

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.)

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

Department of Agriculture and Markets

EMERGENCY RULE MAKING

Firewood (All Hardwood Species) and Other Host Tree Materials Susceptible to the Asian Long Horned Beetle

I.D. No. AAM-39-11-00002-E

Filing No. 805

Filing Date: 2011-09-07

Effective Date: 2011-09-07

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

Action taken: Repeal of section 139.2(c); and relettering of section 139.2(d) to 139.2(c) of Title 1 NYCRR.

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

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

Specific reasons underlying the finding of necessity: The rule, which will lift the Asian Long Horned Beetle (ALB) quarantine in the Town of Islip in Suffolk County, is being adopted as an emergency measure because after three comprehensive ALB surveys over various periods, the pest has not been detected in the Town since June 2002. The lifting of the quarantine at this time is consistent with existing scientific protocols, and will coincide with USDA's lifting of its quarantine in the Town of Islip. The Town includes the Villages of Bayshore, East Islip, Islip and Islip Terrace.

The Asian Long Horned Beetle, *Anoplophora glabripennis*, an insect

species non-indigenous to the United States, can cause serious damage to healthy trees by boring into their heartwood and eventually killing them. Nursery stock, logs, green lumber, firewood, stumps, roots, branches and debris of a half inch or more in diameter are subject to infestation. Host hardwood materials at risk to attack and infestation include species of the following: maple; horse chestnut; silk tree or mimosa; birch; poplar; willow; elm; hackberry, ash; katsura; plane tree, sycamore; and mountain ash. The pest was initially detected in the Greenpoint section of Brooklyn in August of 1996. Subsequent survey activities delineated other locations in Brooklyn as well as locations in and about Amityville, the Town of Islip, Queens, Manhattan and Staten Island. As a result, 1 NYCRR Part 139 was adopted, establishing a quarantine of the areas in which the Asian Long Horned Beetle had been observed. The boundaries of those areas are described in 1 NYCRR section 139.2. The lifting of the quarantine in the Town of Islip will ease regulatory burdens on nursery dealers, nursery growers, landscaping companies, transfer stations, compost facilities and general contractors as well as private citizens within that area, by allowing them to move ALB host materials from the Town, without the need for compliance agreements or phytosanitary certificates and incurring costs incident thereto. By lifting the quarantine in an area where ALB has not been detected since June 2002, the rule will ease burdens on regulated parties without compromising plant health, thereby preserving the general welfare. It will also conform the State quarantine to the federal quarantine, which was lifted in the Town of Islip on August 23rd.

Based on the facts and circumstances set forth above, the Department has determined that the immediate adoption of this amendment is necessary for the preservation of the general welfare and that compliance with subdivision one of section 202 of the State Administrative Procedure Act would be contrary to the public interest.

Subject: Firewood (all hardwood species) and other host tree materials susceptible to the Asian Long Horned Beetle.

Purpose: To lift the Asian Long Horned Beetle quarantine in the Town of Islip, since the pest has not been found since 2002.

Text of emergency rule: Subdivision (c) of section 139.2 of 1 NYCRR is repealed, and subdivision (d) of section 139.2 of 1 NYCRR is re-lettered subdivision (c).

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 December 5, 2011.

Text of rule and any required statements and analyses may be obtained from: Kevin S. King, NYS Department of Agriculture and Markets, 10B Airline Drive, Albany, New York 12235, (518) 457-2087

Regulatory Impact Statement

1. Statutory authority:

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

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

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

2. Legislative objectives:

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

3. Needs and benefits:

The Asian Long Horned Beetle, *Anoplophora glabripennis*, an insect species non-indigenous to the United States, can cause serious damage to healthy trees by boring into their heartwood and eventually killing them. Nursery stock, logs, green lumber, firewood, stumps, roots, branches and debris of a half inch or more in diameter are subject to infestation. Host hardwood materials at risk to attack and infestation include species of the following: Acer (Maple); Aesculus (Horse Chestnut), Albizzia (Silk Tree or Mimosa); Betula (Birch); Populus (Poplar); Salix (Willow); Ulmus (Elm); Celtis (Hackberry), Fraxinus (Ash); Cercidiphyllum japonicum (Katsura); Platanus (Plane tree, Sycamore) and Sorbus (Mountain Ash). The pest was initially detected in the Greenpoint section of Brooklyn in August of 1996. Subsequent survey activities delineated other locations in Brooklyn as well as locations in and about Amityville, the Town of Islip, Queens, Manhattan and Staten Island. As a result, 1 NYCRR Part 139 was adopted, establishing a quarantine of the areas in which the Asian Long Horned Beetle had been observed. The boundaries of those areas are described in 1 NYCRR section 139.2.

The lifting of the quarantine in the Town of Islip will ease regulatory burdens on nursery dealers, nursery growers, landscaping companies, transfer stations, compost facilities and general contractors as well as private citizens within that area, by allowing them to move ALB host materials from the Town, without the need for compliance agreements or phytosanitary certificates and incurring expenses incident thereto. By lifting the quarantine after three comprehensive surveys over various periods in an area where ALB has not been detected since June 2002, the rule will ease burdens on regulated parties without compromising plant health, thereby promoting the general welfare. It will also conform the State quarantine to the federal quarantine, which was lifted in the Town of Islip on August 23rd.

4. Costs:

(a) Costs to the State government: None. The Department may realize cost savings by no longer issuing phytosanitary certificates or compliance agreements.

(b) Costs to local government: The proposed amendment will not result in costs to local governments. In fact, there will be lower costs to the Town of Islip and the municipalities within the Town, since they will no longer incur expenses incident to obtaining phytosanitary certificates or compliance agreements in order to move host materials.

(c) Costs to private regulated parties: The rule will not result in costs to private regulated parties. In fact, there will be lower costs to private regulated parties, since they will no longer incur expenses incident to obtaining phytosanitary certificates or compliance agreements in order to move host materials.

(d) Costs to the regulatory agency:

(i) The initial expenses: None.

(ii) The ongoing expenses: None. The Department may realize cost savings by no longer issuing phytosanitary certificates or compliance agreements.

5. Local government mandate:

None. In fact, the Town of Islip and the villages located therein will no longer have to engage in the disposal of host materials. The Town of Islip currently maintains a waste wood disposal program at a cost of \$200,000 per year.

6. Paperwork:

None.

7. Duplication:

None.

8. Alternatives:

The only alternative considered was to leave the quarantine in place in the Town of Islip. This alternative was rejected, since leaving the Asian Long Horned Beetle quarantine in place where the pest has not been observed for three comprehensive surveys since June 2002, is inconsistent with existing scientific protocols and imposes an unnecessary burden on regulated parties. In light of this, the only viable alternative is to lift the quarantine in the Town of Islip. Additionally, lifting of the quarantine will conform the State quarantine to the federal quarantine, which was lifted in the Town of Islip on August 23rd.

9. Federal standards:

The USDA has a parallel Asian Long Horned Beetle quarantine in the Town of Islip, which was lifted on August 23rd.

10. Compliance schedule:

It is anticipated that regulated parties would be able to comply with the rule immediately.

Regulatory Flexibility Analysis

1. Effect on small business.

There are approximately 467 nursery dealers, nursery growers, land-

scaping companies, transfer stations, compost facilities and general contractors located within Suffolk County and potentially affected by the quarantine which would be lifted under this rule. Most of these entities are small businesses. Since the rule will lift the Asian Long Horned Beetle (ALB) quarantine in the Town of Islip, regulated businesses in the Town will be able to freely move regulated materials without the need for compliance agreements and phytosanitary certificates and without incurring costs incident thereto.

2. Compliance requirements.

None.

3. Professional services.

None.

4. Compliance costs:

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

(b) Annual cost for continuing compliance with the proposed rule: None. In fact, there will be lower costs to private regulated parties, since they will no longer incur expenses incident to obtaining phytosanitary certificates or compliance agreements in order to move host materials.

5. Minimizing adverse impact.

Since the rule will lift the ALB quarantine in the Town of Islip, the rule minimizes adverse impact since regulated parties in the Town of Islip will no longer be subject to the quarantine and the requirements incident thereto.

6. Small business and local government participation.

None.

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

The economic and technological feasibility of compliance with the rule by small businesses and local governments has been addressed and such compliance has been determined to be feasible. The basis for this determination is that by lifting the ALB quarantine, the rule actually eliminates a regulatory burden on small businesses and local governments in the Town of Islip.

Rural Area Flexibility Analysis

The rule will not impose any adverse impact or reporting, recordkeeping or other compliance requirements on public or private entities in rural areas. This finding is based upon the fact that the quarantine areas to which the amendments apply are not situated in "rural areas," as defined in section 481(7) of the Executive Law.

Job Impact Statement

It is anticipated that the rule will not have a substantial adverse impact on jobs and employment opportunities. In fact, by easing regulatory burdens and costs incident thereto, the lifting the Asian Long Horned Beetle quarantine in the Town of Islip may have a positive impact on jobs within the Town.

NOTICE OF ADOPTION

Definitions and Standards of Identity Relating to Milk and Milk Products

I.D. No. AAM-36-10-00004-A

Filing No. 806

Filing Date: 2011-09-07

Effective Date: 2011-09-28

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

Action taken: Amendment of sections 2.2(a), (gg)(1), (2), 17.12, 17.18, 17.19 and 17.20.

Statutory authority: Agriculture and Markets Law, sections 16, 18, 46, 46-a, 50-k, 71-a, 71-n and 214-b

Subject: Definitions and Standards of Identity relating to milk and milk products.

Purpose: To update the incorporations by reference contained in sections 2.2(a), (gg)(1), (2), 17.12, 17.18, 17.19 and 17.20.

Text or summary was published in the September 8, 2010 issue of the Register, I.D. No. AAM-36-10-00004-P.

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

Text of rule and any required statements and analyses may be obtained from: Casey McCue, Assistant Director, Division of Milk Control, NYS Department of Agriculture and Markets, 10B Airline Drive, Albany, New York 12235, (518) 457-1772

Assessment of Public Comment

The agency received no public comment.

NOTICE OF ADOPTION

Definitions, Standards of Identity and/or Standards of Enrichment, Packaging and Labeling Relating to Food and Food Additives

I.D. No. AAM-36-10-00005-A

Filing No. 807

Filing Date: 2011-09-07

Effective Date: 2011-09-28

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

Action taken: Amendment of Parts 250, 252 and 259; and sections 261.8, 262.1, 265.1, 266.1, 267.1, 271-4.7, 271-5.3(h), (j), 271-5.4(g), 272-2.1, 277.1, 279.1 and 280.1 of Title 1 NYCRR.

Statutory authority: Agriculture and Markets Law, sections 16(1), 18(2), (6), 214-b and 215-a

Subject: Definitions, Standards of Identity and/or Standards of Enrichment, packaging and labeling relating to food and food additives.

Purpose: To update the incorporations by reference contained in various Parts and sections of 1 NYCRR, relative to food and milk.

Text or summary was published in the September 8, 2010 issue of the Register, I.D. No. AAM-36-10-00005-P.

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

Text of rule and any required statements and analyses may be obtained from: Stephen D. Stich, Director, Div. of Food Safety and Insp., NYS Department of Agriculture and Markets, 10B Airline Drive, Albany, New York 12235, (518) 457-4492

Assessment of Public Comment

The agency received no public comment.

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

Incorporation by Reference in 1 NYCRR of the 2011 Edition of National Institute of Standards and Technology (“NIST”) Handbook 44

I.D. No. AAM-39-11-00003-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 220.2(a) of Title 1 NYCRR.

Statutory authority: Agriculture and Markets Law, sections 16, 18 and 179

Subject: Incorporation by reference in 1 NYCRR of the 2011 edition of National Institute of Standards and Technology (“NIST”) Handbook 44.

Purpose: To incorporate by reference in 1 NYCRR the 2011 edition of NIST Handbook 44.

Text of proposed rule: Subdivision (a) of section 220.2 of 1 NYCRR is amended to read as follows:

(a) Except as otherwise provided in this Part, the specifications, tolerances and regulations for commercial weighing and measuring devices shall be those adopted by the [93rd] 95th National Conference on Weights and Measures [2009] 2010 as published in the National Institute of Standards and Technology Handbook 44, [2009] 2011 edition. This document is available from the National Conference on Weights and Measures, [15245 Shady Grove Road, Rockville, MD 20850] 1135 M Street, Suite 110, Lincoln, NE 68508, or the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402. It is available for public inspection and copying in the office of the Director of Weights and Measures, Department of Agriculture and Markets, 10B Airline Drive, Albany, NY 12235, or in the office of the Department of State, One Commerce Plaza, 99 Washington Avenue, Suite 650, Albany, New York 12231.

Text of proposed rule and any required statements and analyses may be obtained from: Mr. Mike Sikula, New York State Department of Agriculture and Markets, 10B Airline Drive, Albany, New York 12235, (518) 457-3146, email: mike.sikula@agmkt.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

The proposed rule will amend 1 NYCRR section 220.2 to incorporate by reference the 2011 edition of National Institute of Standards and Technology Handbook 44 in place of the 2009 edition which is presently incorporated by reference.

The proposed rule is non-controversial. The 2011 edition of Handbook 44 has been adopted by or is in use in every state other than New York; the state’s manufacturers of weighing and measuring devices already, therefore, conform their operations to the provisions of this document in order to sell their products in interstate commerce. Furthermore, the state’s users of commercial weighing and measuring devices also already use devices that conform to the provisions of this document due to its nearly-nationwide applicability. The proposed rule will not, therefore, have any adverse impact upon regulated businesses and is, therefore, non-controversial.

Job Impact Statement

The proposed rule will not have an adverse impact on jobs or on employment opportunities.

The proposed rule will incorporate by reference in 1 NYCRR section 220.2 the 2011 edition of National Institute of Standards and Technology Handbook 44 (henceforth, “Handbook 44 (2011 edition)”) which contains specifications, tolerances and regulations for commercial measuring devices. The 2009 edition of Handbook 44 is presently incorporated by reference. Handbook 44 (2011 edition) differs from the 2009 edition in that it amends the scale code to incorporate advances in weighing technology; amends the water meter code to improve its accuracy; and adopts a hydrogen gas measuring devices code. Handbook 44 (2011 edition) has been adopted by or is in use in every state other than New York; the state’s manufacturers and users of weighing and measuring devices already, therefore, conform their operations to the provisions of this document in order to sell their products in interstate commerce.

The proposed rule will not, therefore, have any adverse impact upon jobs or employment opportunities.

Office of Children and Family Services

NOTICE OF ADOPTION

Child Care Market Rate Regulations

I.D. No. CFS-30-11-00009-A

Filing No. 818

Filing Date: 2011-09-13

Effective Date: 2011-10-01

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

Action taken: Amendment of section 415.9(j)(1); repeal of section 415.9(j)(3); and addition of new section 415.9(j)(3) to Title 18 NYCRR.

Statutory authority: Social Services Law, sections 20(3)(d), 34(3)(f), 410(1); and title 5-C

Subject: Child Care Market Rate Regulations.

Purpose: To revise the market rates in accordance with State and Federal requirements.

Text or summary was published in the July 27, 2011 issue of the Register, I.D. No. CFS-30-11-00009-P.

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

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

Assessment of Public Comment

The Office of Children and Family Services (OCFS) received one comment from a child care provider. The commentator stated that child care providers need to be reimbursed on a timely basis for registration fees, and when a child is absent from a child care program. The commentator also stated that she believed family day care providers and group family day care providers should be paid the same rate as day care centers. Additionally, the commentator stated that established neighborhood rates should be taken into consideration when determining the market rate and should be comparable to other existing neighborhood rates.

OCFS reviewed the comment, and determined after review that

reimbursement for registration fees and child absences are not addressed in this regulatory proposal, but are addressed in 05 OCFS ADM 03 and in Title 18 of the Official Compilation of Codes, Rules and Regulations of the State of New York section 415.6, respectively. Family and group family day care providers are each a separate legal entity and can only be reimbursed at their rates, not day care center rates. Finally, the market rates are based on a local market rate survey, which are analyzed and the rates from the survey are clustered into five district groupings of counties. Neighborhood groupings, if done statewide, would result in samples that were too small to be statistically representative of the specific modality of care, its duration, and the age of child being served. As a result, OCFS determined that no changes to the proposed regulations were required in response to this comment.

Division of Criminal Justice Services

PROPOSED RULE MAKING NO HEARING(S) SCHEDULED

Probation Management

I.D. No. CJS-39-11-00015-P

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

Proposed Action: Amendment of section 347.4 of Title 9 NYCRR.

Statutory authority: Executive Law, section 243(1)

Subject: Probation Management.

Purpose: To provide probation departments certain mandate relief with respect to probation management operations.

Text of proposed rule: Section 347.4 of Part 347 of Title 9 NYCRR is amended to read as follows:

(f) The recruitment, selection, and promotion of probation professional personnel shall be based on the "Standard Specifications for Professional Probation Positions" (Appendix H-10, *infra*), as promulgated by the [State Director] *Commissioner* of [Probation and Correctional Alternatives] *the Division of Criminal Justice Services* in cooperation with the *Office of Commission Operations and Municipal Assistance* [Services Division] of the New York State Department of Civil Service.

(h) Written statements of probation policies and procedures shall be developed and maintained with the involvement of all *appropriate* levels of employees.

(i) [All employees shall attend and participate in regular staff meetings, scheduled to insure effective and timely two-way communication regarding probation matters.

(j) An employee performance evaluation program shall be conducted.

(k) Periodic progress reports on probation operations shall be made to all staff, appropriate authorities and the public.

Text of proposed rule and any required statements and analyses may be obtained from: Linda J. Valenti, Assistant Counsel, NYS Division of Criminal Justice Services, 4 Tower Place, Albany, NY 12203, (518) 485-8413, email: linda.valenti@dcjs.state.ny.us

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

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

Regulatory Impact Statement

1. Statutory authority:

Pursuant to Chapter 56 of the Laws of 2010, the former Division of Probation and Correctional Alternatives (DPCA) was merged within the Division of Criminal Justice Services (DCJS) and is now the Office of Probation and Correctional Alternatives. Section 8 of Part A of this Chapter specifically transferred all rules and regulations of DPCA to DCJS and established that such shall continue in full force and effect until duly modified or abrogated by the Commissioner of DCJS. Additionally, section 17 of Part A of this Chapter amended Executive

Law Section 243(1) to make conforming changes and establish in pertinent part that the Commissioner of DCJS has authority to "adopt general rules which shall regulate methods and procedure in the administration of probation services..." so as to secure the most effective application of the probation system and the most effective enforcement of the probation laws throughout the state. "Such rules are binding with the force and effect of law. Consistent with this statutory language, there exists a rule governing Probation Management, specifically 9 N.Y.C.R.R. Part 347.

2. Legislative objectives:

These regulatory amendments are consistent with legislative intent to regulate the administration of probation functions and the promotion of professional standards which govern administration and delivery of probation services. The overarching goal of these amendments is to provide additional flexibility to probation departments with respect to certain routine business operations in an effort to provide mandate relief.

3. Needs and benefits:

With respect to the proposed regulatory changes governing probation management, these amendments are proposed pursuant to and consistent with Executive Order No. 17 which led to the former DPCA preparing an initial Internal Rule Review Findings, receiving feedback from probation departments and other statewide professional associations as to proposed regulatory changes that would afford them operational relief, and finalizing agency recommendations. There was overwhelming favorable support for the proposed regulatory changes in the area of probation management. The proposed amendments will better assist probation management in carrying out its day-to-day operations. It will afford them with relief in no longer requiring all levels of employees to be involved in the development of policy and procedures but rather appropriate levels of employees. Further, it removes the requirement that all agency staff must attend and participate in regular staff meetings and delete reference to an employee performance evaluation program be conducted. These changes acknowledge that more flexibility should be afforded to probation departments in this area to maximize staff efficiencies and address time demands and that such rigid standards are not necessary, but rather ought to take into consideration local needs, resources, and practices.

