service Company and First Communications, L.L.C., affiliates of Waverly Electric Light and Power Company, 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-M-0080SA1)

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

Short Term Loans by Berkshire Telephone Corporation to its Parent Holding Company, FairPoint Communications

I.D. No. PSC-19-05-00012-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 approve short term loans by Berkshire Telephone Corporation to its parent holding company, FairPoint Communications, or any of its affiliates in the implementation of a cash management system.

Statutory authority: Public Service Law, section 106

Subject: Approval of loans.

Purpose: To allow short term loans by Berkshire Telephone Corporation to its parent holding company or any of its affiliates in the implementation of a cash management system.

Substance of proposed rule: The Public Service Commission is considering whether to approve short term loans by Berkshire Telephone Corporation to its parent holding company, FairPoint Communications, or any of its affiliates, in the implementation of a cash management system. This issue is discussed in the Order Approving Acquisition Subject to Conditions, issued March 18, 2005 in Case 03-C-0972, Joint Petition of Berkshire Telephone Corporation, FairPoint Communications, Inc., MJD Ventures, Inc., and FairPoint Berkshire Corporation for Approval of the Merger of FairPoint Berkshire Corporation with and into Berkshire Telephone Corporation.

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

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

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

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

Statements and analyses are not submitted with this notice because the proposed rule is within the definition contained in section 102(2)(a)(ii) of the State Administrative Procedure Act. (03-C-0972SA2)

PROPOSED RULE MAKING NO HEARING(S) SCHEDULED

Renewable Portfolio Standard Program by NGP Power Corporation on Behalf of its Lyonsdale Biomass, LLC

I.D. No. PSC-19-05-00013-P

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

Proposed action: The commission is considering matters related to the application of NGP Power Corporation on behalf of its Lyonsdale Biomass, LLC facility for Renewable Portfolio Standards (RPS) Program funding as a maintenance resource pursuant to the commission's order approving implementation plan, adopting clarifications, and modifying Environmental Disclosure Program that was issued on April 14, 2005.

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

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

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

Substance of proposed rule: Pursuant to the Commission's Order Approving Implementation Plan, Adopting Clarifications, and Modifying Environmental Disclosure Program that was issued on April 14, 2005 (Implementation Plan Order), NGP Power Corporation submitted on April 15, 2005 an application for a determination on RPS Program eligibility and funding for its Lyonsdale Biomass LLC facility. The Lyonsdale facility is a 19 MW wood-fired cogeneration plant located in Lyons Falls, New York. The application asserts that the facility has not been able to operate profitably on a sustained basis since the buyout of the Niagara Mohawk PURPA contract in 1999. The application states that RPS Program funds are necessary to stabilize operations and provide an incentive for investors to commit capital for plant improvements and to fund local fuel infrastructure programs.

Based on a review of the application and supporting documentation, the Director of the Commission's Office of Electricity and Environment has determined, pursuant to the delegation afforded him by the Implementation Plan Order, that the facility is eligible to participate in the RPS Program as a maintenance resource. The Commission will render a decision on NGP Power's RPS Program funding request. Options under consideration may include offering NGP performance payments based on renewable energy produced over a period of years at a level the Commission deems appropriate to assist the facility to achieve solvency during the term of its participation in the RPS Program. Other appropriate actions

may be considered as well, such as, allowing NGP to participate in a future Main Tier solicitation. The Commission may also decide to impose conditions on any such award to ensure protection of the public interest and achievement of its renewable energy policy goals.

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

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

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

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

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

(03-E-0188SA7)

PROPOSED RULE MAKING NO HEARING(S) SCHEDULED

Petition for Rehearing by New York State Electric & Gas Corporation and Rochester Gas & Electric Corporation

I.D. No. PSC-19-05-00014-P

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

Action taken: The commission is considering what actions it should take with respect to a petition for rehearing filed by New York State Electric & Gas Corporation and Rochester Gas & Electric Corporation on April 1, 2005 with respect to a petition for clarification filed by KeySpan Energy Services, Inc. on April 13, 2005, and with respect to a petition for rehearing and clarification filed by the Public Utility Law Project, Inc. (PULP) on April 25, 2005.

Statutory authority: Public Service Law, sections 5, 22, 31, 65, 66 and 75

Subject: Terms of a three-year electric rate plan pertaining to Consolidated Edison Company of New York, Inc.'s (Con Edison) retail access program, the terms of Con Edison's market supply charge and monthly adjustment clause related to New York Independent System Operator rebills, and the bill impacts associated with demand management initiatives to be undertaken by Con Edison and the New York State Energy Research and Development Authority.

Purpose: To change and clarify some terms of the recently adopted three-year electric rate plan for Con Edison.

Substance of final rule: In an order issued March 24, 2005, the Public Service Commission adopted a three-year electric rate plan for Consolidated Edison Company of New York, Inc. (Con Edison). The rate plan included many terms, including several pertaining to an electric retail access program, to Con Edison's Market Supply Charge and Monthly Adjustment Clause, and to demand management initiatives.