Additionally, technical changes have been made to reflect the merger and update other language with respect to the New York State Department of Civil Service.

4. Costs:

The proposed amendments will streamline certain probation management operations. It will not result in increased costs, and may in fact result in minor cost efficiencies as all staff will not need to be involved in meetings and development of agency policies and procedures. While the proposed rule removes certain language as to employee performance evaluations and reference as to all employees attending and participating in regular staff meetings, cost efficiencies will vary depending on each probation department's reexamination of their respective management operations, including staffing resources, personnel requirements and service delivery needs to ensure the effective administration of its probation department operations.

5. Local government mandates:

The proposed amendments will provide local probation departments certain mandate relief with respect to probation management operational requirements. Proposed regulatory changes better allow local probation management to engage in administrative activities in accordance with local practice and available resources.

6. Paperwork:

No additional paperwork is necessary for implementation of these proposed rule changes.

7. Duplication:

These amendments do not duplicate any State or Federal law or regulation.

8. Alternatives:

As probation management is at the core of ensuring that probation departments effectively carry out probation functions, programs and

services pursuant to laws, policies and rules, it is not a viable alternative to have no rule in this area.

With respect to the proposed regulatory changes governing probation management, pursuant to Executive Order No. 17, the former DPCA prepared an initial Internal Rule Review Findings in October 2009 of all of its rules and regulations and disseminated these findings to all probation departments, the Council of Probation Administrators (COPA) (which is the statewide professional association of probation directors), the New York State Probation Officers Association (NYSPOA), the New York State Association of Counties (NYSAC), the State Probation Commission, and the Division of the Budget (DOB). Additionally, DPCA convened an October 26, 2009 meeting in Albany which over a dozen probation departments (representative of urban, suburban, and rural counties), COPA and NYSPOA Presidents, NYSAC, and DOB representatives attended and where DPCA staff went over all rules and regulations and reviewed them individually, discussed proposed regulatory changes, and solicited feedback from the audience. DPCA received overwhelming favorable support for the proposed regulatory changes in the area of probation management.

9. Federal standards:

There are no federal standards governing probation management.

10. Compliance schedule:

Through prompt dissemination to staff of the proposed amendments, local departments should be able to promptly implement these amendments and comply with its provisions. These regulatory amendments shall take effect as soon as they are published in the State Register under a Notice of Adoption.

Regulatory Flexibility Analysis

1. Effect of Rule:

The proposed rule amendments revise existing regulatory procedures in the area of Probation Management.

The proposed amendments will better assist probation management in carrying out its day-to-day operations. It will afford them with relief in no longer requiring all levels of employees to be involved in the development of policy and procedures but rather appropriate levels of employees. Further, it removes the requirement that all agency staff must attend and participate in regular staff meetings and delete reference to an employee performance evaluation program be conducted. These changes acknowledge that more flexibility should be afforded to probation departments in this area to maximize staff efficiencies and address time demands and that certain state regulatory standards are not necessary, but rather ought to take into consideration local needs, resources, and practices. Additionally, technical changes have been made to reflect the merger and update other language with respect to the New York State Department of Civil Service.

Overall, the proposed amendments will provide local probation departments certain mandate relief with respect to probation management operational requirements. Proposed regulatory changes better allow local probation management to engage in administrative activities in accordance with local practice and available resources.

No small businesses are impacted by these proposed regulatory amendments.

2. Compliance Requirements:

Local probation departments should have no problem in complying with the proposed regulatory changes as they afford mandate relief. Through prompt dissemination to staff of the proposed amendments, local departments will be able to promptly implement these amendments and readily comply with its provisions. These regulatory amendments shall take effect as soon as they are published in the State Register under a Notice of Adoption.

There are no small business compliance requirements imposed by these proposed rule amendments.

3. Professional Services:

No professional services are required upon probation departments to comply with the proposed rule changes.

There are no professional services required of small business associated with these proposed rule amendments.

4. Compliance Cost:

Proposed changes provide greater flexibility and therefore probation departments will not incur any compliance costs. Depending upon what changes local probation departments may make in these reformed regulatory areas, some may realize cost savings or at a minimum improved efficiencies. The proposed amendments will streamline certain probation management operations. While the proposed rule removes certain language as to employee performance evaluations and reference as to all employees attending and participating in regular staff meetings, and provides additional latitude with respect to staff involvement in development of policy and procedure, cost efficiencies will vary depending on each probation department's reexamination of their respective management operations, including staffing resources, personnel requirements and service delivery needs to ensure the effective administration of its probation department operations.

5. Economic and Technological Feasibility:

There are no economic or technological issues or problems arising from these proposed regulatory reforms in this area.

6. Minimizing Adverse Impacts:

DCJS foresees that these regulatory amendments will have no adverse impact on any local government. As noted in more detail below, the former Division of Probation and Correctional Alternatives (DPCA), now the Office of Probation and Correctional Alternatives within DCJS pursuant to Chapter 56 of the Laws of 2010, collaborated with jurisdictions across the state, including rural areas, and probation professional associations with rural membership in soliciting feedback as to the proposed regulatory changes in order to provide sound probation mandate relief. The proposed changes afford greater flexibility in current regulatory requirements with respect to probation management operations consistent with public safety and good professional practice.

As the probation management rule does not impact upon small businesses, the proposed changes have no negative impact upon small business operations.

7. Small Business and Local Government Participation:

With respect to the proposed regulatory changes governing probation management, pursuant to Executive Order No. 17, the former DPCA prepared an initial Internal Rule Review Findings in October 2009 of all of its rules and regulations and disseminated these findings to all probation departments, the Council of Probation Administrators (COPA) (which is the statewide professional association of probation directors), the New York State Probation Officers Association (NYSPOA), the New York State Association of Counties (NYSAC), the State Probation Commission, and the Division of the Budget (DOB). Additionally, DPCA convened an October 26, 2009 meeting in Albany which over a dozen probation departments (representative of urban, suburban, and rural counties), COPA and NYSPOA Presidents, NYSAC, and DOB representatives attended and where DPCA staff went over all rules and regulations and reviewed them individually, discussed proposed regulatory changes, and solicited feedback from the audience. The Director of Probation and Correctional Alternatives has communicated that there was overwhelming favorable support for the proposed regulatory changes in the area of probation management.

As this rule does not impact upon small businesses, there was no business involvement with respect to the proposed regulatory changes.

Rural Area Flexibility Analysis

1. Types and estimated numbers of rural areas:

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

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

The proposed regulatory changes impose no new reporting, record keeping, other compliance requirements nor any professional services with respect to probation management operations. Rural counties will benefit from the proposed regulatory changes as it will afford their respective probation departments greater flexibility in managing probation operations consistent with local practice and resources.

3. Costs:

The proposed amendments will streamline certain probation management operations. It will not result in increased costs, and may in fact result in minor cost efficiencies as all staff will not need to be involved in meetings and development of agency policies and procedures. While the proposed rule removes certain language as to employee performance evaluations and reference as to all employees attending and participating in regular staff meetings, cost efficiencies will vary depending on each probation department's reexamination of their respective management operations, including staffing resources, personnel requirements and service delivery needs to ensure the effective administration of its probation department operations.

4. Minimizing adverse impact:

DCJS foresees that these regulatory amendments will have no adverse impact on any jurisdiction, including rural areas. As noted in more detail below, the former Division of Probation and Correctional Alternatives (DPCA), now the Office of Probation and Correctional Alternatives within DCJS pursuant to Chapter 56 of the Laws of 2010, collaborated with jurisdictions across the state, including rural areas, and probation professional associations with rural membership in soliciting feedback as to the proposed regulatory changes in order to provide sound probation mandate relief. The proposed changes afford greater flexibility in current regulatory requirements with respect to probation management operations consistent with public safety and good professional practice.

5. Rural area participation:

With respect to the proposed regulatory changes governing probation management, pursuant to Executive Order No. 17, the former DPCA prepared an initial Internal Rule Review Findings in October 2009 of all of its rules and regulations and disseminated these findings to all probation departments, the Council of Probation Administrators (COPA) (which is the statewide professional association of probation directors), the New York State Probation Officers Association (NYSPOA), the New York State Association of Counties (NYSAC), the State Probation Commission, and the Division of the Budget (DOB). Additionally DPCA convened an October 26, 2009 meeting in Albany which over a dozen probation departments (representative of rural, urban, and suburban counties), COPA and NYSPOA Presidents, NYSAC, and DOB representatives attended and where DPCA staff went over all rules and regulations and reviewed them individually, discussed proposed regulatory changes, and solicited feedback from the audience. The Director of Probation and Correctional Alternatives has communicated that there was overwhelming favorable support for the proposed regulatory changes in the area of probation management from rural, urban, and suburban jurisdictions.

Job Impact Statement

A job impact statement is not being submitted with these proposed regulations because it will have no adverse effect on private or public jobs or employment opportunities. The revisions are procedural in nature. Specific changes modify and/or eliminate certain regulatory language to provide local probation departments more flexibility regarding staff meeting attendance, performance evaluations, and staff input as to development of policies and procedures. These amendments recognize that local probation management can engage in these activities in accordance with local practice and available resources.

Department of Economic Development

EMERGENCY RULE MAKING

Economic Transformation and Facility Redevelopment Program

I.D. No. EDV-39-11-00004-E

Filing No. 808

Filing Date: 2011-09-08

Effective Date: 2011-09-08

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

Action taken: Addition of Parts 200 - 204 to Title 5 NYCRR.

Statutory authority: Economic Development Law, art. 18

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

Specific reasons underlying the finding of necessity: Regulatory action is needed immediately to implement the Economic Transformation and Facility Redevelopment Program ("the Program") which was created by Chapter 61 of the Laws of 2011. The Program is created to support communities affected by the closure of correctional and juvenile justice facilities. The Program will provide tax credits to firms that create jobs and make investments in certain areas designated as economic transformation areas. The Program will leverage private sector job creation and investments and help transform the economies of the communities in these areas and lessen the impact of the facility closures.

New York is in the midst of a national economic slowdown. The impact of the national financial crisis and resulting slowed economic growth was particularly devastating to New York State and could be even more severe for those communities where correctional and juvenile justice facilities will be closed.

The Economic Transformation and Facility Redevelopment Program will be a key economic development tool for creating jobs and private sector investment in communities affected by the facility closures. It is imperative that this Program be implemented immediately so that the State can respond quickly to the dislocation and job losses that will likely result from the closure of these facilities.

It bears noting that section 403 of the Economic Development Law directs the Commissioner of Economic Development to promulgate regulations and explicitly indicates that such regulations may be adopted on an emergency basis.

Subject: Economic Transformation and Facility Redevelopment Program.

Purpose: Allow Department to implement the Economic Transformation and Facility Redevelopment Program.

Substance of emergency rule: The regulation creates new Parts 200-204 in 5 NYCRR as follows:

1) The regulation adds the definitions relevant to the Economic Transformation and Facility Redevelopment Program (the "Program"). Key definitions include, but are not limited to, certificate of eligibility, preliminary schedule of benefits, net new jobs, new business, economic transformation area, and closed facility.

2) The regulation creates the application and review process for the Program. In order to become a participant in the Program, an applicant must submit a complete application by the later of: (1) the date that is three years after the date of the closure of the closed facility located in the economic transformation area in which the business entity would operate or (2) January 1, 2015. An applicant must also agree to a variety of requirements, including, but not limited to, the following: (a) allowing the exchange of its tax information between Department of Taxation and Finance and Department of Economic Development (the "Department"); (b) allowing the exchange of its tax and employer information between the Department of Labor and the Department; and (c) agreeing to not participate in either the Excelsior Jobs Program, the Empire Zones Program or claim any tax credits under the Brownfield Cleanup Program if admitted into the Economic Transformation and Facility Redevelopment Program specifically with regard to the facility located in the economic transformation area.

3) Upon receiving a complete application, the Commissioner of the Department shall review the application to ensure it meets eligibility criteria set forth in the statute (see 5 below). If it does not, the application shall not be accepted. If it does meet the eligibility criteria, the Commissioner may admit the applicant into the Program. If admitted into the Program, an applicant will receive a certificate of eligibility. When considering an application, the Commissioner shall consider factors including, but not limited to, the overall cost and effectiveness of the project, and whether the project is consistent with the intent of the Program. If a participant does not start construction on or acquire a qualified investment or create at least one net new job within one year of the issuance of its certificate of eligibility, the participant will not be eligible for any of the Program's tax credits.

4) The regulation sets forth the eligibility criteria for the Program. In order to qualify for the Program, (1) a participant must create and maintain at least five net new jobs in an economic transformation area, and must demonstrate that its benefit-cost ratio is at least ten to one; (2) a participant must be in compliance with all worker protection and environmental laws and regulations; (3) a participant must not owe past due federal or state taxes or local property taxes, unless those taxes are being paid pursuant to an executed payment plan; and (4) the location of the participant's operations for which it seeks tax benefits must be wholly located within the economic transformation area.

5) In addition, a business entity that is primarily operated as a retail business is not eligible to participate in the program if its application is for

any facility or business location that will be primarily used in making retail sales to customers who personally visit such facilities. A business entity that is engaged in offering professional services licensed by the state or by the courts of this state is not eligible to participate in the Economic Transformation and Facility Redevelopment Program. In addition, a business entity that is or will be principally operated as a real estate holding company or landlord for retail businesses or entities offering professional services licensed by the state or by the courts of this state is also not eligible to participate in the Note, however, that the commissioner may determine that such a business entity described in the preceding three sentences may be eligible to participate in the Program at the site of a closed facility if it is pursuant to an adaptive reuse plan for a substantial portion of such facility, the adaptive reuse plan is consistent with the strategic plan of the Regional Economic Development Council and it has been recommended by the Regional Economic Development Council to the Commissioner.

6) The regulation sets forth the fourteen (14) evaluation standards that the Commissioner can utilize when determining whether to admit an applicant to the Program. These include, but are not limited to, the following: (1) the number of net new jobs to be created in New York State; or (2) the amount of capital investment to be made; or (3) whether the applicant is proposing to substantially renovate and reuse closed facilities; or (4) whether the applicant will use energy-efficient measures, including, but not limited to, the reduction of greenhouse gas and emissions and the Leadership in Energy and Environmental Design (LEED) green building rating system for the project identified in its application; or (5) whether the application has been recommended by the Regional Economic Council representing the region where the project will be located; or (6) the degree to which the project is consistent with the strategic plan and priorities for the region; or (7) the degree of economic distress in the area where the applicant will locate the project identified in its application; or (8) the degree of an applicant's financial viability, strength of financials, readiness and likelihood of completion of the project identified in the application; or (9) the degree to which the project identified in the application supports New York State's minority and women business enterprises; or (10) the degree to which the project identified in the application supports the principles of Smart Growth; or (11) the estimated return on investment that the project identified in the application will provide to the state; or (12) the overall economic impact that the project identified in the application will have on a region, including, but not limited to, the impact of any direct and indirect jobs that will be created; or (13) the degree to which other state or local incentive programs are available to the applicant; or (14) the likelihood that the project identified in the application would be located outside of New York State or would not occur but for the availability of state or local incentives.

7) The regulation states that the Commissioner shall prepare a program report on a quarterly basis for posting on the Department's website.

8) The regulation calls for removal of a participant in the Program for failing to meet the application requirements or eligibility criteria of the statute. Upon removal, a participant will be notified in writing and have the right to appeal such removal.

9) The regulation lays out the appeal process for participants who have been removed from the Program. A participant will have thirty (30) days to appeal to the Department. An appeal officer will be appointed and shall evaluate the merits of the appeal and any response from the Department. The appeal officer will determine whether a hearing is necessary and the level of formality required. The appeal officer will prepare a report and make recommendations to the Commissioner. The Commissioner will then issue a final decision in the case.

The full text of the emergency rule is available at the Department's website at <http://esd.ny.gov/BusinessPrograms/EconomicTransformation.html>.

This notice is intended to serve only as an emergency adoption, to be valid for 90 days or less. This rule expires December 6, 2011.

Text of rule and any required statements and analyses may be obtained from: Thomas P Regan, NYS Department of Economic Development, 30 South Pearl Street, Albany NY 12245, (518) 292-5123, email: tregan@empire.state.ny.us

Regulatory Impact Statement

STATUTORY AUTHORITY:

Chapter 61 of the Laws of 2011 established Article 18 of the Economic Development Law, creating the Economic Transformation and Facility Redevelopment Program and authorizing the Commissioner of Economic Development to adopt, on an emergency basis, rules and regulations governing the Program.

LEGISLATIVE OBJECTIVES:

The emergency rulemaking accords with the public policy objectives the Legislature sought to advance because they directly address the legislative findings and declarations that New York State needs, as a matter of

public policy, to create competitive financial incentives for businesses to create jobs and invest in the redevelopment of closed facilities and the economic transformation of surrounding communities. The Economic Transformation and Facility Redevelopment Program is created to support communities affected by closure of correctional and juvenile justice facilities. The Program will provide tax credits to firms that create jobs and make investments in certain areas designated as economic transformation areas. The Program will leverage private sector job creation and investments and help transform the economies of the communities in these areas and lessen the impact of the facility closures. The emergency rule is specifically authorized by the Legislature.

NEEDS AND BENEFITS:

The emergency rule is required in order to immediately implement the statute contained in Article 18 of the Economic Development Law, creating the Economic Transformation and Facility Redevelopment Program. The statute directed the Commissioner of Economic Development to adopt regulations with respect to an application process and eligibility criteria and authorized the adoption of such regulations on an emergency basis notwithstanding any provisions to the contrary in the state administrative procedures act.

New York is in the midst of a national economic slowdown. The impact of the national financial crisis and resulting slowed economic growth was particularly devastating to New York State and could be even more severe for those communities where correctional and juvenile justice facilities will be closed.

The Economic Transformation and Facility Redevelopment Program will be one of the State's key economic development tools for creating jobs and private sector investment in communities affected by the facility closures. It is imperative that this Program be implemented immediately so that the State can respond quickly to the dislocation and job losses that will likely result from closure of these facilities.

This rule will establish the process and procedures for launching this new Program in the most efficient and cost-effective manner while protecting all New York State taxpayers with rules to ensure accountability, performance and adherence to commitments by businesses choosing to participate in the Program.

COSTS:

A. Costs to private regulated parties: None. There are no regulated parties in the Economic Transformation and Facility Redevelopment Program, only voluntary participants.

B. Costs to the agency, the State, and local governments: The Department of Economic Development does not anticipate any significant costs with respect to implementation of this program. There is no additional cost to local governments.

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

LOCAL GOVERNMENT MANDATES:

None. There are no mandates on local governments with respect to the Economic Transformation and Facility Redevelopment Program. This emergency rule does not impose any costs to local governments for administration of the Economic Transformation and Facility Redevelopment Program.

PAPERWORK:

The emergency rule requires businesses choosing to participate in the Economic Transformation and Facility Redevelopment Program to establish and maintain complete and accurate books relating to their participation in the Economic Transformation and Facility Redevelopment Program for a period of three years beyond their participation in the Program. However, this requirement does not impose significant additional paperwork burdens on businesses choosing to participate in the Program but instead simply requires that information currently established and maintained be shared with the Department in order to verify that the business has met its job creation and investment commitments.

DUPLICATION:

The emergency rule does not duplicate any state or federal statutes or regulations.

ALTERNATIVES:

No alternatives were considered with regard to amending the regulations in response to statutory revisions.

FEDERAL STANDARDS:

There are no federal standards in regard to the Economic Transformation and Facility Redevelopment Program. Therefore, the emergency rule does not exceed any Federal standard.

COMPLIANCE SCHEDULE:

The period of time the state needs to assure compliance is negligible, and the Department of Economic Development expects to be compliant immediately.

Regulatory Flexibility Analysis

1. Effect of rule

The emergency rule imposes record-keeping requirements on all busi-

nesses (small, medium and large) that choose to participate in the Economic Transformation and Facility Redevelopment Program. The emergency rule requires all businesses that participate in the Program to establish and maintain complete and accurate books relating to their participation in the Program for the duration of their term in the Program plus three additional years. Local governments are unaffected by this rule.

2. Compliance requirements

Each business choosing to participate in the Economic Transformation and Facility Redevelopment Program must establish and maintain complete and accurate books, records, documents, accounts, and other evidence relating to such business's application for entry into the program and relating to annual reporting requirements. Local governments are unaffected by this rule.

3. Professional services

The information that businesses choosing to participate in the Economic Transformation and Facility Redevelopment Program would be required to keep is information such businesses already must establish and maintain in order to operate, i.e. wage reporting, financial records, tax information, etc. No additional professional services would be needed by businesses in order to establish and maintain the required records. Local governments are unaffected by this rule.

4. Compliance costs

Businesses (small, medium or large) that choose to participate in the Economic Transformation and Facility Redevelopment Program must create new jobs and/or make capital investments in order to receive any tax incentives under the Program. If businesses choosing to participate in the Program do not fulfill their job creation or investment commitments, such businesses would not receive the tax incentives. There are no other initial capital costs that would be incurred by businesses choosing to participate in the Economic Transformation and Facility Redevelopment Program. Annual compliance costs are estimated to be negligible for businesses because the information they must provide to demonstrate their compliance with their commitments is information that is already established and maintained as part of their normal operations. Local governments are unaffected by this rule.

5. Economic and technological feasibility

The Department of Economic Development ("DED") estimates that complying with this record-keeping is both economically and technologically feasible. Local governments are unaffected by this rule.

6. Minimizing adverse impact

DED finds no adverse economic impact on small or large businesses with respect to this rule. Local governments are unaffected by this rule.

7. Small business and local government participation

DED is in compliance with SAPA Section 202-b(6), which ensures that small businesses and local governments have an opportunity to participate in the rule-making process. DED has conducted outreach within the small and large business communities and maintains continuous contact with small and large businesses with regard to their participation in this program. Local governments are unaffected by this rule.

Rural Area Flexibility Analysis

The Economic Transformation and Facility Redevelopment Program is a tax credit program available to new businesses that locate in communities affected by the closure of correctional and juvenile justice facilities, create jobs and make private sector investments. Economic transformation areas will be designated through implementation of these regulations. New businesses to these areas that create jobs and make investments are eligible to apply to participate in the Program entirely at their discretion. Municipalities are not eligible to participate in the Program. The emergency rule does not impose any special reporting, recordkeeping or other compliance requirements on private entities in rural areas. Therefore, the emergency rule will not have a substantial adverse economic impact on rural areas nor on the reporting, recordkeeping or other compliance requirements on public or private entities in such rural areas. Accordingly, a rural area flexibility analysis is not required and one has not been prepared.

Job Impact Statement

The emergency rule relates to the Economic Transformation and Facility Redevelopment Program. The Economic Transformation and Facility Redevelopment Program will enable New York State to provide financial incentives to businesses that create jobs and make investments in communities affected by the closure of correctional and juvenile justice facilities. This Program, given its design and purpose, will have a substantial positive impact on job creation and employment opportunities. The emergency rule will immediately enable the Department to fulfill its mission of job creation and investment in certain areas designated as economic transformation areas. Because this emergency rule will authorize the Department to immediately begin offering financial incentives to firms that commit to creating new jobs and/or to making significant capital investment in these areas, it will have a positive impact on job and employ-

ment opportunities. Accordingly, a job impact statement is not required and one has not been prepared.

Education Department

EMERGENCY RULE MAKING

Teaching Certificate in Earth Science, Biology, Chemistry, Physics, Mathematics or a Closely Related Field

I.D. No. EDU-09-11-00005-E

Filing No. 815

Filing Date: 2011-09-09

Effective Date: 2011-09-09

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

Action taken: Renumbering of section 80-1.1(b)(45)-(47) to section 80-1.1(b)(46)-(48); addition of sections 80-1.1(b)(45) and 80-5.22; and amendment of sections 80-3.3(b)(2)(i) and 80-3.7 of Title 8 NYCRR.

Statutory authority: Education Law, sections 207, 305(1), (2), 3001(2), 3004(1), (6) and 3006(1)

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

Specific reasons underlying the finding of necessity: Supply and demand data has shown that in many regions of New York there is a shortage of certified teachers in the areas of science and mathematics. To address this issue, the proposed regulations have been developed to create an expedited pathway for individuals with advanced degrees in STEM and related teaching experience at the postsecondary level to become certified teachers in mathematics or one of the sciences or a closely related field.

At its February 2011 meeting, the Board of Regents adopted the proposed amendment which provides eligible candidates with advanced degrees in the STEM areas and teaching experience at the postsecondary level with two certification options. The candidate could obtain a Transitional G certificate to teach math or one of the sciences at the secondary level without completing additional pedagogical study for two years. The district would commit to providing mentoring and appropriate professional development in the areas of pedagogy during the period that the teacher is employed on a Transitional G certificate. After two years of successful teaching experience with the district on a Transitional G certificate the teacher would be eligible for the initial certificate in that subject area.

The other option is for individuals who meet the other requirements but do not have an offer of employment by a school district they would still have the option of completing six credits of undergraduate pedagogical core study or four credits of graduate pedagogical study.

Following publication of the proposed amendment in the State Register on March 2, 2011, the Department received two comments. An assessment of public comment is attached. In response to these comments, the proposed amendment has been amended in three ways:

1. To address the commenter's concerns about teachers using this expedited pathway to immediately teach in the middle school grades, the proposed amendment has been revised to apply only to Grades 7-12 level certificates.

2. The deadline for individual evaluation has been extended beyond February 1, 2012 for candidates pursuing this expedited pathway.

3. The Department has also added language to the regulation to require the school district that will employ the candidate seeking a Transitional G certificate, to create and maintain a plan for mentoring and instructional support. This is in addition to the required 70 or more hours of professional development targeted toward pedagogical skills.

A Notice of Revised Rule Making was published in the State Register on June 1, 2011. It is anticipated that the proposed amendment will be presented to the Board of Regents for adoption as a permanent rule at its September 2011 meeting. Emergency action is needed to ensure that the revised rule remains continuously in effect until it can be adopted as a permanent rule on October 5, 2011.

Subject: Teaching certificate in Earth Science, Biology, Chemistry, Physics, Mathematics or a Closely Related Field.

Purpose: To allow individuals with advanced degrees in the STEM areas and related teaching experience to teach certain subjects in 7-12.

Text of emergency rule: 1. Paragraphs (45) through (47) of subdivision

(b) of Section 80-1.1 of the Regulations of the Commissioner of Education should be renumbered (46) through (48) of Section 80-1.1 of the Regulations of the Commissioner of Education, effective September 9, 2011.

2. A new paragraph (45) of subdivision (b) is added to Section 80-1.1 of the Regulations of the Commissioner of Education, effective September 9, 2011, to read as follows:

(45) *Transitional G certificate means the first teaching certificate obtained by a candidate who holds an appropriate graduate degree in science, technology, engineering or mathematics and has two years of acceptable experience teaching in a post-secondary institution, that qualifies that individual to teach in the public schools of New York State, subject to the requirements and limitations of this Part, and excluding the provisional certificate, initial certificate, internship certificate, conditional initial certificate, transitional A certificate, transitional B certificate and transitional C certificate.*

3. Subparagraph (i) of paragraph (2) of subdivision (b) of section 80-3.3 of the Regulations of the Commissioner of Education is amended, effective September 9, 2011, to read as follows:

(i) [The] (a) *Except as otherwise provided in subdivision (b) of this section, the candidate shall submit evidence of having achieved a satisfactory level of performance on the New York State Teacher Certification Examination liberal arts and sciences test, written assessment of teaching skills, and content specialty test(s) in the area of the certificate, except that a candidate seeking an initial certificate in the title of Speech and Language Disabilities (all grades) shall not be required to achieve a satisfactory level of performance on the content specialty test.*

(b) *Examination requirement for candidates with a graduate degree in science, technology, engineering or mathematics and two years of post-secondary teaching experience in the area of the certificate sought. Any candidate seeking an initial certificate in earth science, biology, chemistry, physics, mathematics or in a closely related field as determined by the Department in (grades 7-12) and who is seeking an initial certificate through individual evaluation under section 80-3.7(a)(3)(ii)(c) shall not be required to achieve a satisfactory level of performance on the written assessment of teaching skills examination or the content specialty test.*

4. Section 80-3.7 of the Regulations of the Commissioner of Education is amended, effective September 9, 2011, to read as follows:

This section prescribes requirements for meeting the education requirements for classroom teaching certificates through individual evaluation. [This] *Except as otherwise provided in this section, this option for meeting education requirements shall only be available for candidates who apply for a certificate in childhood education by February 1, 2007 and for candidates who apply for any other certificate in the classroom teaching service by February 1, 2012, and who upon application qualify for such certificate. Candidates with a graduate degree in science, technology, engineering or mathematics who apply for an initial teaching certificate under 80-3.7 (a)(3)(ii)(3) may continue to meet the education requirements for classroom teaching certificates through individual evaluation after February 1, 2012.* The candidate must have achieved a 2.5 cumulative grade point average or its equivalent in the program or programs leading to any degree used to meet the requirements for a certificate under this section. In addition, a candidate must have achieved at least a C or its equivalent in any undergraduate level course and at least a B- or its equivalent in any graduate level course in order for the semester hours associated with that course to be credited toward meeting the content core or pedagogical core semester hour requirements for a certificate under this section. All other requirements for the certificate, including but not limited to, examination and/or experience requirements, as prescribed in this Part, must also be met.

(a) Satisfaction of education requirements through individual evaluation for initial certificates in all titles in classroom teaching service, except in specific career and technical subjects within the field of agriculture, business and marketing and consumer services, health, a technical area, or a trade (grades 7 through 12).

- (1) . . .
- (2) . . .
 - (i) . . .
 - (ii) . . .
 - (iii) . . .
 - (iv) . . .
 - (v) . . .

(3) Additional requirements. A candidate seeking to fulfill the education requirement for the initial certificate through individual evaluation of education requirements shall meet the additional requirements in this paragraph or their substantial equivalent as determined by the commissioner, if so prescribed for that certificate title, in addition to the general requirements prescribed in paragraph (2) of this subdivision.

- (i) . . .
- (ii) Specialist in middle childhood education (5-9) and adolescence education (7-12).

- (a) . . .
- (b) . . .

(c) *For candidates with a graduate degree in science, technology, engineering or mathematics and two years of postsecondary teaching experience in the certificate area to be taught or in a closely related subject area acceptable to the Department, who apply for a certificate or license in (grades 7-12) on or after February 2, 2011 in earth science, biology, chemistry, physics, mathematics or a closely related field, the candidate shall not be required to meet the general requirements in paragraph (2) (iii), (iv) or (v) of subdivision (a) of this section. However, the candidate shall meet the following requirements:*

(1) *Degree completion. The candidate shall possess a graduate degree in science, technology, engineering or mathematics from a regionally or nationally accredited institution of higher education, a higher education institution that the Commissioner deems substantially equivalent, or from an institution authorized by the Board of Regents to confer degrees and whose programs are registered by the Department. The candidate shall have completed a graduate major in the subject of the certificate sought, or in a related field approved by the department for this purpose.*

(2) *Post-secondary teaching experience. The candidate must show evidence of at least two years of satisfactory teaching experience at the post-secondary level in the certificate area to be taught or in a closely related subject area acceptable to the Department.*

(3) *Pedagogical study or two years of satisfactory teaching experience in a school district under a Transitional G certificate. The candidate shall complete one of the following:*

(i) *at least six credits of undergraduate pedagogical core study or four credits of graduate pedagogical study for the initial certificate in the area of the candidate's certificate, as prescribed for the certificate title in this paragraph, which shall include study in the methods of teaching in the certificate area, teaching students with disabilities; curriculum and lesson planning aligned with the New York State Learning Standards; and classroom management and teaching at the developmental level of students to be taught; or*

(ii) *at least two years of satisfactory teaching experience in a school district while the candidate holds a Transitional G certificate under this Part.*

- (iii) . . .
- (iv) . . .
- (v) . . .
- (vi) . . .
- (vii) . . .
- (viii) . . .
- (ix) . . .
- (x) . . .
- (xi) . . .
- (xii) . . .

- (b) . . .
- (c) . . .

5. Section 80-5.22 of the Regulations of the Commissioner is added, effective September 9, 2011 as follows:

§ 80-5.22 *Transitional G certificate for career changers and others holding a graduate or higher degree in science, technology, engineering or mathematics and with at least two years of acceptable post-secondary teaching experience.*

(a) *General requirements.*

(1) *Time validity. The transitional G certificate shall be valid for two years.*

(2) *Limitations. The transitional G certificate shall authorize a candidate to teach only in a school district for which a commitment for employment has been made. The candidate shall meet the requirements in each of the following paragraphs:*

(i) *Education. A candidate shall hold a graduate degree in science, technology, engineering or mathematics from a regionally or nationally accredited institution of higher education, a higher education institution that the Commissioner deems substantially equivalent, or from an institution authorized by the Board of Regents to confer degrees. A candidate shall complete study in the means for identifying and reporting suspected child abuse and maltreatment, which shall include at least two clock hours of coursework or training in the identification and reporting of suspected child abuse or maltreatment in accordance with the requirements of section 3004 of the Education Law. In addition, the candidate shall complete at least two clock hours of coursework or training in school violence prevention and intervention, as required by section 3004 of the Education Law, which is provided by a provider approved or deemed approved by the Department pursuant to Subpart 57-2 of this Title.*

(ii) *Examination. The candidate shall submit evidence of having achieved a satisfactory level of performance on the New York State Teacher Certification Examination liberal arts and sciences test.*

(iii) *Post-secondary teaching experience.* The candidate shall submit evidence of at least two years of satisfactory teaching experience at the post-secondary level in the certificate area to be taught or in a closely related subject area acceptable to the Department.

(iv) *Employment and support commitment.* The candidate shall submit satisfactory evidence of having a commitment from a school district of at least two years of employment as a teacher with the school district in the area of the certificate sought, which shall include a plan from the school district for mentoring, appropriate instructional support as determined by school leadership and at least 70 hours of professional development targeted toward appropriate pedagogical skills, over the two years of employment.

This notice is intended to serve only as a notice of emergency adoption. This agency intends to adopt the provisions of this emergency rule as a permanent rule, having previously submitted to the Department of State a notice of proposed rule making, I.D. No. EDU-09-11-00005-EP, Issue of March 2, 2011. The emergency rule will expire November 8, 2011.

Text of rule and any required statements and analyses may be obtained from: Chris Moore, State Education Department, Office of Counsel, State Education Building, Room 148, 89 Washington Ave., Albany, NY 12234, (518) 473-8296, email: legal@mail.nysed.gov

Regulatory Impact Statement

1. STATUTORY AUTHORITY:

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

Subdivision (1) of section 305 of the Education Law empowers the Commissioner of Education to be the chief executive officer of the state system of education and of the Board of Regents and authorizes the Commissioner to enforce laws relating to the educational system and to execute educational policies determined by the Regents.

Subdivision (2) of section 305 of the Education Law authorizes the Commissioner of Education to have general supervision over all schools subject to the Education Law.

Subdivision (2) of section 3001 of the Education Law establishes certification by the State Education Department as a qualification to teach in the public schools of New York State.

Subdivision (1) of section 3004 of the Education Law authorizes the Commissioner of Education to prescribe, subject to the approval of the Regents, regulations governing the examination and certification of teachers employed in all public schools in the State.

Subdivision (6) of section 3004 of the Education Law requires the Regents and the Commissioner to develop programs to assist in the expansion of alternative teacher preparation programs.

Paragraph (b) of subdivision (1) of section 3006 of the Education Law provides that the Commissioner of Education may issue such teacher certificates as the Regents Rules prescribe.

2. LEGISLATIVE OBJECTIVES:

The proposed amendment carries out the objectives of the above referenced statutes by establishing an alternative certification pathway for candidates with an advanced degree in either science, technology, engineering or mathematics and two years of teaching experience at the post-secondary level, to teach in the certificate area of their advanced degree or one closely related to it.

3. NEEDS AND BENEFITS:

The proposed amendment establishes a transitional G certificate to create a mechanism for schools to employ applicants with a graduate degree or higher in science, technology, engineering or mathematics, and two years of experience teaching at the college level in the same area as the certificate requested, or in a closely related field as determined by the Commissioner, to address demonstrated shortage areas in these subjects. School districts and BOCES that wish to employ a teacher with the transitional G certificate must certify to the State Education Department that the district has made a commitment of employment to the transitional G holder for two years of employment, which shall a plan for mentoring, appropriate instructional support as determined by school leadership and at least 70 hours of professional development targeted toward appropriate pedagogical skills over the two years of employment. For individuals who meet the other requirements but do not have an offer of employment by a school district they would still have the option of completing six credits of undergraduate pedagogical core study or four credits of graduate pedagogical study.

The proposed amendment is needed to facilitate the State's ability to address persistent shortages of certified teachers who are qualified to teach in one of the sciences or mathematics at the 7-12 grade level. The proposed amendment is designed to support the Department's continuing efforts to certify a sufficient number of properly qualified candidates to fill the need for science and mathematics teachers in the State's schools.

The transitional G certificate will be valid for two years from its effective

date and will not be renewable. It will be limited to employment with an employing entity.

4. COSTS:

(a) Cost to State government. The amendment will not impose any additional cost on State government, including the State Education Department. The State Education Department will use existing staff and resources to process certificate applications.

(b) Cost to local government. The amendment does not impose additional costs upon local governments, including schools districts and BOCES.

(c) Cost to private regulated parties. A candidate seeking a transitional G certificate will be required to pay a \$100 application fee.

(d) Costs to the regulatory agency. As stated above in Costs to State Government, the amendment will not impose any additional costs on the State Education Department.

5. LOCAL GOVERNMENT MANDATES:

School districts and BOCES that wish to employ a teacher with the transitional G certificate must certify to the State Education Department that the district has made a commitment of employment to the transitional G holder, and that the district or BOCES has a plan for mentoring, appropriate instructional support services and at least 70 hours of professional development targeted toward appropriate pedagogical skills over the two years of employment.

6. PAPERWORK:

The proposed amendment will not increase reporting or recordkeeping requirements beyond existing requirements. The employing school district or BOCES will be required to certify that the district wants to employ the candidate in a position for which the candidate would need the transitional G certificate to qualify, and that it will provide a plan for mentoring, appropriate instructional support as determined by school leadership and at least 70 hours of professional development targeted toward appropriate pedagogical skills over the two years of employment.