The adopted retail access program provides, in part, that customers switching from full service to retail access service will receive a seven percent discount on the commodity portion of their bill for two months after which they could continue with retail access with no discount with the same or a different Energy Service Company (ESCO), or revert to full service. New York State Electric & Gas Corporation and Rochester Gas & Electric Corporation seek rehearing concerning this program, alleging this part of the Commission's decision is based on errors of fact and law, could be harmful to customers that take retail access service after the discount period, may involve a violation of the Commission's Uniform Business Practices, and amounts to partial abdication of some of the Commission's statutory responsibilities. PULP, meanwhile, contends that the two-month discount amounts to unlawful price fixing and market division, results in unfair rate discrimination, is inconsistent with the filed rate doctrine, and is otherwise unjust and unreasonable.

The Commission is asked by KeySpan Energy Services, Inc., in a petition dated April 13, 2005, to clarify whether New York Independent System Operator rebills, to be recovered through Con Edison's electric Monthly Adjustment Clause in the future, will continue to exclude charges for energy, capacity, and ancillary services. According to this petitioner, rebills for energy, capacity, and ancillary services are more properly allo-

cated to and recovered through Con Edison's Electric Market Supply Charge.

Finally, given the maximum amount of demand management costs that might be recovered under the new rate plan, PULP argues that Con Edison's Monthly Adjustment Clause tariff should be modified to require that customers be notified quarterly of the prospective recovery of the costs associated with the authorized demand management initiatives.

Final rule compared with proposed rule: No changes.

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

Assessment of Public Comment

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

(04-E-0572SA3)

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

Petition for Rehearing by Consolidated Edison Company of New York, Inc.

I.D. No. PSC-19-05-00015-P

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

Proposed action: The Public Service Commission (Commission) is considering whether to approve, reject, or modify, in whole or in part, a petition for rehearing by Consolidated Edison Company of New York, Inc. (Con Edison) of the Feb. 18, 2005 Commission order directing the submission of unbundled bill formats. Specifically, Con Edison seeks rehearing on the belief that the order's requirement that sales tax, although calculated based upon the utility delivery charge, should be included in the utility commodity charge portion of customers' bills, violates certain provisions of the New York State Tax Law and Regulations. The commission may also consider other matters related to the submission of unbundled bill formats.

Statutory authority: Public Service Law, sections 2, 4, 5, 65 and 66

Subject: Rehearing request of Con Edison concerning the commission directed submission of unbundled bill formats, and other related matters.

Purpose: To consider whether it is consistent with New York State Tax Laws and Regulations to require that customer bills, for gas and electric service, reflect the sales tax associated with the provision of delivery service to bundled sales customers, in the commodity section of customers bill, and other related matters.

Substance of proposed rule: The Public Service Commission (Commission) is considering whether to accept, reject or modify, in whole or in part, a petition for rehearing by Consolidated Edison Company of New York, Inc. (Con Edison) of the February 18, 2005 Commission Order directing the submission of unbundled bill formats. Specifically, Con Edison seeks rehearing on the belief that the Order's requirement that sales tax, although calculated based upon the utility delivery charge, should be included in the utility commodity charge portion of customers' bills, violates certain provisions of the New York State Tax Law and Regulations. The Commission may also consider other matters related to the submission of unbundled bill formats.

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

Data, views or arguments may be submitted to: Jaelyn 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.

(00-M-0504SA15)

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

Retail Access Plan by New York State Electric and Gas Corporation

I.D. No. PSC-19-05-00016-P

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

Proposed action: The Public Service Commission is considering a retail access plan filed by New York State Electric and Gas Corporation on April 14, 2005.

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

Subject: Retail access plan.

Purpose: To consider the plan.

Substance of proposed rule: The Public Service Commission is considering whether to adopt, modify, or reject, in whole or in part, the Retail Access Plan by New York State Electric and Gas Corporation filed April 14, 2005 pursuant to the Statement of Policy on Further Steps Toward Competition in Retail Energy Markets in Case 00-M-0504, issued and effective August 25, 2004. The Retail Access Plan outlines New York State Electric and Gas Corporation's proposed next steps to facilitate retail access in its service territory.

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

Data, views or arguments may be submitted to: Jaelyn 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-M-0453SA1)

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

Retail Access Plan by Rochester Gas and Electric Corporation

I.D. No. PSC-19-05-00017-P

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

Proposed action: The Public Service Commission is considering a retail access plan filed by Rochester Gas and Electric Corporation on April 14, 2005.

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

Subject: Retail access plan.

Purpose: To consider the plan.

Substance of proposed rule: The Public Service Commission is considering whether to adopt, modify, or reject, in whole or in part, the Retail Access Plan by Rochester Gas and Electric Corporation filed April 14, 2005 pursuant to the Statement of Policy on Further Steps Toward Competition in Retail Energy Markets in Case 00-M-0504, issued and effective August 25, 2004. The Retail Access Plan outlines Rochester Gas and Electric Corporation's proposed next steps to facilitate retail access in its service territory.