7. DUPLICATION:

The amendment does not duplicate other existing State or Federal requirements.

8. ALTERNATIVES:

No alternative proposals were considered.

9. FEDERAL STANDARDS:

There are no Federal standards that address alternative certification requirements in the areas of science and mathematics.

10. COMPLIANCE SCHEDULE:

Regulated parties must comply with the proposed amendment on its effective date. Because of the nature of the proposed amendment, no additional period of time is necessary to enable regulated parties to comply.

Regulatory Flexibility Analysis

(a) Small Businesses:

The purpose of the proposed amendment is to establish an expedited pathway for individuals with advanced degrees in science, technology, engineering and mathematics and at least two years of postsecondary teaching experience to become certified in science or mathematics in grades 7-12 to address the demonstrated shortage areas in these subjects and grade levels. The amendment does not impose any reporting, record-keeping, or compliance requirements and will not have an economic impact on small businesses. Because it is evident from the nature of the rule that it does not affect small businesses, no further steps were needed to ascertain that fact and none were taken.

(b) Local Governments:

1. Effect of the rule:

The proposed amendment affects all school districts and BOCES in the State that wish to hire a teacher for employment that holds a transitional G certificate.

The purpose of the proposed amendment is to establish an expedited pathway for individuals with advanced degrees in science, technology, engineering and mathematics and at least two years of postsecondary teaching experience to become certified in science or mathematics in grades 7-12 to address the demonstrated shortage areas in these subjects and grade levels.

The proposed amendment establishes a transitional G certificate which authorizes a qualified applicant, upon meeting the prescribed requirements, a certification to teach at the 7-12 grade level in science, mathematics, or a closely related field as determined by the Commissioner. School districts and BOCES that wish to employ a teacher with the transitional G certificate must certify to the State Education Department that the district has made a commitment of employment to the transitional G holder, with a plan for mentoring and appropriate instructional support as determined by school leadership and at least 70 hours of professional development targeted toward appropriate pedagogical skills over the two years of employment.

2. Compliance requirements:

The purpose of the proposed amendment is to establish an expedited

pathway for individuals with advanced degrees in science, technology, engineering and mathematics and at least two years of postsecondary teaching experience to become certified in science or mathematics in grades 7-12 to address the demonstrated shortage areas in these subjects and grade levels.

The proposed amendment establishes a transitional G certificate which authorizes a qualified applicant, upon meeting the prescribed requirements, a certification to teach at the 7-12 grade level in science, mathematics, or a closely related field as determined by the Commissioner. School districts and BOCES that wish to employ a teacher with the transitional G certificate must certify to the State Education Department that the district has made a commitment of employment to the transitional G holder, with a plan for mentoring and appropriate instructional support as determined by school leadership and at least 70 hours of professional development targeted toward appropriate pedagogical skills over the two years of employment.

3. Professional services:

The proposed amendment does not mandate school districts or BOCES to contract for additional professional services to comply.

4. Compliance costs:

There are no compliance costs for school districts or BOCES that exercise the option of employing a teacher under a transitional G certificate. However, the candidate will be required to pay an application fee of \$100 for the transitional G certificate.

5. Economic and technological feasibility:

Meeting the requirements of the proposed amendment is economically and technologically feasible. As stated above in compliance costs, the amendment imposes no costs on school districts or BOCES.

6. Minimizing adverse impact:

The amendment establishes requirements for the issuance of a transitional G certificate. The State Education Department does not believe that establishing different standards for local governments is warranted. A uniform standard ensures the quality of the State's teaching workforce.

7. Local government participation:

Comments on the proposed rule were solicited from the State Professional Standards and Practices Board for Teaching. This is an advisory group to the Board of Regents and the Commissioner of Education on matters pertaining to teacher education, certification, and practice. The Board has representatives of school districts and BOCES.

Rural Area Flexibility Analysis

1. Types and estimate of number of rural areas:

The proposed amendment will affect candidates, New York State school districts and BOCES in all parts of the State, including the 44 rural counties with fewer than 200,000 inhabitants and the 71 towns and urban counties with a population density of 150 square mile or less.

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

The purpose of the proposed amendment is to establish an expedited pathway for individuals with advanced degrees in science, technology, engineering and mathematics and at least two years of postsecondary teaching experience to become certified in science or mathematics in grades 7-12 to address the demonstrated shortage areas in these subjects and grade levels. The proposed amendment also establishes requirements regarding the application for and issuance of the transitional G certification. This certification will authorize a qualified applicant, with an advanced degree in either science, technology, engineering, mathematics or a closely related field as determined by the Commissioner, and two years of teaching experience at the post-secondary level, to teach in the certificate area of their advanced degree or one closely related to it, for the period of two years, at which time the candidate may apply for an initial certificate in that subject area. For individuals who meet the other requirements but do not have an offer of employment by a school district they would still have the option of completing six credits of undergraduate pedagogical core study or four credits of graduate pedagogical study. Certificate areas identified for the transitional G include: Biology, Chemistry, Earth Science, Physics, Mathematics, or a closely related field as determined by the Commissioner, at the 7-12 grade level.

School districts and BOCES that wish to employ a teacher with the transitional G certificate must certify to the State Education Department that the district has made a commitment of employment to the transitional G holder, which shall include a plan for appropriate mentoring and instructional support as determined by school leadership and at least 70 hours of professional development targeted toward appropriate pedagogical skills over the two years of employment.

3. Costs:

There are no compliance costs for school districts or BOCES that exercise the option of employing a teacher under a transitional G certificate. However, the candidate will be required to pay an application fee of \$100 for the transitional G certificate.

4. Minimizing adverse impact:

The State Education Department does not believe that establishing different standards for candidates who live or work in rural areas is warranted. A uniform standard ensures the quality of the State's teaching workforce.

5. Rural area participation:

Comments on the proposed rule were solicited from the State Professional Standards and Practices Board for Teaching. This is an advisory group to the Board of Regents and the Commissioner of Education on matters pertaining to teacher education, certification, and practice. The Board has representatives who live and/or work in rural areas, including individuals who are employed as educators in rural school districts and BOCES.

Job Impact Statement

The purpose of the proposed amendment is to establish requirements for an expedited certification pathway for individuals with advanced degrees in science, technology, engineering and mathematics and at least two years of postsecondary teaching experience to become certified in science and mathematics in grades 5-9 and 7-12.

The proposed amendment is needed to facilitate the Department's continuing ability to certify a sufficient number of properly qualified candidates to address shortage areas in the State's public schools and BOCES. This proposal is intended to increase the supply of teachers who are certified in the sciences and mathematics in grades 5-9 and 7-12, all of which are shortage areas.

Because it is evident from the nature of the rule that it could only have a positive impact or no impact on jobs and employment opportunities, no 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.

Assessment of Public Comment

The agency received no public comment

Department of Environmental Conservation

PROPOSED RULE MAKING HEARING(S) SCHEDULED

High Volume Hydraulic Fracturing

I.D. No. ENV-39-11-00020-P

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

Proposed Action: Addition of Parts 52, 560 and Subpart 750-3; amendment of Parts 190, 550-555; and Subpart 750-1 of Title 6 NYCRR.

Statutory authority: Environmental Conservation Law, sections 1-0101, 3-0301, 9-0105, 9-0301, 9-0303, 9-0501, 9-0507, 11-0303, 11-0305, 11-2101, 11-2103, 15-0103, 15-0105, 15-0109, 17-0101, 17-0103, 17-0303, 17-0501, 17-0511, 17-0807, 17-1709, 71-1929, 23-0303, 23-0305, 23-0502, 23-0503, 45-0117; and NYS Constitution art. 14

Subject: High Volume Hydraulic Fracturing.

Purpose: Administrative changes to existing regulations and regulation of activities associated with high volume hydraulic fracturing.

Public hearing(s) will be held at: 1:00 p.m. and 6:00 p.m., Nov. 16, 2011 at Dansville Middle School Auditorium, 31 Clara Barton St., Dansville, NY; 1:00 p.m. and 6:00 p.m., Nov. 17, 2011, at The Forum Theatre, 236 Washington St., Binghamton, NY; 1:00 p.m. and 6:00 p.m., Nov. 29, 2011 at Sullivan County Community College, Seelig Theatre, 112 College Rd., Loch Sheldrake, NY; and 1:00 p.m. and 6:00 p.m., Nov. 30, 2011 at Tribeca Performing Arts Center, 199 Chambers St., New York, NY.

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

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

Substance of proposed rule (Full text is posted at the following State website: <http://www.dec.ny.gov>): The proposed rules include revisions and additions to the Department's oil and gas regulations, regulations on the management of state land and regulations pertaining to State Pollutant Discharge Elimination System (SPDES) permitting. The proposed rules

include some administrative changes to the Department's regulations. However, most of the revisions and additions are intended to promulgate mitigation measures identified in the Department's revised draft Supplemental Generic Environmental Impact Statement (2011 dSGEIS) related to the approval of permits to drill a natural gas well when high-volume hydraulic fracturing (HVHF) is planned. HVHF involves the fracturing of wells utilizing more than three hundred thousand gallons of water as the base fluid for fracturing operations. Issuance of a permit to drill, deepen, plug back or convert an HVHF well or issuance of a SPDES permit covering HVHF will involve programs administered by the Divisions of Mineral Resources; Lands and Forests; Fish Wildlife and Marine Resources; and, Water.

Mineral Resources.

Several of the changes proposed for the oil and gas well regulations are administrative in nature and are necessary to update existing regulations to current Department and industry practices. Included in this category of changes is the language proposed to be added to section 552.2, which will clarify that the expiration of a permit to drill, deepen, plug back or convert a well does not relieve an operator from compliance with the terms specified in a permit when the operator commences operations during the permit term. Definitions will also be added to Part 550 for the terms hydraulic fracturing, true measured depth, true vertical depth, well spud, and workover.

The proposed rules will also modify 6 NYCRR section 551.6 to remove the blanket bond available to operators who drill multiple wells and will revise 6 NYCRR section 552.2 to extend the term of a permit to drill, deepen, plug back or convert a well from six months to two years. 6 NYCRR section 552.3 is proposed to be modified to allow the Department to re-issue a permit to another operator for a location that has already been permitted by the Department.

Several provisions in the proposed rules will also modernize the Department's regulations to make them consistent with statutory changes made to ECL Article 23 in 2005 and 2008. Chapter 386 of the Laws of 2005 made a number of significant changes to the statewide spacing scheme in place for natural gas wells and the proposed rules will incorporate some of those changes. Statutory statewide spacing provisions for oil and gas wells were also adopted by the Legislature in 2008. The proposed rules will promulgate the 2008 legislative changes related to shale well development.

Additional recordkeeping requirements are included in the proposed rules, including a provision that will require operators to file an interim completion report for any gap in drilling operations lasting longer than thirty days. Enhancements are also proposed for Part 555, which contains standards for the plugging and abandonment of wells under the Department's jurisdiction. Other proposed changes to section 555.5 would require operators to obtain well logs prior to plugging to aid in determining the appropriate plugging procedures. The proposed rules will also clarify the density of the fluid that may be utilized between plugs set in the bore hole during plugging of the well and will clarify the reclamation requirements for the land adjacent to the surface location of the well.

A new Part 560 is proposed in the Department's rulemaking to address HVHF. Part 560 will consist of seven sections, beginning with section 560.1 which makes Part 560 applicable to all wells where HVHF is planned. Section 560.1 also states that Parts 550-558 will continue to apply to the extent not superseded by Part 560. Proposed section 560.2 contains several definitions related to HVHF including chemical additives, chemical constituent, flowback, and HVHF, as well as definitions related to new setbacks specific to HVHF surface activities.

Proposed section 560.3 will promulgate many of the application requirements specified in the 2011 dSGEIS including: the need for a blowout preventer use and testing plan; detailed mapping requirements; and disclosure of chemical additives proposed to be used during hydraulic fracturing including the proposed volume of each additive and the proposed percent by weight of water, chemical additives and proppants.

In section 560.4, the Department proposes to promulgate additional setbacks for HVHF for surface activities, including setbacks for wells proposed within 500 feet of a primary aquifer and specified distances from water resources such as private water wells and reservoirs. Section 560.5 of the proposed rules will promulgate the well testing, recordkeeping and reporting requirements in the 2011 dSGEIS. This section will include requirements for well operators to test residential water wells within a specified distance from the proposed gas well. The regulations will also authorize the Department to require additional water well testing after the wells permitted under 6 NYCRR Part 552 are completed, to investigate whether drilling activities have impacted residential water well quality.

Section 560.6 of the proposed rules contains detailed well construction and operational requirements for HVHF wells and separate subdivisions are included in the rule to specify requirements for: site preparation; site maintenance, such as the design standards for reserve pits; drilling, hydraulic fracturing and flowback, such as the need for intermediate casing

and monitoring requirements during fracturing operations; and reclamation requirements that specify how wastes generated on the well pad should be managed and further specifying that partial and final reclamation of the well site must be approved by the Department.

Lands and Forests and Fish, Wildlife and Marine Resources.

Parts 52 and 190 of 6 NYCRR will be modified to prohibit the leasing of state-owned land for surface activities related to HVHF. The prohibition, however, will not prevent the Department from leasing state land to allow subsurface access to the state's mineral rights from locations adjacent to state-owned land.

Ground and Surface Water.

The proposed rules will update sections 750-1.1, 750-1.4, and 750-1.5 of 6 NYCRR. The updates to section 750-1.1 ensure protection of water resources by including language to clearly state that the regulations provide water quality protection for activities that do not require a SPDES permit and to refer to the certain prohibited activities and discharges associated with HVHF. The updates to section 750-1.4 and 750-1.11 ensure the protection of water resources by requiring a SPDES permit for HVHF operations so that there is no discharge of a pollutant in a manner other than prescribed by the SPDES permit. The revision to section 750-1.5 clarifies the existing regulation to conform to the current federal process for issuance of Underground Injection Control permits.

A new Part 750-3 will also be added. The new Part 750-3 will consist of twenty-five sections. Section 750-3.2 incorporates the definitions provided in 750-1.2 and provides additional definitions specific to HVHF. Section 750-3.3 incorporates the requirements provided in section 750-1.3. Section 750-3.3 prohibits certain HVHF activities and discharges and does not allow the issuance of a SPDES permit for such activities or discharges. Similar to the setbacks proposed for Part 560, these specifically include HVHF operations on the ground surface: within 4,000 feet of an unfiltered surface water supply watershed; within 500 feet of a primary aquifer; and within specified distances from other water resources such as floodplains and water supply wells.

Section 750-3.4 incorporates the requirements provided in section 750-1.4. To obtain a SPDES permit for HVHF operations section 750-3.4 also provides a list of the certifications required by the well operator or provides for alternative plans that are approvable by the Department. This list includes: proper handling and disposal of waste fluids from HVHF operations; closed loop system; depth of the HVHF drilling; and evaluation and use of less toxic alternative additive products.

Section 750-3.5 incorporates the requirements provided in section 750-1.5. Section 750-3.5 explains that the Department's determination under 750-1.5(a)(6)(ii) that groundwater or surface water quality will not be degraded shall be based in part upon the certifications submitted in compliance with and pursuant to 750-3.4. Section 750-3.6 incorporates the requirements provided in section 750-1.6. Section 750-3.6 requires the development of a comprehensive stormwater pollution prevention plan (SWPPP), which addresses the construction, HVHF and production phases of an HVHF well. This section further identifies the criteria required to obtain an HVHF SPDES permit and provides triggers for when each phase of HVHF may commence.

Section 750-3.11 incorporates the requirements provided in section 750-1.11. Section 750-3.11 includes the details of the Construction SWPPP and HVHF SWPPP and requires that such SWPPPs be developed in accordance with the Department's technical standards. This section also includes conditions applicable to all HVHF operations, including: stabilization of all disturbed areas; the development and use of less toxic alternative additive fluids and maintenance of a list of such on-site; proper disposal of wastewater; partial site reclamation; spill prevention, control and countermeasure plan; and use of closed loop tank system. A new section 750-3.12.2 will be added. This section details the requirements for the permittee to demonstrate that all flowback water and production brine will be treated, recycled or otherwise disposed of over the projected life of the well. The SPDES permit application must include a Fluid Disposal Plan. This section details the requirements for disposal options, including: disposal at publicly owned treatment works; disposal at privately owned industrial treatment facilities; on-site treatment and recycling; disposal wells; disposal in accordance with the terms of a Department-approved beneficial use determination; and disposal in accordance with another option subject to the Department's approval.

Section 750-3.13 incorporates the requirements provided in section 750-1.13. Section 750-3.13 will also include monitoring, reporting and recording requirements applicable to all phases of the HVHF operation. Monitoring is required for stormwater discharges during HVHF operations. The HVHF SWPPP must include provisions for monitoring, recording and reporting, source water and additives for HVHF operations, and HVHF wastewater.

Section 750-3.14 incorporates the requirements provided in section 750-1.14, which details the requirements to ensure no increase in discharge loading of the listed pollutant of concern for stormwater discharges

to impaired waterbodies listed pursuant to Clean Water Act § 303(d) or for which there has been an approved Total Maximum Daily Load.

Section 750-3.20 incorporates the requirements provided in section 750-1.20. Section 750-3.20 also provides the Department with the ability to deny, suspend or revoke a SPDES permit for HVHF operations if the Department determines that the permittee has failed to implement any measures certified pursuant to section 750-3.4 or has otherwise violated any provision of Part 750-3.

Section 750-3.21 incorporates the requirements provided in section 750-1.21. Section 750-3.12 provides the requirements for obtaining and maintaining coverage under the HVHF General Permit, including development of a SWPPP and the operation and maintenance of stormwater management practices; duration of the HVHF General Permit; transfer of the HVHF General Permit; denial, suspension, or revocation of the HVHF General Permit; fee for coverage under the HVHF General Permit; and termination of the HVHF General Permit. Section 750-3.21 also includes the authority for the Department to issue a stop work order.

This section lists activities that are ineligible for coverage under the General Permit, which for HVHF operations specifically includes: construction of centralized flowback impoundments; construction for HVHF operations on steep slopes; HVHF operations at certain depths of hydraulic fracturing; and HVHF operations within certain buffers to water resources.

Sections 750-3.1, 750-3.7, 750-3.8, 750-3.9, 750-3.10, 750-3.15, 750-3.16, 750-3.17, 750-3.18, 750-3.19, 750-3.22, and 750-3.23 simply incorporate corresponding and related existing protections in 750-1 into the regulations for HVHF operations. Section 750-3.12 clarifies that 750-1.12 does not apply to HVHF operations. Section 750-3.24 incorporates the requirements provided in section 750-1.24. Section 750-3.24 also specifically references the Department's technical standards for the development of an HVHF SWPPP.

Section 750-3.25 incorporates the requirements provided in section 750-2. Section 750-3.25 also requires that both the Construction SWPPP and HVHF SWPPP must be kept current and that all stormwater management controls be operated and maintained in effective operating condition.

Text of proposed rule and any required statements and analyses may be obtained from: Eugene Leff, Deputy Commissioner, Department of Environmental Conservation, 625 Broadway, Albany, New York 12233-6510, (518) 402-8044, email: public@gw.dec.state.ny.us

Data, views or arguments may be submitted to: Eugene Leff, Re: dSGEIS Comments, Department of Environmental Conservation, 625 Broadway, Albany, New York 12233-6510, (518) 402-8044, email: http://www.dec.ny.gov/energy/76838.html

Public comment will be received until: December 12, 2011.

Additional matter required by statute: Draft Supplemental Generic Environmental Impact Statement (SGEIS) related to high-volume hydraulic fracturing available at www.dec.ny.gov. This rule must be approved by the Environmental Board.

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

Summary of Regulatory Impact Statement

The proposed rulemaking will modify the Department of Environmental Conservation's (Department) existing regulations and promulgate new regulations related to the use of high-volume hydraulic fracturing (HVHF) to facilitate production of natural gas from wells permitted by the Department. Also included in the proposed rules are updates to the Department's oil and gas and State Pollutant Discharge Elimination System (SPDES) regulations.

Statutory Authority and Legislative Objectives. The Department proposes these regulations to ensure potential environmental impacts resulting from HVHF are mitigated to the maximum extent practicable consistent with the legislative objectives provided in the Environmental Conservation Law (ECL). The Department's general authority for the proposed rules is found at ECL Article 1 and Article 3, which identifies the state's responsibility to manage water, land, fish, wildlife and air resources to assure their protection, enhancement, and balanced utilization, without risk to health and safety.

The ECL at sections 23-0301, 23-0303, 23-0305, 23-0501 and 23-0503 provides specific authority for proposed changes to Parts 550 through Part 555, and a new Part 560. These provisions provide the Department with the power to regulate drilling, casing, operation, plugging, replugging and posting of financial security for wells and the reclamation of surrounding land.

Among the changes to the Department's existing rules are: clarifying language to Section 552.2 to specify that the expiration of a permit to drill, deepen, plug back or convert a well does not relieve an operator from compliance with the terms in a permit once operations have commenced; removal of a cap on financial security requirements for wells longer than 6,000 feet; updates to statewide spacing regulations; and, enhancements to

the Department's minimum requirements for the plugging and abandonment of wells.

The new Part 560, applicable to all HVHF wells, will promulgate much of the mitigation specified in the revised draft Supplemental Generic Environmental Impact Statement on the Oil and Gas Regulatory Program (2011 dSGEIS). Included in the proposed rule are: the need for a blowout preventer use and testing plan; detailed mapping requirements; disclosure of chemical additives; and, well pad siting setbacks. The proposed rules also contain detailed well construction, site preparation, operational, and maintenance requirements for HVHF wells.

These proposed regulations further the state's legislative goals by ensuring that wells are properly constructed and operated. Having a comprehensive regulatory scheme in place also facilitates the state's goal to provide for the efficient development, production and utilization of natural resources of oil and gas in such a manner as to prevent injury to the operator, mineral rights' owners and the state as a whole.

With respect to the proposed rules related to SPDES, the ECL provides broad authority for the protection of the waters of the State, including groundwaters. Statutory authority for the proposed rules is provided in ECL Sections 15-0103, 15-0105, 17-0101, 17-0303, 17-0501 and 17-0511 17-0807 17-1709 and 71-1929. These sections authorize the Department to regulate activities that damage or otherwise adversely affect the waters of the State and to perform its duties to conserve and control water resources of the State for public health, safety or welfare.

Additional specific authority for the proposed water regulations is found at ECL Sections 17-0101 and 17-0303, which declares it to be the public policy of the State to maintain reasonable standards of water purity and authorizes the Department to prevent the pollution of the waters of the State in accordance with water quality standards. Furthermore, ECL Section 17-0501 makes it unlawful to discharge to any water of the State in violation of a water quality standard.

This proposed rulemaking updates Sections 750-1.1, 750-1.4, and 750-1.5 and will add a new Part 750-3. The updates to Sections 750-1.1 and 750-1.4 are necessary to clarify which activities do not require a SPDES permit, while ensuring the protection of water resources by requiring a SPDES permit for HVHF operations. The update to Section 750-1.5 conforms the regulation to the current federal process for issuance of Underground Injection Control permits.

Part 750-3 will prohibit certain HVHF activities and discharges and prevent the issuance of a SPDES permit for such activities or discharges within the following specified distances from water resources: within 4,000 feet of an unfiltered surface water supply watershed; within 500 feet of a primary aquifer; and, within 100 year floodplains.

The proposed changes to Part 750 also specify the conditions under which an applicant may receive a SPDES permit. Included in the proposed rule are: a list of certifications required by the applicant; the need to develop a comprehensive stormwater pollution prevention plan (SWPPP); construction, reclamation and drilling requirements for HVHF wells; requirements that all flowback water and production brine will be treated, recycled or otherwise disposed of; monitoring, reporting and recording requirements; and, testing requirements for residential water wells.

The proposed rules also contain requirements regarding coverage under a new HVHF General Permit. Several other sections of Part 750 are proposed to be modified to make those sections applicable to HVHF, or to clarify if HVHF does not apply.

Statutory authority for the proposed rules concerning state-owned lands is found in New York State Constitution, Article XIV, and at ECL Sections 9-0105, 9-0301, 9-0501, 9-0507, 11-2101, 11-2103, and 45-0117. The Department has the responsibility to exercise care, custody and control of state-owned lands and to make rules and regulations governing their use. The ECL also provides the Department with the authority to receive and accept land for conservation, watershed protection, forest management and to conserve rare plants and ecological communities on state-owned lands and lands under the jurisdiction of the Department. The proposed regulation fulfills the legislative objectives by ensuring that the production of natural gas using HVHF does not interfere with the purpose for which state-owned land was acquired.

Needs and Benefits. The proposed revisions to Parts 550 through 558 will update and improve regulatory conditions in the state by ensuring that well operators obtain adequate financial security to cover the cost of plugging deep wells, providing the regulated community with sufficient time to commence operations, and specifying requirements for properly plugging and abandoning a well. The new Part 560 and new Part 750-3 are proposed to ensure the potential environmental impacts to New York's water resources, ecosystems, and air quality, as well as the impacts of HVHF on communities where these wells are expected to be drilled, is minimized. These regulatory revisions will inform and serve the public and regulated community, supplement the Department's ability to monitor and enforce certain measures identified in the 2011 dSGEIS, and will update some of the Department's regulations to reflect technological advances and current industry practice.

Benefits of the adoption of these regulations would accrue to the environment as well as the public. The regulations, by providing for a balanced use of both the surface environment and the natural gas in the subsurface, promote a greater level of environmental protection than would be the case without the regulations. Greater environmental protection includes minimizing the probability and risk to uncontaminated aquifers and drinking water wells, streams and surface waters, and maintaining the passive use of natural resources, amongst others. Additionally, as identified in the 2011 dSGEIS, by approving the utilization of HVHF it is expected that there will be extensive job creation.

Costs to Industry. The costs to the regulated community for the proposed regulations will generally not differ from the potential costs that should have expected from the mitigation measures and permit conditions identified in the 2011 dSGEIS. The use of the General Permit for stormwater management will reduce regulatory fees and other burdens below what would be required if individual permits were issued. The proposed prohibition of surface activities associated with HVHF on state-owned lands might render some gas resources unavailable, which could result in potential lost opportunity for industry and leaseholders. In addition, costs to such leaseholders could increase if they choose to acquire surface access outside state-owned lands.

State Costs. The adoption of these regulations will create additional costs for several state agencies, including the Departments of Environmental Conservation (DEC), Health (DOH), Transportation (DOT), Public Service and Agriculture and Markets. DOH would incur costs investigating possible public health issues; DOT would be expected to review transportation plans that drillers submit with well applications; Public Service staff would be involved in the siting and construction of natural gas transmission pipelines; and, Agriculture and Markets would incur additional costs in its Agricultural District Program.

The actual costs that may be incurred by DEC and other state agencies cannot be currently estimated, given a lack of necessary information. However, the implementation of these regulations can be expected to require a significant increase from the existing DEC staffing levels to carry out the large number of activities relating to permits.

Local Government Mandates. While the proposed regulations do not mandate the expenditure of funds by any sector of local government, local governments will likely incur some indirect effects as a result of the Department's approval to utilize HVHF. The proposed rules would require well operators to test private residential water wells within 1,000 feet of a well pad's location, or 2,000 feet in some circumstances. County health departments may need to respond to issues with these residential water wells that may arise as a result of testing. Those costs will be complaint driven and cannot be quantified at this time.

An element of this proposal allows operators, under certain requirements, to dispose of flowback water and production brine through publicly owned treatment works (POTWs). To accept this water, POTWs must perform a headworks analysis to ensure they can properly remove contaminants expected to be present in flowback water and production brine prior to discharge.

In addition, heavy truck traffic will result in local costs for road maintenance, though the proposed rules contain requirements to assist in mitigating those impacts. It is projected that HVHF activities would result in a substantial increase in economic activity in the affected areas and also result in a substantial increase in tax revenues to the state and to localities. These revenues are expected to offset local government costs that may result from HVHF activities.

Paperwork. The proposed rules include new paperwork requirements for all well operators, including: the need to notify and receive approval to re-fracture a well; a requirement to submit an interim Well Drilling and Completion Report; and new paperwork requirements specific to HVHF. The draft regulations also require certain submissions to the Department pursuant to the stormwater general permit. However, since the majority of HVHF activities would be done pursuant to the General Permit using standardized forms, less paperwork will be generated than required by an individual permit.

Duplication. This proposal is not intended to duplicate any other federal or State regulations or statutes, as there is no federal regulatory program covering HVHF.

Alternatives. The Department examined the no regulatory action or "no-action" alternative, in which mitigation measures and other requirements resulting from the environmental review process would stand-alone to direct these operations. However, the no-action alternative would create uncertainty for the regulated community and the public because controls over HVHF activities would not become state law. The Department also considered the denial of permits for HVHF, but while this alternative would fully protect the environment from any environmental impacts associated with HVHF, it would also eliminate all of the economic benefits generated by the activity.

Federal Standards. There is no federal regulatory framework over

HVHF and there are no applicable Federal standards for groundwater protection. Thus, the proposed rules exceed minimum federal government standards. There are applicable Federal standards for stormwater and New York meets or exceeds all federal requirements.

Compliance Schedule. The regulated community will be required to comply upon enactment of the rules.

Regulatory Flexibility Analysis

The New York State Department of Environmental Conservation (Department) proposes to revise 6 NYCRR Parts 52, 190, 550-555, 560 and 750. The purpose of the proposed rulemaking is to amend the Department's oil and gas regulations to modernize existing regulations to reflect current Department and industry practice and to add new regulations to the Department's state lands, mineral resources and water regulations to address the use of high-volume hydraulic fracturing (HVHF). The Department is currently involved in a multi-year environmental review of HVHF. As a result of this process, the Department has identified a number of application requirements and mitigation measures that are expected to be uniformly applied to all HVHF wells to ensure such wells are drilled and operated properly.

The proposed rules will supplement the Department's ability to monitor and enforce certain measures identified in the Department's revised draft Supplemental Generic Environmental Impact Statement (2011 dSGEIS), and will, at the same time, update some of the Department's regulations to reflect technological advances and current industry practice. The Department's review of HVHF under the State Environmental Quality Review Act (SEQRA) has already been the subject of one public comment period and the Department will receive further public comments on a 2011 dSGEIS.

Effect of rules. These rules will not have substantial adverse effects on small businesses and local governments. The proposed rules will apply to any well operator who intends to utilize HVHF to produce natural gas from wells permitted by the Department. This will, for the most part, involve large national and international corporations. Approval of well drilling permits where HVHF is planned will create opportunities for small businesses to engage in waste hauling, water hauling, basic construction services such as land clearing and grading, as well as lodging, food and other personal services.

This proposal does not directly mandate the expenditure of funds by any sector of local government, although municipally owned wastewater treatment plants may opt to treat wastewater from gas wells subject to the proposed rules. Although the acceptance of wastewater from regulated entities will involve some costs, those costs are expected to be offset by the income generated by acceptance of the waste. In addition, one of the measures contained in the proposed rules will require well operators to test residential water wells prior to drilling. Results of water well testing may increase complaints to the county health department regardless of whether contamination is pre-existing or attributed to nearby HVHF wells. These costs are speculative and cannot be quantified. Approval of HVHF is also expected to impact local roads, leading to increased maintenance costs. To mitigate this impact the proposed rules require an applicant for HVHF to submit a transportation plan detailing proposed routes, estimated number of truck trips and local road conditions, and such plan will assist local government to respond to local infrastructure needs. Well operators will also be encouraged to engage local government early in the planning process by entering into road use agreements, so that both the regulated community and local governments can prepare for the potential impacts of HVHF use in a given area.

Compliance requirements. The regulated community which is the main focus of the proposed rules are well operators who plan to drill wells and utilize HVHF to facilitate production of natural gas. Well operators capable of acquiring sufficient mineral rights to enable them to apply for a Department permit, and who plan to utilize HVHF, are typically well funded national and international companies. The costs to the regulated community for the proposed regulations related to HVHF will not differ substantially from the potential costs that the regulated community should have expected from the mitigation measures and/or permit conditions that have been identified in the 2011 dSGEIS.

Certain aspects of drilling a well, such as clearing the site to construct the well pad and securing enough fresh water to use during fracturing operations will, however, likely involve some small businesses. The proposed rules do not impose substantial costs on small business, with such costs limited to paperwork requirements. Small businesses, to the extent that small businesses apply for a permit to drill a well where HVHF will be used, are required to comply with the same permitting requirements as other regulated entities.

In situations where a small business controls the mineral rights in an area where HVHF may be used, and such small business enters into a joint operating agreement with the well operator or elects to participate in the operation through the Department's compulsory integration process, the proposed rules will increase the costs of participating in the operation. In

such cases, the cost of complying with the proposed rules will still fall largely on the well operator since the well operator is required by the Environmental Conservation Law to control a requisite percentage of the mineral rights in the area that will be produced before the well operator is allowed to apply for a permit to drill. The new application, reporting and operating requirements proposed to be added as a new Part 560, are identified by the Department as necessary measures to ensure HVHF wells are drilled and operated properly and to ensure all waste generated during well construction, hydraulic fracturing and production are handled appropriately.

Local governments are not required to take any affirmative actions under the proposed rules. However, municipalities that operate publicly owned treatment works (POTW) may elect to accept wastewater from HVHF operations for disposal. In general, POTWs must have a DEC approved pretreatment program for accepting any HVHF wastewater and must notify DEC if they plan to receive wastewater at their facility. POTWs are required to perform certain analyses to ensure they can handle the wastewater without upsetting their system or causing a problem in the receiving water. While there are costs associated with the POTW analyses and securing DEC approval of such, this is offset by the disposal fee the municipality may impose for allowing disposal of the HVHF wastewater at their facility.

Indirectly, the proposed rules may also require local governments to respond to additional complaints about water well quality as well owners are made aware of water well testing required by the proposed rules. Approval of HVHF is also expected to increase local traffic and in some areas, increase the local population. As a result, local governments may experience increased demand on local services, such as emergency response and local road maintenance. The 2011 dSCEIS contains a detailed analysis of the socioeconomic impacts associated with approval to utilize HVHF.

Professional services. Local governments are not required to take any affirmative actions under the proposed rules. However, in order to be responsive to situations that could arise, local governments may want to retain professional services to assist with emergency response and traffic control in certain circumstances. It is not anticipated that small businesses associated with high-volume hydraulic fracturing will need to enter into contracts for professional services to comply with these regulations.

Compliance costs. For small businesses and local governments that are not actively participating in an HVHF operation, the compliance costs for the proposed rules will be associated with: additional paperwork requirements for waste tracking; additional paperwork, permitting, testing and enforcement costs associated with operation of a wastewater treatment plant when such small business or local government plans to treat wastewater from an HVHF well; emergency response activities; impacts to county health departments who respond to complaints about water well quality; and for local government, costs associated with road maintenance. As stated above, the regulated community which is the focus of the proposed rules related to HVHF are typically large national and international corporations. It is not expected that small businesses or local government will be engaged in HVHF. For small businesses that apply for a permit to drill an HVHF well, the new Part 560 and 750-3 rules will result in increased compliance costs compared to a non-HVHF well. However, the costs are not expected to materially differ from the costs expected to implement the mitigation measures identified in the 2011 dSCEIS. Through the rulemaking process and further outreach with the regulated community, the Department expects to gather cost information for each aspect of the proposed rules.

Apart from the provisions in the proposed rules related to HVHF, the proposed changes to Parts 550-555 of 6 NYCRR will raise the minimum requirements to plug and abandon a well under the Department's jurisdiction. The proposed rules will also add a new reporting requirement for any break in drilling operations lasting longer than thirty days and will require well operators to receive approval to re-fracture a well. There have been occasions where local governments have drilled self-help wells, or wells meant to supply gas to local buildings. There also exists the possibility that abandoned wells may exist on public lands. The proposed updates mentioned above, including the changes to Part 555, would impact those wells. Part 555 currently provides minimum plugging standards for wells; however, plugging procedures often depend on site-specific factors such as the condition of the well and well construction methods. As a result, the Department often requires more stringent plugging requirements than the minimum requirements specified in the regulations. The proposed revisions to Part 555 would still specify minimum standards but the proposed changes to Part 555 would not raise the cost of plugging a well above that which is often already required by current Department practices. The costs associated with the new reporting requirements contained in the proposed changes to 6 NYCRR Parts 550-555 are expected to be minimal.

Economic and technological feasibility. There should be no economic or technological feasibility issues created by the proposed rules. To the extent that local governments or small business may want to be responsive

or proactive regarding the proposed rules, HVHF activities would result in a substantial increase in economic activity in the affected areas and also result in a substantial increase in tax revenues to the state and to localities.

Minimizing adverse impact. The proposed rules contain some measures to mitigate potential impacts on local government, such as the need for well operators to submit a transportation plan to the Department prior to issuance of a drilling permit. A transportation plan would assist localities in planning for HVHF to allocate resources and initiate a dialogue with well operators. As stated above, the regulated community under the proposed rules includes large national and international corporations. Small businesses who intend to drill an HVHF well will be subject to the same rules as larger businesses and the costs of complying with the proposed rules is not expected to differ from the cost of complying with the application requirements and mitigation measures identified in the dSCEIS. Small businesses, such as waste haulers and water haulers, who provide support services to well operators will have minimal costs to comply with the rules, with such costs limited to paperwork requirements such as the need to track waste from an HVHF well pad to a destination for disposal or reuse.

Small business and local government participation. The Department participated in outreach to the regulated community through this process, including the solicitation of comments from affected industry. Additionally, the proposed use of HVHF in New York has been the subject of substantial public outreach and input over the last several years. During scoping sessions, before and after issuance of the 2009 draft SGEIS, and prior to issuance of the 2011 dSCEIS, the Department received thousands of written comments, received hundreds of verbal comments at public meetings in several of the potentially affected areas, and has had multiple interactions with the regulated community, small business, and local governments on HVHF and the quickly-evolving HVHF industry. The scope of the revised draft SGEIS also considers the impact of proposed additions and revisions of the Department's HVHF regulations, allowing for extensive participation on both the rules and the environmental review process simultaneously.

Rural Area Flexibility Analysis

The proposed rulemaking will modify the Department of Environmental Conservation's (Department) existing regulations and promulgate new regulations related to the use of high-volume hydraulic fracturing (HVHF). HVHF involves the fracturing of wells utilizing more than three hundred thousand gallons of water as the base fluid for fracturing operations and is proposed to be used in natural gas wells permitted by the Department. Also included in the proposed rules are updates to the Department's oil and gas and State Pollutant Discharge Elimination System (SPDES) regulations.