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

Data, views or arguments may be submitted to: Jaelyn 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-M-0454SA1)

Racing and Wagering Board

NOTICE OF ADOPTION

Drug Testing of Horses

I.D. No. RWB-09-05-00001-A

Filing No. 441

Filing date: April 26, 2005

Effective date: May 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 4038.18, 4043.6, 4043.7, 4109.7, 4113.3, 4120.10, 4120.11 of Title 9 NYCRR.

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

Subject: Drug testing of horses.

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

Text or summary was published in the notice of proposed rule making, I.D. No. RWB-09-05-00001-P, Issue of March 2, 2005.

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

Text of rule and any required statements and analyses may be obtained from: Gail Pronti, Secretary to the Board, Racing and Wagering Board, One Watervliet Ave. Ext., Albany, NY 12206, (518) 453-8460

Assessment of Public Comment

The agency received no public comment.

Office of Real Property Services

EMERGENCY RULE MAKING

Notice of Public Condemnation Hearings

I.D. No. RPS-14-05-00003-E

Filing No. 442

Filing date: April 26, 2005

Effective date: April 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 188-2.9(b)(4) of Title 9 NYCRR.

Statutory authority: Real Property Tax Law, sections 202(1)(l), 318(4) and 1530(3)(f), and L. 2004, ch. 53

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

Specific reasons underlying the finding of necessity: This proposal will allow payment of expenses of local officials from appropriated funds.

Subject: State reimbursement of expenses of local officials in satisfying training requirements.

Purpose: To authorize payment of late vouchers if funds are available.

Text of emergency rule: Section 1. Paragraph 4 of subdivision b of section 188-2.9 is amended to read as follows:

Reimbursement for completing components of the basic course of training for attaining certification as a State Certified Assessor and for satisfaction of continuing education requirements shall be made [only] upon claims submitted no later than 30 days following completion of such training. Submissions by mail shall be deemed to have been submitted when postmarked. *Claims submitted more than 30 days following the completion of such training will be reviewed for possible payment on or before the first day of June of the succeeding fiscal year. If funds remain from the appropriation for training reimbursement in the fiscal year in which the assessor completed such training, claims will be paid in full or, if the remaining funds are insufficient, prorated.*

Section 2. This amendment shall first apply to the State Fiscal Year 2004-2005.

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 June 24, 2005.

Text of emergency rule and any required statements and analyses may be obtained from: James J. O'Keefe, General Counsel, Office of Real Property Services, 16 Sheridan Ave., Albany, NY 12210-2714, (518) 474-8821, e-mail: internet.legal@orps.state.ny.us

Regulatory Impact Statement

1. Statutory Authority: Section 202(1)(l) of the Real Property Tax Law (RPTL) authorizes the State Board of Real Property Services to adopt such rules "as may be necessary for the exercise of its powers and the performance of its duties."

Section 318(4) of the RPTL provides that "travel and other actual and necessary expenses" incurred by an assessor in satisfactorily completing required training "shall be a state charge upon audit by the comptroller".

Section 1530(3)(f) provides reimbursement of necessary and actual expenses incurred by directors of county real property tax services agencies.

Chapter 53 of the Laws of 2004, at page 592, provides an appropriation for training reimbursement of \$350,000.

2. Legislative Objectives: Payment of expenses of assessors who satisfactorily complete required training.

3. Needs and Benefits: Section 318(4) RPTL provides that "travel and other actual and necessary expenses" incurred by an assessor in satisfactorily completing required training "shall be a state charge upon audit by the comptroller." Section 1530(3)(f) contains similar language providing reimbursement of necessary and actual expenses incurred by directors of county real property tax services agencies. The office of Real Property Services (NYSORPS) receives an annual appropriation to satisfy this obligation. The appropriation of \$300,000 in Chapter 53 of the Laws of 2002 was accompanied by the language "the amount appropriated herein shall represent fulfillment of the state's obligation for this purpose". In other words, irrespective of the categorical language of sections 318 and 1530, the Legislature capped reimbursement expenditures at \$300,000. Based upon past experience, NYSORPS feared that the 2002-2003 appropriation might be insufficient.

The State Board of Real Property Services adopted a proposal establishing a delayed payment system with a possible proration of payments if an annual appropriation was insufficient that is contained in 9 NYCRR 188-2.9(f). Briefly one-half of the annual appropriation is allocated to the first third of the State fiscal year (April 1 to July 31), one-third to the second third of the State fiscal year (August 1 to November 30) and one-sixth to the last third (December 1 to March 31). Throughout the year, basic training, which was deemed to be of a higher importance, is paid as vouchers are received. Vouchers for continuing education received in the first third are held until August 31. If the remainder of the first allotment is sufficient, all continuing education vouchers are paid in full and any surplus is added to the second allotment. If the remainder or "net" allotment is insufficient, a pro-ration factor is calculated. This factor is the net allotment divided by the total of vouchers. The factor is applied to each voucher so that each individual would receive the same percentage of the voucher submitted. To insure the effectiveness of the process, the rules contain a requirement that vouchers be submitted within thirty days of the completion of training.