Type and Estimate of the Number of Rural Areas Affected. The proposed revisions and additions to the Department's regulations will apply to the use HVHF statewide; however, two formations likely to be initially targeted for production are the Marcellus and the Utica Shales. The prospective region for the extraction of natural gas from the Marcellus and Utica Shales has been roughly described as an area extending from Chautauqua County eastward to Greene, Ulster and Sullivan counties, and from the Pennsylvania border north to the approximate location of the east-west portion of the New York State Thruway between Schenectady and Auburn. According to 2010 Census figures, all of these nearly 30 counties, except for portions of Erie, Monroe, Onondaga, and Albany counties, would be considered rural areas. The updates to the Department's oil and gas and SPDES regulations will also apply statewide.

Compliance with the Rules. The proposed rules include recordkeeping and reporting requirements for well operators related to: well construction; private water well testing; and well completion reporting, when an operator proposes to use HVHF. These proposed requirements are applicable to HVHF activities statewide, and would not result in any disproportionate impact on the regulated community in rural areas. The proposed rules will apply to any well operator who intends to utilize HVHF to produce natural gas from wells permitted by the Department. This will, for the most part, involve large national and international corporations and the well operator's ability to comply with the proposed rules is not expected to be affected by the fact that a well is located in a rural area.

Similarly, the proposed changes to the Department's existing oil and gas regulations which include: a new reporting requirement to re-fracture an existing well; the need to file an interim completion report and enhanced minimum plugging requirements, will apply statewide. The capital required to secure the requisite percentage of mineral rights needed to obtain a permit from the Department, and to drill a natural gas well with or without the use of HVHF, is substantial. Therefore, the Department does not expect public or private sector interests in rural areas to be adversely affected by the proposed changes to the Department's existing oil and gas regulations. Moreover, the costs associated with notifying and receiving approval to re-fracture a well or to submit an interim completion

report are expected to be minimal. Enhancement of the Department's minimum plugging requirements will also not adversely affect the regulated community, as the regulations provide only minimum standards and the Department regularly requires more stringent plugging procedures depending on site-specific circumstances. Therefore, due to current Department and industry practices, the costs associated with plugging a well by either the public or private sector in rural areas will not substantially change as a result of the proposed regulations.

Another sector of the regulated community that will be impacted by the proposed rules are mineral rights owners involved in compulsory integration proceedings administered by the Department. Compulsory integration, governed by Environmental Conservation Law (ECL) Article 23, Title 9, is the process by which the Department addresses un-leased mineral rights in the area surrounding the well established by the Department-issued permit to drill. In situations where a mineral rights owner elects to participate in the costs of developing a well where HVHF will be used, the proposed rules will increase the costs of participation. In such cases, the cost of complying with the proposed rules will still fall largely on the well operator since the well operator is required by the ECL to control at least sixty percent of the mineral rights in the area that will be produced before the well operator may apply for a permit to drill. The new application, reporting and operating requirements proposed to be added as a new Part 560 to 6 NYCRR will impact mineral rights owners. However, these requirements have been identified by the Department as necessary measures to ensure HVHF wells are drilled and operated properly and to ensure all waste generated during well construction, hydraulic fracturing and production are handled appropriately.

The proposed rules also contain testing, monitoring and recordkeeping requirements for operators of publicly owned treatment works (POTW). Therefore, POTW operators in rural areas may be affected by the proposed rules, to the extent that such POTWs accept wastewater associated with wells where HVHF was utilized. In general, POTWs must have a DEC approved pretreatment program for accepting any HVHF wastewater and must notify DEC if they plan to receive wastewater at their facility. POTWs are required to perform certain analyses to ensure they can handle the wastewater without upsetting their system or causing a problem in the receiving water. While there are costs associated with the POTW analyses and securing DEC approval of such, this is offset by the disposal fee that the municipality may impose for allowing disposal of the HVHF wastewater at their facility. Therefore, the costs associated with complying with the rule will not vary across the state or in rural areas, since the decision to accept wastewater from HVHF wells is voluntary.

Although the Department does not expect the proposed rules to adversely affect the regulated community in rural areas, the proposed rules will indirectly impact the ability of rural areas to respond to activities associated with the approval of HVHF. Indirectly, the proposed rules may require local governments to respond to additional complaints about water well quality as well owners are made aware of water well testing required by the proposed rules. Approval of HVHF is also expected to increase local traffic and in some areas, increase the local population. As a result, local governments may experience increased demand on local services, such as emergency response and local road maintenance. The 2011 dSGEIS contains a detailed analysis of the socioeconomic impacts associated with approval to utilize HVHF and proposed mitigation measures.

With respect to professional services in rural areas, the proposed rules may require the regulated community to hire professionals to assist in compliance activities required by the regulations. The additional stormwater requirements and requirements for POTWs are two examples where the proposed rules may require well operators to hire experts. However, the ability of a well operator to comply with the proposed rules is not expected to be affected by the fact that a well is located in rural areas.

Local governments are not required to take any affirmative actions under the proposed rules. However, local governments may retain professional services to assist with emergency response and traffic control in certain circumstances, where approval of HVHF leads to impacts in those areas of local government.

Costs. The recordkeeping, reporting and compliance requirements included in the proposed 6 NYCRR Part 560 and the Part 750-3, will promulgate the application requirements and mitigation measures identified by the Department in the State Environmental Quality Review Act (SEQRA) process currently underway related to HVHF. In many cases, the proposed rules adopt verbatim the permit conditions recommended for inclusion in a Department-issued permit to drill. Therefore the costs of complying with the proposed regulations pertaining to HVHF will not differ substantially from the costs of complying with the 2011 dSGEIS. The Department is awaiting cost figures from private industry on estimates to comply with the proposed rules. Until the Department receives input from the regulated community through the SEQRA and rulemaking process, costs cannot be quantified at this time.

Public entities will incur minimal costs under this proposal as the public

sector is not the focus of the proposed rules. Concerning HVHF, public entities in rural areas that operate POTWs will incur costs if a POTW accepts wastewater from an operator of an HVHF well. This is no different than the public entities' role with respect to other industries, and public entities will be able to use increased tax and other revenue generated through HVHF activities to offset any increased burden on services it provides.

Apart from the provisions in the proposed rules related to HVHF, the proposed changes to Parts 550-555 of 6 NYCRR will raise the minimum requirements to plug and abandon a well under the Department's jurisdiction. The proposed rules will also add a new reporting requirement for any break in drilling operations lasting longer than thirty days and will require well operators to receive approval to re-fracture a well. There have been occasions where local governments have drilled self-help wells, or wells meant to supply oil or gas to local buildings. There also exists the possibility that abandoned wells may exist on public lands. The proposed updates mentioned above, including the changes to Part 555, would impact those wells. However, as described above, the proposed revisions to Part 555 would still specify minimum standards and the proposed changes to Part 555 would not raise the cost of plugging a well above that which is often already required by current Department practices. The costs associated with the new reporting requirements contained in the proposed changes to 6 NYCRR Parts 550-555 are expected to be minimal.

Minimizing Adverse Impact. The regulated community which is the main focus of the proposed rules are well operators who plan to drill wells and utilize HVHF to facilitate production of natural gas. Although natural gas wells will be located in rural areas, the proposed rules will not have an adverse impact on private or public members of the regulated community in rural areas due to the location of the well. With respect to indirect costs on local governments in rural areas, the proposed rules contain some measures to mitigate potential impacts, such as the need for well operators to submit a transportation plan to the Department prior to issuance of a drilling permit. A transportation plan would assist localities in planning for HVHF operations to allocate resources and initiate a dialogue with well operators. Supporting industries, such as waste haulers and water haulers, who provide a service to well operators will have minimal costs to comply with the rules, with such costs limited to paperwork requirements such as the need to track waste from an HVHF well pad to a destination for disposal or reuse.

Rural Area Participation. The Department participated in outreach to the regulated community through this process, including the solicitation of comments from affected industry. Additionally, the proposed use of HVHF in New York has been the subject of substantial public outreach and input over the last several years through the SEQRA process. During scoping sessions and following the release of the 2009 draft SGEIS, the Department received thousands of written comments, received hundreds of verbal comments at public meetings in several of the potentially affected rural areas, and has had multiple interactions with the regulated community, and public and private entities in rural areas. Additionally, the Department will hold public hearings on both of the 2011 dSGEIS and the draft regulations in some of the affected rural areas, which will provide additional opportunities for affected rural areas to participate in the rulemaking process.

Job Impact Statement

The New York State Department of Environmental Conservation (Department) proposes to revise 6 NYCRR Parts 52, 190, 550-555, 560 and 750. The regulations will apply statewide. The Department does not expect the proposed regulations to have a negative impact on jobs and employment opportunities in the state.

The proposed rules will amend the Department's existing regulations and will add new regulations to address the use of high-volume hydraulic fracturing (HVHF) as a method to facilitate production of natural gas from wells permitted by the Department. The Department is currently involved in a multi-year environmental review of HVHF. As a result of this process, the Department has identified a number of application requirements and mitigation measures that are expected to be uniformly applied to all HVHF wells to ensure such wells are drilled and operated properly. The proposed rules will supplement the Department's ability to monitor and enforce certain measures identified in the Department's revised draft Supplemental Generic Environmental Impact Statement (2011 dSGEIS), and will, at the same time, update some of the Department's regulations to reflect technological advances and current industry practice.

Nature of Impact. The approval of permits to drill natural gas wells and produce from low-permeability reservoirs, such as the Marcellus and Utica Shales, utilizing horizontal drilling and HVHF will promote economic activity. The proposed rules, implemented in combination with the 2011 dSGEIS, will have a positive impact on jobs and employment opportunities for such businesses as waste haulers, construction firms and providers of lodging, food and other services. Positive impacts will be created through direct employment, induced employment and indirect effects.

This impact is expected to be concentrated in the counties where the Marcellus and Utica Shales are more likely to be commercially producible. Lesser though still positive impacts may also be experienced in adjacent localities and statewide.

Categories and Numbers Affected. The proposed rules themselves will not negatively affect employment opportunities, and the activities guided by the proposed rules will create jobs. Approval to utilize HVHF will provide significant economic benefits to the state. Section 6.8 of the 2011 dSGEIS provides a detailed discussion of the potential economic, population and income impacts that may accrue if the use of HVHF is approved. Based on industry estimates of potential drilling activity, and after applying certain assumptions about the amount of activity that could proceed under the 2011 dSGEIS, the Department estimates that approval of HVHF could bring as many as 6,198 jobs assuming a low rate of development. This figure is an estimate of the total number of direct jobs associated with construction and operation of well pads at the lower end of potential activity.

Assuming an average rate of development, the number of direct jobs could reach 24,795 full time equivalents. The 2011 dSGEIS also discusses the potential employee earnings associated with HVHF and the number of indirect jobs that could be created as a result of approval to use HVHF in the State. The 2011 dSGEIS also contains a detailed discussion of the tax revenue which may result from production associated with HVHF. Section 6.8 of the 2011 dSGEIS should be consulted for a more detailed summary of the potential economic benefits associated with HVHF, which was the focus of the Department's review under the State Environmental Quality Review Act (SEQRA).

Regions of Adverse Impact. There are no regions of the State expected to be negatively impacted from the proposed rules. Revisions to the Department's existing regulations for natural gas drilling are intended to modernize the regulations, to make the rules consistent with current Department and industry practices. New rules proposed to address HVHF are intended to promulgate mitigation measures identified by the Department during the SEQRA process, which will apply statewide.

Minimizing Adverse Impact. The proposed rules are not expected to have an adverse impact on jobs and employment. The Department already regulates the drilling of natural gas wells and the proposed rules, while adding new regulatory requirements applicable to HVHF, will on balance lead to new employment opportunities in some areas of the state and will have positive impacts on both income and employment levels. Having the rules in place will allow for a more consistent level of development which will be the basis for longer-term employment. Having the rules in place will also allow those jobs that rely on other natural resources and the environment such as tourism and forestry to remain viable.

Self-Employment Opportunities. Drilling a natural gas well where HVHF is planned requires extensive capital. Therefore, companies directly impacted by the proposed rules are not expected to involve many self-employment opportunities. However, there will be opportunities for self-employment for supporting industries like waste hauling, water hauling, cement mixing, construction, lodging, and food services. There may also be opportunities for self-employed consultants to advise well operators on how to comply with the proposed rules.

reimbursement for hospital acquired conditions. The Centers for Medicare and Medicaid Services (CMS) issued a final rule prohibiting Medicaid payments to providers for conditions that are reasonably preventable, referred to as hospital acquired conditions, effective on or after July 1, 2011. The proposed regulations will comply with CMS regulations.

Public Health Law section 2807-c(35), as amended by Chapter 59 of the Laws of 2011, Part H, § 35-a, specifically provides the Commissioner of Health with authority to issue these emergency regulations.

Further, there is compelling interest in enacting these regulations immediately in order to secure federal approval of the associated Medicaid State Plan Amendment.

Subject: Potentially Preventable Negative Outcomes.

Purpose: Denies additional reimbursement for hospital acquired conditions.

Text of emergency rule: Pursuant to the authority vested in the Commissioner of Health by section 2807-c(35) of the Public Health Law, Subpart 86-1 of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York, is amended, effective on or after July 1, 2011, by adding a new section 86-1.42 to read as follows:

86-1.42 Potentially preventable negative outcomes.

(a) *Effective for discharges occurring on or after July 1, 2011, payments pursuant to this Subpart shall be denied with regard to the following potentially preventable negative outcomes if they are acquired during a patient's inpatient stay at the hospital seeking such payments:*

- (1) *A foreign object retained within a patient's body after surgery.*
- (2) *The development of an air embolism within a patient's body.*
- (3) *A patient blood transfusion with incompatible blood.*
- (4) *A patient's development of stage III or stage IV pressure ulcers.*
- (5) *Patient injuries resulting from accidental falls and other trauma,*

including, but not limited to:

- i. Fractures*
- ii. Dislocations*
- iii. Intracranial injuries*
- iv. Crushing injuries*
- v. Burns*
- vi. Electronic shock*

(6) *A patient's manifestations of poor glycemic control, including, but not limited to:*

- i. Diabetic ketoacidosis*
- ii. Nonketotic hyperosmolar coma*
- iii. Hypoglycemic coma*
- iv. Secondary diabetes with ketoacidosis*
- v. Secondary diabetes with hyperosmolarity*

(7) *A patient's development of a catheter-associated urinary tract infection.*

(8) *A patient's development of a vascular catheter-associated infection.*

(9) *A patient's development of a surgical site infection following:*

- i. a coronary artery bypass graft - mediastinitis;*
- ii. bariatric surgery, including, but not limited to, laparoscopic gastric bypass, gastroenterostomy, and laparoscopic gastric restrictive surgery; or*

iii. orthopedic procedures, including, but not limited to, such procedures performed on the spine, neck, shoulder and elbow.

(10) *A patient's development of deep vein thrombosis or a pulmonary embolism in connection with a total knee replacement or a hip replacement, excluding pediatric patients, defined as patients under eighteen years of age, and also excluding obstetric patients, defined as patients with at least one primary or secondary diagnosis code that includes an indication of pregnancy.*

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 December 5, 2011.

Text of rule and any required statements and analyses may be obtained from: Katherine Ceroalo, DOH, Bureau of House Counsel, Reg. Affairs Unit, Room 2438, ESP Tower Building, Albany, NY 12237, (518) 473-7488, email: regsqa@health.state.ny.us

Regulatory Impact Statement

Statutory Authority:

The requirement to deny reimbursement for hospital acquired conditions, which are avoidable hospital complications and medical errors that are identifiable, preventable, and serious in their consequences to patients, is set forth in section 2807-c(35)(b)(v) of the Public Health Law, as amended by section 35-a of Part H of Chapter 59 of the Laws of 2011. Further, section 111(a) of Part H of Chapter 59 of the Laws of 2011 permits such regulations to be implemented retroactively.

Legislative Objectives:

The Legislature chose to address the issue of patient safety and quality

Department of Health

EMERGENCY RULE MAKING

Potentially Preventable Negative Outcomes

I.D. No. HLT-39-11-00001-E

Filing No. 804

Filing Date: 2011-09-07

Effective Date: 2011-09-07

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

Action taken: Addition of section 86-1.42 to Title 10 NYCRR.

Statutory authority: Public Health Law, section 2807-c(35)

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

Specific reasons underlying the finding of necessity: It is necessary to issue the proposed regulations on an emergency basis in order to meet the statutory timeframes prescribed by Section 2807-c(35)(b)(v) of the Public Health Law, as amended by Chapter 59 of the Laws of 2011 related to the

of care through this proposal, which denies reimbursement for hospital acquired conditions. The proposal is also the result of a federal requirement and recommendations submitted by the Medicaid Redesign Team.

Needs and Benefits:

The Patient Protection & Affordable Care Act (HR 3590) requirement, effective on or after July 1, 2011, mandates states to implement a policy for Medicaid that prohibits federal payments for any costs of providing medical assistance for hospital acquired conditions (HACs). This proposal appropriately implements those requirements. HACs are conditions deemed to be reasonably preventable in accordance with evidence-based guidelines. Healthcare providers, patients and payers are all adversely impacted by the occurrence of HACs.

This proposal offers more direct and accountable reimbursement of healthcare services, thereby incentivizing providers to improve quality and provide higher valued healthcare for Medicaid beneficiaries.

COSTS:

Costs to State Government:

Section 2807-c(35)(b)(v) of the Public Health Law requires that the rates of payment for hospital inpatient services do not include, for APR-DRG assignment purposes, any conditions as a secondary diagnosis that were not present on admission and are therefore deemed a HAC. Since less than 0.1% of total Medicaid discharges (2009 data) were found to include a HAC, the denial in reimbursement results in an insignificant decrease in aggregate Medicaid payments.

Costs of Local Government:

There will be no additional cost to local governments as a result of these amendments.

Costs to the Department of Health:

There will be no additional costs to the Department of Health as a result of this amendment.

Local Government Mandates:

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

Paperwork:

There is no additional paperwork required of providers as a result of this amendment.

Duplication:

These regulations do not duplicate existing State and federal regulations.

Alternatives:

No significant alternatives are available. New York State is required by federal regulations to implement a policy, and the Department is required by the Public Health Law sections 2807-c(35)(b)(v) to promulgate implementing regulations.

Federal Standards:

This amendment does not exceed any minimum standards of the federal government for the same or similar subject areas.

Compliance Schedule:

Section 86-1.42 requires reimbursement for hospital acquired conditions, which are avoidable hospital complications and medical errors that are identifiable, preventable, and serious in their consequences, to be denied effective on or after July 1, 2011; there is no period of time necessary for regulated parties to achieve compliance.

Regulatory Flexibility Analysis

Effect on Small Business and Local Governments:

For the purpose of this regulatory flexibility analysis, small businesses were considered to be general hospitals with 100 or fewer full time equivalents. Based on recent financial and statistical data extracted from the Institutional Cost Report, seven hospitals were identified as employing fewer than 100 employees.

Health care providers subject to the provisions of this regulation under section 2807-c(35)(b)(v) of the Public Health Law will not be reimbursed for any cost associated with the ten identified categories of hospital acquired conditions. Using 2009 Medicaid data, a total of 728 HACs were identified, accounting for less than 0.1% of total Medicaid discharges.

This rule will have no direct effect on local governments.

Compliance Requirements:

No new reporting, recordkeeping or other compliance requirements are being imposed as a result of these rules. Affected health care providers will bill Medicaid using procedure codes and ICD-9 codes approved by the American Medical Association, as is currently required.

The rule should have no direct effect on local governments.

Professional Services:

No new or additional professional services are required in order to comply with the proposed amendments.