This process functioned as intended in the face of a slight shortfall in fiscal 2002-2003. In fiscal 2003-2004, the appropriation was increased to \$350,000. At the end of that fiscal year, a surplus of \$50,087.28 remained. In other words, reimbursement remained about the same, but the increased appropriation removed the pressure of a possible shortfall. This proposal addresses an issue that has been raised by local officials. As noted, the

proration process adopted in 2002 also included a thirty-day submission requirement. Local officials that have missed the requirement, often with good reason, have been denied reimbursement. At the same time, the increased appropriation has left a surplus at the end of the fiscal year. For example, in fiscal 2003-2004, with the \$50,000 surplus, \$2,310.04 in vouchers was denied for late filing. In 2004-2005, NYSORPS has so far denied \$2,836.02 in vouchers. The agency expects a surplus far in excess of this amount.

This proposal would address this situation by allowing payment of late vouchers out of any surplus that might occur. The status of the appropriation and late vouchers would be reviewed after the last date for submitting vouchers (which would be around May 1). This review would take place by June 1. If there is no surplus, no late vouchers would be paid. If the surplus is large enough, all vouchers would be paid. If the surplus is insufficient, payments would be prorated.

4. Costs: (a) To State Government: An amount estimated at between \$5,000 and \$10,000.

(b) To local governments: None.

(c) To private regulated parties: None. There are no private regulated parties in this program.

(d) Basis of cost estimates: The amount of untimely vouchers submitted in the last two years.

5. Local Government Mandates: None. The initial submission of a voucher is discretionary.

6. Paperwork: None. The proposal only affects vouchers that have already been submitted.

7. Duplication: There are no comparable State or Federal requirements.

8. Alternatives: Continued failure to pay untimely submissions.

9. Federal Standards: There are no Federal regulations concerning this subject.

10. Compliance Schedule: None.

Regulatory Flexibility Analysis

The amendment proposed would not impose any adverse economic conditions or any reporting, recordkeeping or other compliance requirements on small businesses. The rule imposes no additional recordkeeping or reporting requirements on local governments. The rule allows for payment, if funds are available at the end of the State fiscal year, of submitted vouchers that were not timely. The rule would only affect those local governments in which assessors sought reimbursement of expenses but did not file vouchers in a timely manner. The rule imposes no additional requirements. The rule does not require any additional expense for compliance.

Rural Area Flexibility Analysis

A rural area flexibility analysis is not required for this rule making because the amendment would not impose any adverse economic conditions, any reporting, recordkeeping or compliance requirements on public or private entities in rural areas. It provides for payment of vouchers from assessors seeking reimbursement of training expenses that were not filed within the existing timing requirement if funds remain from the annual appropriation. The new provision applies to all assessing units. It is intended to benefit all assessing units, including those in rural areas, by providing reimbursement that would not otherwise be available.

Job Impact Statement

A job impact statement is not required for this rule making because the amendment only concerns reimbursement of municipal assessors for training expenses. The amendments thus has no impact on employment opportunities.

Temporary State Commission on Lobbying

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

Adjudicatory Hearing Procedures

I.D. No. TCL-19-05-00001-P

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

Proposed action: This is a consensus rule making to add Part 250 to Title 21 NYCRR.

Statutory authority: Legislative Law; Consolidated Laws, ch. 32, art. 1-A; Lobbying Act, section 1-p, 1-q

Subject: Adjudicatory hearing procedures held pursuant to the New York State Lobbying Act.

Purpose: To establish hearing procedures compatible with Federal and State constitutions and law.

Text of proposed rule: Part 250

Violations, Hearings and Penalties.

A. Violations of the Lobbying Act

The following acts by any lobbyist, public corporation or client are violations of the Lobbying Act:

1. The knowing and willful failure to file a complete and accurate statement of registration, bi-monthly or semi-annual report, or any amendment thereto, within the time required.

2. The knowing and willful offering or giving a gift with a value exceeding \$75 to a public official.

3. The knowing and willful filing of a false statement or report required to be filed.

B. Penalties

Violations of the Lobbying Act can subject an individual or entity to both civil and criminal penalties, as set forth in the Act. The Commission's direct enforcement authority is limited to the imposition of civil penalties, as set forth in the Lobbying Act. Upon a finding that a violation of the Act has occurred, the Commission may refer its finding to the appropriate law enforcement official, in addition to imposing a civil penalty.

1. Civil Penalties

(a) Up To \$25,000 The knowing and willful failure to file a statement of registration, bi-monthly or semi-annual report within the time required or the knowing and willful offering or giving a gift with a value exceeding \$75 to a public official will subject the violator to a civil penalty not to exceed \$25,000, per violation.

(b) Up To \$50,000 The knowing and willful filing of a false statement will subject the violator to a civil penalty not to exceed \$50,000, per violation.

(c) Hearing Required The Commission may assess a civil penalty only after conducting a hearing at which that party charged shall be entitled to appear, present evidence and be heard. The procedures governing such hearings are set forth below in subsection C of this section.

2. Criminal Sanctions

(a) Class A Misdemeanor Any lobbyist, public corporation or client who knowingly and willfully fails to file a timely statement or report, files false information, or offers or gives a gift with a value exceeding \$75 to a public official shall be guilty of a Class A misdemeanor.

(b) Class E Felony Any lobbyist, public corporation or client who knowingly and willfully commits a violation after having previously been convicted of a violation in the preceding five years shall be guilty of a Class E felony.

C. Hearing Procedures

1. Preliminary Findings

If, after an investigation, Commission staff finds a basis for believing that any lobbyist, public corporation or client has failed to register and report as required by the Lobbying Act, or has filed a false report, or has offered or given a gift with a value exceeding \$75 to a public official, staff shall make a recommendation to the Commissioners at a public meeting to refer such lobbyist, public corporation or client to a hearing.

If, upon review of the information presented by staff, a majority of the Commissioners does not agree with the staff recommendation, the Commission may decide that the matter shall be closed, or may decide to refer the matter back to staff for further inquiry. Any matter referred back to Commission staff for further inquiry, and any closed matter in which further information is obtained or which Commission staff decides should be reopened for any other reason, may again be presented to the Commissioners at a public meeting for referral to a hearing.

If, upon review of the information presented by staff, a majority of the Commissioners agrees with the staff recommendation and determines that there is reasonable cause to believe that a violation of the Lobbying Act has occurred, the Commissioners shall direct that the matter be referred to a hearing and a notice of reasonable cause shall be sent to the lobbyist, public corporation or client.

2. Notice of Reasonable Cause

Written notice of reasonable cause to believe that a violation of the Lobbying Act has occurred shall be sent by certified and first-class mail to

the subject lobbyist, public corporation or client and shall contain the following:

(a) The date, time and place of the hearing.

(b) Notice of the nature of the alleged violation upon which the notice of reasonable cause is based and notice of intent to assess a penalty if cause is found after a hearing.

(c) Notice of the lobbyist, public corporation or client's right to be represented, to testify, to produce witnesses, to present documentary evidence, and to examine opposing witnesses and evidence at the hearing.

(d) A statement for hearing impaired parties and participants concerning the provision of deaf interpretation without charge.

(e) Information concerning circumstances under which an adjournment may be granted and the result of failure to appear for a scheduled hearing.

3. Presiding Officer

Any member of the Commission may serve as the presiding officer at the hearing. At the outset of the hearing, the Chairman of the Commission, or in his or her absence the Vice-Chairman, shall designate which member of the Commission shall serve as the presiding officer.

4. Record

While not required by the Lobbying Act to do so, the Commission shall make a record of all hearings using whatever means it deems appropriate, including but not limited to the use of stenographic transcriptions or electronic recording devices. Upon request by any party to the hearing, the Commission will, within a reasonable time, furnish a copy of the transcript or recording of the hearing upon payment to the Commission of its cost for the preparation and furnishing of such transcript or recording.

5. Representation

Any person compelled to appear in person or who voluntarily appears at any Commission hearing herein has the right to be accompanied, represented and advised by counsel. In addition, counsel for any party subject of a hearing may appear on the subject party's behalf, but may only testify with regard to matters about which he or she has personal knowledge.

6. Evidence and Proof

The formal rules of evidence shall not apply to hearings conducted by the Commission. Objections to evidentiary offers may be made and shall be a part of the record. The burden of proof shall be on the party initiating the hearing. Any party may, for the purpose of expediting the hearing, and when the interests of the parties will not be substantially prejudiced thereby, submit all or part of the evidence in written form, with copies provided to the opposing party, with copies to the opposing party. Each party shall have the right of cross examination. The presiding officer may exclude irrelevant or unduly repetitive evidence or cross examination from any hearing. Official notice may be taken of all facts of which judicial notice could be taken and of other facts within the specialized knowledge of the Commission. When official notice is taken, every party shall be given notice thereof and shall on timely request be afforded an opportunity prior to decision to dispute the fact or its materiality.

7. Oaths

Oaths shall be administered to all witnesses who testify or appear at a Commission hearing. All oaths may be taken before any person authorized to administer oaths within the State of New York.

8. Decision after Hearing Upon hearing all the evidence and arguments presented, the Commission shall determine if there has been a violation of the Act. No decision shall be made except upon consideration of the record as a whole or such portion thereof as may be cited to by any party to the hearing and as supported by and in accordance with substantial evidence. If the Commission finds that a violation has occurred, it shall determine the appropriate penalty to be imposed.

All final decisions of the Commission shall be in writing and shall include findings of fact, conclusions of law, and, if a penalty is imposed, the amount of the penalty and the reason(s) therefor.

The Commission shall mail by certified mail to each party to the hearing and to its representatives of record a copy of all final decisions.

9. Judicial Review

Any determination that a party has violated the Lobbying Act shall be subject to review in a proceeding commenced under Article 78 of the Civil Practice Law and Rules.