Compliance Costs:

No initial capital costs will be imposed as a result of this rule, nor will there be an annual cost of compliance. As a result of this proposal there will be a minimal decrease in hospital Medicaid revenues for hospital inpatient services that include HACs.

Economic and Technological Feasibility:

Small businesses will be able to comply with the economic and technological aspects of this rule. The proposed amendments are technologically feasible because it requires the use of existing technology. The overall economic impact to comply with the requirements of this regulation is expected to be minimal.

Minimizing Adverse Impact:

The proposed amendments reflect statutory intent and requirements.

Small Business and Local Government Participation:

Hospital associations participated in discussions and contributed comments through the State's Medicaid Redesign Team process regarding these changes.

Rural Area Flexibility Analysis

Effect on Rural Areas:

Rural areas are defined as counties with a population less than 200,000 and, for counties with a population greater than 200,000, includes towns with population densities of 150 persons or less per square mile. The following 43 counties have a population less than 200,000:

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

The following 9 counties have certain townships with population densities of 150 persons or less per square mile:

Albany	Erie	Oneida
Broome	Monroe	Onondaga
Dutchess	Niagara	Orange

Compliance Requirements:

No new reporting, recordkeeping, or other compliance requirements are being imposed as a result of this proposal.

Professional Services:

No new additional professional services are required in order for providers in rural areas to comply with the proposed amendments.

Compliance Costs:

No initial capital costs will be imposed as a result of this rule, nor is there an annual cost of compliance.

Minimizing Adverse Impact:

The proposed amendments reflect statutory intent and requirements.

Rural Area Participation:

This amendment is the result of federal requirement, effective on or after July 1, 2011, that requires states to implement a policy for Medicaid that prohibits federal payments for any costs of providing medical assistance for hospital acquired conditions (HACs).

Job Impact Statement

A Job Impact Statement is not required pursuant to Section 201-a(2)(a) of the State Administrative Procedure Act. It is apparent, from the nature and purpose of the proposed rules, that they will not have a substantial adverse impact on jobs or employment opportunities. The proposed regulations establish quality-related measures pertaining to the reimbursement for hospital acquired conditions. The proposed regulations have no implications for job opportunities.

EMERGENCY RULE MAKING

Medicaid Estate Definition

I.D. No. HLT-39-11-00005-E

Filing No. 809

Filing Date: 2011-09-08

Effective Date: 2011-09-08

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

Action taken: Amendment of section 360-7.11 of Title 18 NYCRR.

Statutory authority: Public Health Law, sections 201 and 206; and Social Services Law, sections 363-a and 369(6)

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

Specific reasons underlying the finding of necessity: Chapter 59 of the laws of 2011 enacted a number of proposals recommended by the Medicaid Redesign Team established by the Governor to reduce costs and increase quality and efficiency in the Medicaid program. The changes to SSL section 369(6) that require the Department, by regulation, to implement an expanded definition of estate for Medicaid recovery purposes, took effect April 1, 2011. Paragraph (t) of section 111 of Part H of Chapter 59 authorizes the Commissioner to promulgate, on an emergency basis, any regulations needed to implement such law. The Commissioner has determined it necessary to file these regulations on an emergency basis to achieve the savings intended to be realized by the Chapter 59 provisions regarding Medicaid estate recoveries.

Subject: Medicaid Estate Definition.

Purpose: Expand the estate definition for Medicaid recovery purposes to include assets that pass outside of an individuals probate estate.

Text of emergency rule: Section 360-7.11 is amended to read as follows:

Section 360-7.11. Medical assistance liens and recoveries.

(a) Definitions.

(1) Estate means: (i) all of a decedent's real and personal property and other assets passing under the terms of a valid will or by intestacy; and (ii) any other real and personal property and other assets in which the decedent had any legal title or interest at the time of death, including such assets conveyed to a survivor, heir, or assign of the decedent through joint tenancy, tenancy in common, survivorship, life estate, living trust or other arrangement, to the extent of the decedent's interest in the property immediately prior to death.

(2) Interest in property immediately prior to death includes the value of:

- (i) the person's proportionate share of real property held in a joint tenancy, tenancy in common, or similar arrangement;
- (ii) a retained life estate, based on the actuarial life expectancy of the life tenant;
- (iii) funds in a jointly owned bank account, except to the extent that the surviving joint owner documents his or her interest in the account through verifiable deposits and withdrawals;
- (iv) the person's per capita share of jointly owned securities;
- (v) the principal and accumulated interest of a revocable trust;
- (vi) the principal and accumulated interest of an irrevocable trust funded in whole or in part with the assets of the person or the person's spouse to the extent that the person was entitled to the distribution of such principal and interest pursuant to the terms of the trust, and if the person was entitled to receive trust income, any income that, as of the date of the person's death, was required to be but had not been distributed; and
- (vii) remaining payments from an annuity purchased by or with the assets of the person or the person's spouse.

(3) Retained life estate means: (i) a life estate created by a person or the person's spouse in property in which the person or spouse held any interest at the time the life estate was created; or (ii) a life estate created for the benefit of a person or the person's spouse in property in which the person or spouse held any interest within five years prior to the creation of the life estate.

(b) Liens.

(1) The [social services district] MA program may not impose any lien against a person's property prior to his or her death for MA paid or to be paid on his or her behalf except:

[(1)] (i) based upon a court judgment for benefits incorrectly paid;

or

[(2)] (ii) against claims and suits for personal injuries, to recover the amount of MA furnished to a person on and after the date the person incurred the injuries; or

[(3)] (iii) with respect to the real property of a person who is an inpatient in a nursing facility, intermediate care facility for the mentally retarded, or other medical institution, and who is not reasonably expected to be discharged from the medical institution and return home, provided that:

[(i)] (a) any such lien will dissolve upon the person's discharge and return home; and

[(ii)] (b) no lien may be imposed on the person's home if the person's spouse, child under 21 years of age, certified blind or certified disabled child of any age, or sibling who has an equity interest in the home and who resided in the home for at least one year immediately before the date of the person's admission to the medical institution, is lawfully residing in the home.

(2) Liens shall be imposed on property and assets described in subparagraph (ii) of paragraph (1) of subdivision (a) of this section as soon as practicable after the person's death.

[(b) Adjustments and recoveries] (c) Recoveries - generally.

(1) [A social services district] The MA program may make no adjustment or recovery for MA correctly paid, except that recoveries must be pursued from:

(i) the estate of a person who was [65] 55 years of age or older when he or she received MA; or

(ii) the sale of real property subject to a lien imposed [pursuant to] on account of MA furnished to a person described in [paragraph (a)(3)] subparagraph (b)(1)(iii) of this section, or from the estate of such a person; or

(iii) a legally responsible relative of an MA recipient, and then only the amount of MA granted, provided the relative has sufficient income and resources which he or she fails or refuses to make available. The amount of income and resources required to be contributed by a legally responsible relative is determined under Subpart 360-4 of this Part.

(2) An adjustment or recovery under subparagraph (1)(i) or (ii) of this subdivision may be made from a person's estate only after the death of the person's surviving spouse, and only when the person has no surviving child who is under 21 years of age or who is certified blind or certified disabled.

(3) In addition to the limitations set forth in paragraph (2) of this subdivision, in the case of a lien on a person's home, no adjustment or recovery may be made when:

(i) a sibling of the person has an equity interest in the home, has resided in the home for at least one year immediately before the date of the person's admission to the medical institution, and has lawfully resided in the home on a continuous basis since the date of admission; or

(ii) a child of the person resided in the home for a period of at least two years immediately before the date of the person's admission to a medical institution, provided care to such person which permitted the person to reside at home rather than in an institution, and has lawfully resided in the home on a continuous basis since the date of admission.

(d) Estate recoveries.

(1) Notice of claim. As soon as practicable after the death of a person who received MA or the surviving spouse of such a person, the MA program will provide a written notice of claim to the estate fiduciary, if applicable, and to individuals in possession of property described in subparagraph (ii) of paragraph (1) of subdivision (a) of this section. Such notice will:

(i) set forth the basis for the estate claim, and the specific laws and/or regulations supporting the claim;

(ii) specify the amount determined to be owed to the MA program as of the date of the notice;

(iii) describe the criteria for being granted a deferral or waiver of the estate recovery, and the timeframes for requesting such deferral or waiver;

(iv) indicate that the MA program has imposed or may impose a lien against any real property described in subparagraph (ii) of paragraph (1) of subdivision (a) of this section; and

(v) instruct the estate fiduciary to inform the person's dependents, heirs, or survivors of the MA program's claim and of their right to seek a deferral or waiver of the estate recovery, or to contest the MA program's claim.

(2) Waiver of estate recovery. Recovery of MA correctly paid shall be waived in whole or in part if it would result in undue hardship. Any estate beneficiary, estate fiduciary on behalf of an estate beneficiary, or person in possession of property described in subparagraph (ii) of paragraph (1) of subdivision (a) of this section, may request that recovery be waived on the basis of undue hardship.

(i) Undue hardship may be found to exist when: the estate asset subject to recovery is the sole income-producing asset of the beneficiary or beneficiaries, such as a family farm or business, and income produced by the asset is limited; the estate asset subject to recovery is a home of modest value and the home is the primary residence of the beneficiary; or there are other compelling circumstances.

(ii) *Undue hardship will not be found to exist based solely on the inability of any of the beneficiaries to maintain a pre-existing lifestyle, or where the alleged hardship is the result of MA or estate planning methods involving divestiture of assets.*

(3) Deferral of estate recovery.

(i) *The MA program must defer estate recovery:*

(a) *during the lifetime of the person's surviving spouse;*

(b) *during any period in which the person has a surviving child who is under age 21 or who is certified blind or disabled; and*

(c) *with respect to the home of a deceased Medicaid recipient, when one of the relatives described in paragraph (3) of subdivision (c) of this section is lawfully residing in the home.*

(ii) *The MA program may defer estate recovery if:*

(a) *the asset subject to recovery is an interest in real property and undue hardship has not been found to exist;*

(b) *a dependent, heir, or survivor has lawfully and continuously resided in the real property, beginning prior to the person's death, and is unwilling to sell the real property;*

(c) *the dependent, heir, or survivor cannot pay the MA estate claim in full unless the property is liquidated;*

(d) *the dependent, heir, or survivor has applied for but been unable to obtain financing in order to pay the MA claim; and*

(e) *a written agreement has been entered into between the MA program and the dependent, heir, or survivor whereby the MA program holds a lien on the property, and the dependent, heir, or survivor agrees to pay the amount of the MA claim in accordance with a reasonable payment schedule, subject to reasonable interest.*

[(4)] (e) [A social services district] *The MA program may maintain an action pursuant to sections 101 and 104 of the Social Services Law to collect from a trustee, grantor, or grantor's spouse any beneficial interest of the grantor or grantor's spouse in any trust established other than by will, to reimburse [such district] the program for the amount of MA granted to, or on behalf of, a grantor or grantor's spouse. The beneficial interest of the grantor or grantor's spouse includes any income and principal amounts to which the grantor or grantor's spouse would be entitled under the terms of the trust, by right or in the discretion of the trustee, assuming the full exercise of discretion by the trustee.*

[(5)] (f) *If an MA recipient receives an insurance settlement for personal injuries which includes an amount for medical bills, the [social services district] MA program may recover from such amount the cost of MA provided for the treatment of the injuries.*

[(6)] (g) [A social services district] *The MA program may maintain an action under the Debtor and Creditor Law to set aside any transaction which appears to have been made for the purpose of qualifying a person for MA or for avoiding a lien or recovery of MA paid on behalf of an MA recipient.*

(h) *Nothing in this section shall authorize the imposition of liens or pursuit of MA recoveries against assets exempted from such liens and recoveries by federal or State law.*

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 December 6, 2011.

Text of rule and any required statements and analyses may be obtained from: Katherine Ceroalo, DOH, Bureau of House Counsel, Reg. Affairs Unit, Room 2438, ESP Tower Building, Albany, NY 12237, (518) 473-7488, email: regsqna@health.state.ny.us

Regulatory Impact Statement

Statutory Authority:

Social Services Law (SSL) section 363-a and Public Health Law section 201(1)(v) provide that the Department is the single state agency responsible for supervising the administration of the State's medical assistance ("Medicaid") program and for adopting such regulations, not inconsistent with law, as may be necessary to implement the State's Medicaid program.

Legislative Objectives:

Subdivision 6 of section 369 of the Social Services Law (SSL), as amended by Chapter 59 of the Laws of 2011, provides that pursuant to regulations promulgated by the Commissioner of Health, an individual's estate for Medicaid recovery purposes will include any property in which the individual had any legal title or interest at the time of death, including jointly held property, retained life estates, and interests in trusts, to the extent of those interests. The legislative objective, expressed through SSL section 369(6), is to increase the amount of Medicaid estate recoveries by expanding the definition of estate to include assets that pass outside of an individual's probate estate.

Needs and Benefits:

The proposed regulation is required before the State's Medicaid program can implement the provisions of Chapter 59 of the Laws of 2011

expanding the Medicaid definition of estate. In addition, the proposed regulation amends outdated provisions in 18 NYCRR § 360-7.11 to bring them in conformance with changes made to SSL section 369 by Chapter 170 of the Laws of 1994 that: made Medicaid estate recoveries mandatory rather than permissive; expanded estate recoveries to Medicaid provided to individuals 55 years of age or older, rather than 65 years of age or older; and required Medicaid recoveries to be waived in cases of undue hardship.

The proposed regulation would make a number of substantive changes to the current section dealing with Medicaid liens and recoveries, 18 NYCRR 360-7.11.

Subdivision (a) of the regulation defines various terms related to Medicaid estate recoveries. It defines the term estate in accordance with the statutory definition, but clarifies that having a legal title or interest in property at the time of death means the extent of such interest immediately prior to death. This clarification is necessary because some interests in property that the Legislature clearly intends to be subject to Medicaid recoveries technically end at the time (moment) of death. The definition of the term interest in property immediately prior to death lists typical assets that pass outside an individual's probate estate, and defines the extent of the individual's interest in each such asset immediately prior to death for purposes of asserting a Medicaid recovery claim. The definition of retained life estate further limits Medicaid recoveries from life estates to situations in which the Medicaid recipient or spouse had an interest in the property at the time the life estate was created or within five years prior to the creation of the life estate.

Subdivision (b) of the regulation, relating to the placement of Medicaid liens, is amended to provide that post-death liens against assets will be imposed as soon as practicable after the individual's death.

Subdivision (c) of the regulation, relating to Medicaid recoveries in general, is amended to reflect that recoveries are mandatory and that the cost of correctly paid Medicaid will be recovered from the estates of individuals who were 55 years of age or older when they received assistance.

Subdivision (d) of the regulation, relating specifically to estate recoveries, addresses:

- the requirement for and contents of a Medicaid notice of claim to be provided to the estate fiduciary, if applicable, and to individuals in possession of assets that pass outside the probate estate;
- the right of an estate beneficiary or fiduciary, or person in possession of non-probate assets, to request a waiver of a Medicaid estate recovery, and the criteria for granting such a waiver;
- periods of time during which a Medicaid recovery is prohibited by law, i.e., during the lifetime of the individual's surviving spouse, or when there is a surviving child who is a minor or who is blind or disabled, or, with respect to a home, when certain relatives have lawfully and continuously resided in the home since the date of the Medicaid recipient's admission to a medical institution; and
- circumstances under which a Medicaid recovery may be deferred in order to allow a dependent, heir, or survivor who has lawfully and continuously resided in the individual's home, beginning prior to the individual's death, to continue to live there.

Section (h) of the regulation clarifies that nothing in section 360-7.11 authorizes Medicaid liens or recoveries against assets that are exempted from such liens and recoveries by federal or State law.

In addition to the changes described above, the proposed regulation amends section 360-7.11 to replace references to social services districts with references to the Medicaid program, to reflect the fact that the authority to impose liens and pursue Medicaid recoveries does not rest solely with the local districts. Subdivision 7 of SSL section 369 was added by Chapter 58 of the Laws of 2008 to clarify that the Department has concurrent authority to conduct the full range of Medicaid recovery activities.

COSTS:

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

This amendment will not increase costs to the regulated parties.

Costs to State and Local Government:

This amendment will not increase costs to the State or local governments. Savings to the Medicaid program will be achieved by expanding the scope of assets subject to Medicaid recovery.

Costs to the Department of Health:

There will be no additional costs to the Department.

Local Government Mandates:

This amendment will not impose any program, service, duty, additional cost, or responsibility on any county, city, town, village, school district, fire district, or other special district.

Paperwork:

This amendment will not impose any additional paperwork requirements.

Duplication:

There are no duplicative or conflicting rules identified.

Alternatives:

The expansion of the definition of estate for Medicaid recovery purposes is mandated by section 369(6) of the SSL. No alternatives were considered.

Federal Standards:

The federal Medicaid statute, at 42 USC 1396p(b)(4), provides that for purposes of Medicaid estate recoveries, the term "estate" shall include all real and personal property in the individual's probate estate, and may include, at the option of the State, any other real and personal property and other assets in which the individual had any legal title or interest at the time of death, including assets conveyed through joint tenancy, tenancy in common, survivorship, life estate, living trust, or other arrangement.

Compliance Schedule:

Social services districts should be able to comply with the proposed regulations when they become effective.

Regulatory Flexibility Analysis

Effect of Rule:

The proposed regulation implements the provisions of Chapter 59 of the Laws of 2011. Chapter 59 amended Social Services Law section 369(6) to expand the definition of estate, for Medicaid recovery purposes, to include assets that pass outside of an individual's probate estate. Social services districts currently impose liens and pursue recoveries on behalf of the Medicaid program. The proposed regulation expands the type of assets that are the target of these ongoing recovery activities.

Compliance Requirements:

This amendment does not impose new reporting, recordkeeping or other compliance requirements on small businesses or local governments.

Professional Services:

No new professional services are required as a result of this amendment.

Compliance Costs:

There are no costs of compliance with this amendment.

Economic and Technological Feasibility:

There should be no technological difficulties associated with complying with the proposed regulation.

Minimizing Adverse Impact:

The expansion of the definition of estate for Medicaid recovery purposes is mandated by section 369(6) of the SSL. This will have an adverse impact on some survivors of deceased Medicaid recipients, because Medicaid's estate claim will reduce the amount of non-probate assets that pass to such survivors by operation of law or pursuant to the terms of a trust. This impact cannot be avoided given the statutory mandate.

Small Business and Local Government Participation:

Local government officials have consistently been in favor of measures that would reduce the amount of assets sheltered by Medicaid applicants to achieve eligibility and to avoid estate recoveries. The Department hosted a conference call for program, fiscal, and legal staff of the social services districts to brief them on the policy changes that the Department anticipated making, through regulation and administrative directive, to comply with the expanded estate definition provisions of Chapter 59 of the Laws of 2011. In addition to the discussion that took place during the call, the Department solicited and received written comments and questions from the districts on these policy changes, which the Department considered in preparing the final version of the proposed regulation.

Rural Area Flexibility Analysis

Effect on Rural Areas:

The proposed regulation implements the provisions of Chapter 59 of the Laws of 2011, which expand the definition of estate, for Medicaid recovery purposes, to include assets that pass outside of an individual's probate estate. Social services districts currently impose liens and pursue recoveries on behalf of the Medicaid program. Each upstate county in New York State is a separate social services district; some are rural counties.

Compliance Requirements:

No new reporting, recordkeeping or other compliance requirements are being imposed as a result of the proposed regulation.

Professional Services:

No additional professional services are required for social services districts to comply with the proposed regulation.