Section 73 of the Civil Rights Law

The Commission hereby incorporates into its hearing procedures all requirements and protections that Section 73 of the New York Civil Rights Law provides for parties or witnesses who appear before the Commission.

Text of proposed rule and any required statements and analyses may be obtained from: Kristen Thompson, Public Information Officer, New

York Temporary State Commission on Lobbying, Two Empire State Plaza, Suite 1701, Albany, NY 12223-1254, (518) 474-7126, e-mail: LOBCOM@attglobal.net

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

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

Consensus Rule Making Determination

This rule is proposed so as to ensure personal legal and constitutional rights for those appearing before the New York Temporary State Commission on Lobbying. This proposal formally memorializes these rights and no one should find this proposal objectionable.

Job Impact Statement

The rule proposed will not have a substantial adverse effect on jobs or employment opportunities. The proposed rule creates constitutionally and judicially required hearing procedures that have no adverse affect whatsoever on employment job opportunities.

Thruway Authority

NOTICE OF ADOPTION

Vehicle Classifications and Toll Rate Adjustment

I.D. No. THR-07-05-00008-A

Filing No. 440

Filing date: April 26, 2005

Effective date: May 15, 2005

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

Action taken: Amendment of sections 101.1 and 101.3; repeal of section 101.2; and addition of new section 101.2 to Title 21 NYCRR.

Statutory authority: Public Authorities Law, sections 354, subs. 5, 8 and 15 and 361, subd. 1; and Vehicle and Traffic Law, section 1630

Subject: Vehicle classifications and toll rate adjustment.

Purpose: To simplify the classification schedule for vehicles; reduce the number of vehicle types requiring classification from 43 to 9 and increase toll rates.

Substance of final rule: The Proposed Rule simplifies the current vehicle classification system to reduce the number of vehicle types requiring classification from 43 to 9 and provides that toll rates on the controlled system and the tolls at fixed barriers shall be increased by a rate of 25% for passenger vehicles and 35% for commercial vehicles.

Final rule as compared with last published rule: Nonsubstantive changes were made in section 101.2(b), (d), (e), (f)(1), (2) and (2)(ii).

Text of rule and any required statements and analyses may be obtained from: J. Marc Hannibal, New York State Thruway Authority, 200 Southern Blvd., Albany, NY 12209, (518) 436-2876, e-mail: marc_hannibal@thruway.state.ny.us

Additional matter required by statute: Pursuant to art. 8 of the Environmental Conservation Law and Part 617 of the implementing regulations pertaining thereto, the board of the New York State Thruway Authority determined as of April 25, 2005 that notice of determination of non-significance in relation to a negative declaration in connection with the SEQRA unlisted action, that being the adoption of revised toll schedules and the simplification of a vehicle classification system, should be published herewith. A copy of the negative declaration is on file at the offices of the New York State Thruway Authority located at 200 Southern Blvd., Albany, NY 12209 and may be obtained by contacting John Brizzell, Chief Engineer at (518) 436-2811.

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

The rule as adopted contains nonsubstantial revisions. These revisions do not necessitate that a revised Regulatory Impact Statement, revised Regulatory Flexibility Analysis for Small Businesses and Local Governments, revised Rural Area Flexibility Analysis, or revised Job Impact Statement be issued.

Assessment of Public Comment

The following summarizes comments raised by trucking interests during the public hearings held in Syracuse, Albany, Suffern and Buffalo. Several trucking interests prepared and presented comments at all four hearings. Comments addressing farming and dairy industry concerns are also addressed herein. These comments are summarized under the commentator's name rather than the location of the hearing. Additionally, this memorandum discusses identifiable comments of localized and legislative interest raised during the public hearings.

I. Bill Joyce - Motor Truck Association

Mr. Joyce stated that the significant toll increase for commercial vehicles will result in diversion of trucks to non-toll roads. Such a diversion will result in increased congestion along rural roads, through rural communities and also reduce the Thruway Authority's revenues. Mr. Joyce continued by stating that trucks represent 16 percent of the volume, but 40 percent of the revenue for the toll system, and only a small number of diverted trucks will seriously impact the revenue of the Thruway Authority. Mr. Joyce commented that the Vollmer Associates' Environmental Assessment Report "grossly underestimated" the risk of diversion and that the truck diversions would be long-term, requiring Authority to scale back its Capital Plan. Mr. Joyce commented that the variances both in the amounts and percentages of tolls between passenger vehicles and trucks will grow significantly if the proposed adjustments are implemented. He raised several concerns regarding the E-ZPass discounts, asking why passenger vehicle E-ZPass discounts are 10 percent and the commercial vehicle E-ZPass discount is only 5 percent?

Response (comment 1): As a result of the public comments, the Thruway Authority has revised the toll adjustment numbers which will reduce the proposed tolls to a 35% increase for a majority of the 48 foot vehicles that were originally increasing anywhere from 56% to 120%. This reduction will be provided through a special additional E-ZPass discount available to certain commercial vehicles, providing incentives for trucks to use the E-ZPass system. Further, the volume discount for commercial charge account customers using E-ZPass will be adjusted and phased in over a two year period, thus making the effective raise in toll rates 13.5% in 2005 and approximately 20.7% in 2006. The use of E-ZPass has both economic and environmental benefits by reducing queuing and idle times at toll barriers and plazas throughout the Northeast United States. The revised adjustments will help ensure that diversion onto alternative routes is kept to a minimum.

During the Albany public hearing, Mr. Joyce provided positive comments and stated that truckers support construction and maintenance of roads and bridges. However, Mr. Joyce stated that the toll users should not bear the cost of funding the canal system, I-84 and I-287. He recommends divesting the Canal, I-84 and I-287. Response (comment 2): By New York State statute, the Thruway cannot impose tolls on Interstate 84 and Interstate 287. Neither can the Thruway divest itself of its responsibilities over the Canal System, I-84 and I-287.

Mr. Joyce further questioned why nothing in the Capital Plan addressed the Tappan Zee Bridge replacement. He stated that it is the Motor Truck Association's fear that another toll increase may occur before the Tappan Zee Bridge project is even completed. Response: The Tappan Zee Bridge project is in the planning stage. There is no approved project at this time.

Mr. Joyce commented that the differential (25% to 35%) between cars and trucks is rationalized because trucks cause more damage. Mr. Joyce objects to that justification. There is already a differential built into the base rate. Mr. Joyce, continued by stating that "the 35 percent [increase] is not a bad percentage. . ." Response: See comment 1 and comment 2.

21 other speakers voiced Trucking/Transportation concerns that provided similar comments.

II. Fred Harrington – New York Farm Bureau (Buffalo hearing); Bruce Krupke – New York State Dairy Foods, Incorporated (Syracuse hearing); Gary Latta – Crowley Foods (Syracuse hearing); Senator Velmonette Montgomery (Albany hearing)

Representatives from New York's farm and dairy industries objected to the commercial toll increase because farmers use commercial transport to get crops to markets or to buyers for processing; and for obtaining raw materials needed to produce crops. The costs of transportation are borne by farmers. Vehicle classification causes the costs for a commercial toll increase to be significantly higher than the proposed 35%. Dairy farming concerns indicated that the retail price for milk products has been set monthly by legislative action and the cost is based upon the price that milk companies pay to dairy farmers. The cost of tolls is not included in that calculation. Dairy farmers who produce milk have to pay the transportation costs of bulk trucking companies to get raw milk to milk plants each day for processing. These costs are passed along to dairy farmers. Processed

milk is transported to schools and markets by trucking companies and the increased costs will have to be passed along to school districts and markets. The inability of dairy farmers and dairy industry concerns to readily pass along these costs will have a negative impact on the farming industry, rural communities and the dairy concerns that serve New York state. The costs associated with the proposed increase will have an impact on New York City consumers of fresh farm produce supplied by the green market farmer industry. The increased tolls will have an impact on the prices paid for goods by individual citizens and the restaurant industry in New York City.

Response: (See comment 1) By adding the additional discounts and phasing in the increase for the eligible commercial charge account customers, the Authority intends to address the concerns of the general trucking industry, which will also mitigate the impact of a toll adjustment on the state's agricultural industry and dairy concerns.

8 other Farming/Agricultural/Dairy Concerns that voiced similar opinions:

III. Localized Concerns in Syracuse Area

Robert Green, Mayor of Skaneateles, NY:

The mayor is opposed to the proposed increase because it will force trucks to divert from the Thruway onto Route 20 and Route 41 as a shortcut between the Thruway and Route 81. The Regulatory Flexibility Analysis for Small Business and Local Governments failed to address the impacts associated with diversion and a more comprehensive analysis should be prepared prior to any action by the Thruway Board.

Response: Reports show that trucks use this route to save mileage, not tolls.

Other citizens of Skaneateles raised concerns regarding an increase in garbage truck traffic and that incentives should be done to keep these trucks on the Thruway.

Response: See comment 1.

IV. Localized Concerns in Suffern Area

Sheila Conroy:

Conditional approval – Ms. Conroy would like to see the funds benefit the traveling conditions of those who are paying the tolls, including dedicating some of the funds to the Thruway interchange areas.

Sean Matthews, Rockland County Executive's Office:

Mr. Matthews felt the toll increase represented a burden for Rockland County residents; tolls should be waived for County Power Transit, Trips Program and Tappan Zee Trucks Express at the Springtown and Tarrytown toll plaza. Funds should be allocated to provide congestion relief throughout Rockland County.

Response to each Suffern local comment: Bond covenants preclude using toll revenues on non-thruway projects.

V. Localized Concerns in Buffalo Area

In Buffalo, the local concerns were primarily voiced by those organizations and individuals in opposition to the collection of tolls within the commuting area. There was significant testimony that the tolls at Lackawanna and Williamsville as well as at Breckenridge Bridge and South Ogden Street are a burden to the local citizenry and an impediment to local business. Removal of tolls was widely proposed.

Dave Swarts (Erie County Clerk)

Suggested providing free commuter passes for local residents using I-190 to get to work in the City of Buffalo.

Councilwoman Kathy Hochul (Hamburg Town Council)

Move the Lackawanna toll barrier west to beyond Exit 57A.

Luke Rich, The Buffalo/Niagara Partnership

Offered qualified support for a toll increase, while joining in the local concern about the commuter toll issue.

5 other speakers voiced similar views.

Response: Bond covenants preclude free passage except in limited circumstances.

VI. Localized Concerns in Albany Area

Assemblyman Paul Tonko:

Mr. Tonko found that tax policies, energy policies and other state decisions had hurt this community. A toll adjustment at this time would kill jobs. He advocated for a graduated plan of toll increases.

Response: (See comment 1) By adding the additional discounts and phasing in the increase for the eligible commercial charge account customers, the Authority intends to address the concerns of the general trucking industry, which will also mitigate the impact of a toll adjustment on the state's agricultural industry and dairy concerns.

Additional Legislative Comments:

Assemblyman Daniel Burling:

Expressed concern about traffic on Rte. 63 and advocated rethinking the toll structure for large commercial trucks to keep them on the Thruway. Response: (See comment 1).

Assemblyman Kevin Cahill, and Assemblyman David Koon:

Requested that the Authority hold an additional hearing in Ulster County and Rochester, respectively. Response: Hearing dates were scheduled prior to the date of his request and were published in accordance with SAPA and PAL § 2804. Extensive comments were taken and information concerning the proposed action was available in certain public libraries and published on the Authority's website. Assemblyman Koon cited questions concerning Comptroller comments on Authority management and also questioned the timing of the increase and its impact on business and the traveling public. Response: See comment 1 concerning impact on business and the public and Assemblywoman Christensen response related to management issues.

Assemblywoman Joan Christensen:

Opposes toll increase and believes better management of available Thruway resources is the answer. Response: Last toll increase was in 1988. Authority has undergone continual cost containment, including 11% staff reductions since 1995, while undertaking additional responsibilities – Canal system, I-84 and I-287. Toll increase as proposed is less than 50% of cumulative rise in inflation since 1988. Toll adjustment as adopted is significantly less than inflation increase.

Assemblywoman Francine DelMonte:

Toll increase would cost the state jobs and impede economic development as a part of Governor's plan to increase taxes by raising tolls. Response: Thruway Authority is an independent public benefit corporation and the Board of the Authority sets the policies for the Authority and makes any decision on the need for a toll increase. The Authority has no taxing power and the user fees that are the tolls support the Thruway system.

Assemblywoman Roanne Destito/Assemblyman Brian Kolb/Senator Hugh Farley:

Expressed opposition due to fears that toll increases will hurt New York businesses. Suggests imposition of a volume discount to lessen impact on commercial trucking. Response: See comment 1.

Assemblyman Jack McEneny:

Expressed a desire that the Authority use a portion of toll revenues for noise abatement efforts. Response: The Capital Plan funds a number of noise abatement projects resulting from the Authority's Noise Barrier Prioritization Study.

Assemblyman Jack Quinn:

Expressed a desire to see the Lackawanna toll barrier moved to beyond the Erie county border.

Response: Capital plan includes study on open road tolling, but the Authority's bond covenants preclude removal of tolls from any section of the system that was subject to tolls when bonds were sold in 1988.

Senator William Stachowski:

Expressed desire to see removal of tolls or commuter pass in Buffalo; a study to look at moving the Lackawanna toll barrier and revenues used for noise abatement. Response: Capital plan includes study on open road tolling, but the Authority's bond covenants preclude removal of tolls from any section of the system that was subject to tolls when bonds were sold in 1988. Authority's noise abatement program has proposed four locations in the Buffalo area.

VII. Public Input

The public also sent e-mail, letters and phone calls. There were 30,089 hits to the Authority's website concerning the proposed toll adjustment. An additional 16,362 hits were recorded on the Authority's website toll calculator. There were 103 e-mails received by the Office of Public Affairs. While the majority (70) were in opposition to the toll increase, three were supportive and thirty opposed the toll increase but recognized that it was required. Likewise, 40 letters were recorded as received and of those, 5 were in support, 22 were solely in opposition and 13 saw the need but expressed opposition nonetheless. Four phone calls were logged in by the Authority and they were in opposition to the toll adjustment. Response: There were no suggestions that raised suitable alternatives to the toll increase.

Workers' Compensation Board

EMERGENCY RULE MAKING

Waiver Agreements

I.D. No. WCB-19-05-00002-E

Filing No. 434

Filing date: April 20, 2005

Effective date: April 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: Workers' Compensation Law, section 32, as amended L. 1996, ch. 635 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 Workers' Compensation Law, section 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.

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) 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 July 18, 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) 473-8626, e-mail: OfficeofGeneralCounsel@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. Workers' Compensation Law Section 117(1) further authorizes the Board to adopt reasonable rules consistent with 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 § 32, 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 agree-

ments 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 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.

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.