Compliance Costs:

There are no costs associated with compliance.

Minimizing Adverse Impact:

The expansion of the definition of estate for Medicaid recovery purposes is mandated by section 369(6) of the SSL. This will have an adverse impact on some survivors of deceased Medicaid recipients, because Medicaid estate claims against non-probate assets will reduce the amount of assets that pass to such survivors by operation of law or pursuant to the terms of a trust. This impact cannot be avoided given the statutory mandate.

Opportunity for Rural Area Participation:

The Department hosted a conference call for program, fiscal, and legal staff of the social services districts to brief them on the policy changes that the Department anticipated making, through regulation and administrative directive, to comply with the expanded estate definition provisions of Chapter 59 of the Laws of 2011. In addition to the discussion that took place during the call, the Department solicited and received written comments and questions from the districts on these policy changes, which the Department considered in preparing the final version of the proposed regulation.

Job Impact Statement

Nature of Impact:

The proposed regulation will not adversely impact jobs or employment opportunities in New York. The proposed regulation implements the provisions of Chapter 59 of the Laws of 2011, which expand the definition of estate, for Medicaid recovery purposes, to include assets that pass outside of an individual's probate estate.

Categories and Numbers Affected:

Not applicable.

Regions of Adverse Impact:

Not applicable.

Minimizing Adverse Impact:

Not applicable.

Self-Employment Opportunities:

Not applicable.

**EMERGENCY
RULE MAKING**

NYS Newborn Screening Panel

I.D. No. HLT-39-11-00014-E

Filing No. 816

Filing Date: 2011-09-12

Effective Date: 2011-09-12

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

Action taken: Amendment of section 69-1.2 of Title 10 NYCRR.

Statutory authority: Public Health Law, section 2500-a

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

Specific reasons underlying the finding of necessity: Advancing technology, and emerging and rising public expectations for this critical public health program demand that the panel of screening conditions be expanded through this amendment of 10 NYCRR Section 69-1.2, which would add one inherited disorder of the immune system to the scope of newborn screening services already provided by the Department's Wadsworth Center. This regulatory amendment adds one condition – severe combined immunodeficiency (SCID) – to the 44 genetic/congenital disorders and one infectious disease that comprise New York State's newborn screening test panel. 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) requirements for this rulemaking would be contrary to the public interest.

Immediate implementation of the proposed screening for SCID is both feasible and obligatory at this time. A laboratory test method using a dried blood spot specimen was recently validated by the Department's Newborn Screening Program. The Program has determined that a scaled-up version of the recently developed test method reproducibly generates reliable results for the large number of newborns' specimens accepted by the Program. The required instrumentation (i.e., robots to prepare DNA and thermal cyclers to detect TRECs) is already in operation at the Department's Wadsworth Center laboratory and dedicated to newborn screening. A system for follow-up and ensuring access to necessary treatment for identified infants is fully established and adequately staffed.

Early detection through screening is critical to successful treatment of SCID. A survey of more than 150 patients commissioned by the Immune Deficiency Foundation found that SCID patients who were diagnosed early and treated by 3.5 months showed a 91-percent survival rate; those treated after 3.5 months had a 76-percent survival rate. Average costs for a bone marrow transplant also increase significantly after the infant reaches 3.5 months of age, exceeding \$300,000 because of additional complications and the need for more

supportive care. Now that the Program is technically proficient in DNA technology, data collection and interpretation, and has demonstrated proficiency in triage and referral procedures, failure to include SCID screening immediately would mean infants would go undetected, undetected, and may suffer serious systemic infections and even succumb to an early death. Accordingly, the Department is obligated to avoid further delays in implementing screening for SCID.

Subject: NYS Newborn Screening Panel.

Purpose: Adds Severe Combined Immunodeficiency (SCID) to NYS Newborn Screening Panel.

Text of emergency rule: Section 69-1.2(b) is amended as follows:

(b) Diseases and conditions to be tested for shall include:

argininemia (ARG);

* * * *

propionic acidemia (PA);

severe combined immunodeficiency and other inherited T-cell deficiencies (SCID)

short-chain acyl-CoA dehydrogenase deficiency (SCADD);

tyrosinemia (TYR); and

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

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 December 10, 2011.

Text of rule and any required statements and analyses may be obtained from: Katherine Ceroalo, DOH, Bureau of House Counsel, Reg. Affairs Unit, Room 2438, ESP Tower Building, Albany, NY 12237, (518) 473-7488, email: regsqna@health.state.ny.us

Summary of Regulatory Impact Statement

Statutory Authority:

Public Health Law (PHL) Section 2500-a (a) provides statutory authority for the Commissioner of Health to designate in regulation 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. Emerging medical treatments and the complexity of genetic testing require periodic reassessments of the benefits of newborn screening. These reassessments ensure that the New York State's Newborn Screening Program (the NYS Program) meets the legislative intent of preventing childhood diseases and disorders by early detection. This proposal, which would modify the newborn screening panel currently in regulation by adding severe combined immunodeficiency (SCID), 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:

Severe Combined Immunodeficiency (SCID) is a primary immune deficiency, which results in the infant's failure to develop a normal immune system. The defining characteristic for SCID is a severe defect in the production and function of T-cells and/or B-cells. Affected infants are susceptible to a wide range of infections that are typically controlled by a normal immune system. If undetected and untreated, SCID typically leads to death in the first year of life. It is noteworthy that, in May of 2010, the U.S. Department of Health and Human Services (DHHS) Secretary Kathleen Sebelius added SCID to the core newborn screening panel that represents a national standard 30-test panel that states are encouraged to adopt.

The pediatric immunology community now recognizes this once-fatal disease is a disorder that can be treated and most likely cured at a reasonable cost. Early detection through screening is critical to successful treatment. Current estimates suggest that one in every 50,000 to 100,000 newborns may be affected; however, since many infants may succumb to infection before being diagnosed, the true incidence of SCID and related forms of T-cell immune deficiency may be higher. A DNA-based test for immune deficiency has been recently modified

for accurate, high-throughput analyses, making possible its use for newborn screening. This test detects T-cell Receptor Gene Excision Circles or TRECs, which are produced during normal T-cell maturation but are absent or severely reduced in infants with SCID.

Immediately after confirming a SCID diagnosis, infants are started on intravenous immunoglobulins (IVIG) and antibiotics, and a donor search is initiated to perform stem cell transplant from donor bone marrow or cord blood. SCID infants and children require IVIG for as long as they lack the ability to produce antibodies - before and often for some time after a transplant. If the transplant proves not totally corrective, IVIG may be needed for life. Alternatively, enzyme replacement therapy with bovine pegademase (PEG-ADA), an injectable medication, can be used to treat the approximately 40-percent of SCID patients with a form of the disorder characterized by a deficiency of the enzyme adenosine deaminase. This treatment is typically used only when the patient is not a candidate for the more conventional bone marrow transplant treatment.

General health care costs attributable to treatment of SCID-confirmed infants, including those related to a stem cell transplant (i.e., use of a surgical suite, stays in the neonatal intensive care unit) cannot be assessed due to large variations in charges for the professional component of specialists' and ancillary providers' services, and the scope of potentially required donor-matching services. However, overall health care costs would be reduced since early diagnosis of SCID provides the opportunity for less expensive treatments, and avoids medical complications, thereby reducing the number and average length of hospital stays, and emergency and intensive care services necessary due to recurrent infections in affected children.

If a matched, related donor cannot be found or a transplant fails, infants diagnosed with SCID typically are initially treated using IVIG as an outpatient procedure. Since IVIG only replaces the missing end product, but does not correct the deficiency in antibody production, the replacement therapy usually becomes necessary for the patient's entire lifespan. The cost of lifetime IVIG replacement therapy is estimated to be approximately \$600,000. Costs for enzyme replacement therapy for one form of SCID with PEG-ADA, which is designated as an orphan drug, are estimated at \$3,800 per injection. PEG-ADA is administered by intramuscular injection twice weekly and once weekly after stabilization is reached, usually in one to three weeks. Costs for a transplant including a 1 year follow-up period are \$300,000, while costs for an unscreened and undiagnosed child who does not receive early treatment can exceed \$600,000.

Costs:

Costs to Private Regulated Parties:

Birthing facilities would incur no new costs related to collection and submission of blood specimens to the NYS Program, since the dried blood spot specimens now collected would also be tested for SCID.

The NYS Program estimates that following implementation of this proposal, 125 newborns would screen positive for SCID annually statewide, with SCID being confirmed in seven of those infants.

Birthing facilities would likely incur minimal additional costs related to fulfilling their responsibilities for referral of screen-positive infants; such costs would be limited to human resources costs for less than 0.5 person-hour. Any birthing facility can calculate its specific cost impact based on its annual number of births and related expenses, and a referral rate of one infant per 2,100 births. The Department estimates that on average specialized care facilities would receive referrals of fewer than two infants per month for clinical assessment and additional testing to confirm or refute screening results.

Annual cost for arranging for SCID-related referrals for a facility at which 2,000 babies are delivered each year would range from 1/2 of \$40 to 1/2 of \$100, depending on whether clerical staff or nursing staff arranged for the referral, or specifically \$20-50 a year. Larger birthing facilities (i.e., those with the resources to perform transplants) would not incur even these minimal costs for referral to another facility.

Costs for Implementation and Administration of the Rule:

Costs to State Government:

State-operated facilities providing birthing services and infant

follow-up and medical care would incur costs and savings as described above for private regulated parties.

State Medicaid costs will not increase with regard to referral costs, as such costs are included in rates for delivery-related services, and are not separately reimbursed. Costs associated with treatment for SCIDS for Medicaid-eligible infants would generally be borne by the State, as most counties have already reached their cap for Medicaid liability. However, there would likely be a net savings to Medicaid since early diagnosis provides the opportunity for less expensive treatment, (on the order of \$300,000) and avoids medical complications, thereby reducing the number and average length of hospital stays, and emergency and intensive care services necessary due to recurrent infections (which can exceed \$600,000).

Costs to the Department:

Costs incurred by the Department's Wadsworth Center for performing SCID screening tests, providing short- and long-term follow-up, and supporting continuing research in neonatal and genetic diseases will be covered by State budget appropriations. The Program expects minimal to no additional laboratory instrumentation costs related to this proposal, since the necessary technology has already been purchased.

The Department will incur minimal administrative costs for notifying all New York State-licensed physicians, hospital chief executive officers (CEOs) and their designees, and other affected parties, by letter informing them of a newborn screening panel expansion or, on an ongoing basis, of information regarding positive SCID screening results.

Costs to Local Government:

Local government-operated facilities providing birthing services and medical care to affected infants would incur the costs and savings described above for private regulated parties.

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. 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 of infants with abnormal screening results. Educational materials for parents and health care professionals and forms will be updated to include information on SCID at minimal costs at the next printing.

Duplication:

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

Alternative Approaches:

Potential delays in detection of SCID until onset of clinical symptoms would result in increased infant morbidity and mortality, and are therefore unacceptable. Given the recent recommendation by DHHS, which takes into account that treatment is available to ameliorate adverse clinical outcomes in affected infants, the Department has determined that there are no alternatives to requiring newborn screening for this condition.

Federal Standards:

The DHHS has recommended a core newborn screening panel that represents a national standard 30-test panel that states are encouraged to adopt. A DHHS-commissioned Advisory Committee on Heritable Disorders of Newborns and Children recently recommended that states' newborn screening programs amend their test panels to include SCID. With the addition of SCID to its panel, the NYS Program would include all the DHHS-recommended tests.

Compliance Schedule:

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 to other affected parties.

The infrastructure and mechanisms for making the necessary referrals is already in place in birthing facilities. 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 one new condition - an immunodeficiency disorder known as severe combined immunodeficiency (SCID) to the list of 44 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. No facility recognized as having medical expertise in clinical assessment and treatment of SCID is operated as a small business. Local governments, including the New York City Health and Hospitals Corporation, operate 21 hospitals. 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 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 test proposed by this amendment.

Birthing facilities and at-home birth attendants (i.e., licensed midwives) would be required to follow up infants screening positive for SCID, and assume some responsibility for referral for medical evaluation and additional testing as they do for other conditions. The anticipated increased burden is expected to have a 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 one to two per month in the number of infants requiring referral.

On average, each birthing facility can expect to refer no more than one additional infant per year for clinical assessment and confirmatory testing as a result of this amendment's proposal to add SCID screening to the existing newborn screening panel. This increase is expected to have minimal effect on a birthing facility's workload since at present approximately 30 infants, on average, are referred by birthing facilities statewide; with the addition of SCID this number would increase by an average of one infant. Therefore, no additional staff would be required for these institutions to comply with this proposal.

The Department anticipates that more than 95 percent of approximately 125 referred infants will ultimately be found not to be afflicted with SCID, based on clinical assessment and laboratory tests.

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. Birthing facilities' existing professional staff are expected to be able to assume any increase in workload resulting from the Program's newborn screening for SCID and identification of screen-positive infants. Infants with positive screening tests for SCID would be referred to a

facility employing a physician and other medical professionals with expertise in SCID.

Compliance Costs:

Birthing facilities operated as small businesses and by local governments, and practitioners who are small business owners (e.g., 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 test 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 SCID, primarily because the testing proposed under this regulation is expected to result in, on average, fewer than one referral per year at each of the 11 birthing facilities that are small businesses.

The NYS Program estimates that following implementation of this proposal, 125 newborns would screen positive for SCID annually statewide. Since timing is crucial, i.e., treatment must commence early to be effective, newborns who screen positive will require immediate referral to a facility with the requisite expertise for clinical assessment and laboratory testing. The Department estimates that on average such a facility would receive referrals of fewer than one infant per month for clinical assessment and additional testing to confirm or refute screening results. Cost figures that follow are based on 125 as a high-end estimate for the maximum number of infants statewide needing immediate referral.

Communicating the need for and/or arranging referral for medical evaluation of an identified infant would require less than 0.5 person-hour; no additional staff would be required. Annual cost for arranging for SCID-related referrals for a facility at which 2,000 babies are delivered each year would range from ½ of \$40 to ½ of \$100, depending on whether clerical staff or nursing staff arranged for the referral, or specifically \$20-50 a year. Larger birthing facilities (i.e., those with the resources to perform transplants) would not incur even these minimal costs for referral to another facility.

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. The infrastructure for specimen collection and referrals of affected infants are already in place.

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. The addition of SCID to the newborn screening panel will not impose a unique burden on facilities and practitioners that are operated by a local government or as a small business. 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 specimen collection, reporting, follow-up and recordkeeping practices.

Small Business and Local Government Participation:

The Program will notify all New York State-licensed physicians by letter informing them of this newborn screening panel expansion. An informational letter will also be distributed to hospital chief executive officers (CEOs) and their designees responsible for newborn screening, as well as to other affected parties. Regulated parties that are small businesses and local governments are expected to be prepared to participate in screening and follow-up for SCID on the effective date of this amendment because the staff and infrastructure needed for specimen collection and referrals of affected infants are already in place.

Rural Area Flexibility Analysis

Types of Estimated Numbers of Rural Areas:

Rural areas are defined as counties with a population of fewer than 200,000 residents; 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 one new condition - severe combined immunodeficiency (SCID) - to the list of 44 genetic/congenital disorders and one infectious disease, for which every newborn in the State must be tested, would 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. No facility recognized as having medical expertise in clinical assessment and treatment of SCID 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 birthing 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; 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 test 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 SCID, and assume referral responsibility for medical evaluation and additional testing. 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 one to two per month 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. Birthing facilities' existing professional staff are expected to be able to assume any increase in workload resulting from the Program's newborn screening for SCID and identification of screen-positive infants. Infants with a positive screening test for SCID will be referred to a facility employing a physician and other medical professionals with expertise in SCID.

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 test 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, since the proposed added testing is expected to result in no more than one additional referral per month. Communicating the need and/or arranging referral for medical evaluation of one additional identified infant would require less than 0.5 person-hour, and these tasks are expected to be able to be accomplished with existing staff. Annual cost for arranging for SCID-related referrals for a facility at which 2,000 babies are delivered each year would range from ½ of \$40 to ½ of \$100, depending on whether clerical staff or nursing staff arranged for the referral, or specifically \$20-50 a year. Larger birthing facilities (i.e., those with the resources to perform transplants) would not incur even these minimal costs for referral to another facility. The

Department estimates that more than 95 percent of infants will be clinically found not to be afflicted with the target condition, based on clinical assessment and additional testing.

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. The addition of SCID to the newborn screening panel will not impose a unique burden on facilities and practitioners operating in rural areas. These amendments will not have an adverse impact on the ability of regulated parties in rural areas to comply with Department requirements for mandatory newborn screening, as full compliance would entail minimal changes to present collection, reporting, follow-up and recordkeeping practices.

Rural Area Participation:

The Program will notify all New York State-licensed physicians by letter informing them of this newborn screening panel expansion. An informational letter will also be distributed to hospital chief executive officers (CEOs) and their designees responsible for newborn screening, as well as to other affected parties. Regulated parties in rural areas are expected to be able to participate in screening and follow-up for SCID on the effective date of this amendment.

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 an immune system disorder, severe combined immunodeficiency (SCID), to the scope of newborn screening services provided by the Department. It is expected that no regulated parties will experience other than minimal impact on their workload, and therefore none will need to hire new personnel. Therefore, this proposed amendment carries no adverse implications for job opportunities.

**EMERGENCY
RULE MAKING**

NYS Medical Indemnity Fund

I.D. No. HLT-39-11-00021-E

Filing No. 819

Filing Date: 2011-09-15

Effective Date: 2011-09-15

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

Action taken: Amendment of Part 69 of Title 10 NYCRR.

Statutory authority: Public Health Law, section 2999-j

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

Specific reasons underlying the finding of necessity: These regulations are being promulgated on an emergency basis because of the need for the Fund to be operational as of October 1, 2011. Authority for emergency promulgation was specifically provided in section 111 of Article VII of the New York State 2011-2012 Budget.

Subject: NYS Medical Indemnity Fund.

Purpose: To provide the structure within which the NYS Medical Indemnity Fund will operate.

Substance of emergency rule: As required by new section 2999-j(15) of the Public Health Law (PHL), the New York State Commissioner of Health, in consultation with the Superintendent of Insurance, has promulgated these regulations to provide the structure within which the New York State Medical Indemnity Fund ("Fund") will operate. Included are (a) critical definitions such as "birth-related neurological injury" and "qualifying health care costs" for purposes of coverage, (b) what the application process for enrollment in the Fund will be, (c) what qualifying health care costs will require prior approval, (d) what the claims submission process will be, (e) what the review process will be for claims denials, (f) what the process will be for reviews of prior approval, and (g) how and when the required actuarial calculations will be done.

The application process itself has been developed to be as streamlined as possible. Submission of a completed application form, a signed release form, and a certified copy of a judgment or court-ordered settlement that finds or deems the plaintiff to have sustained a birth-related neurological

injury is all that is required for actual enrollment in the Fund. Prior to coverage being provided, the parent or other person authorized to act on behalf of a qualified plaintiff must provide the Fund with documentation regarding the nature and degree of the plaintiff's birth related neurological injuries, including diagnoses and impact on the applicant's activities of daily living and instrumental activities of daily living. In addition, the parent or other authorized person must submit the name, address, and phone number of all providers providing care to the applicant at the time of enrollment for purposes of both claims processing and case management. To the extent that documents prepared for litigation and/or other health related purposes contain the required background information, that such documentation may be submitted to meet these requirements as well, provided that this documentation still accurately describes the applicant's condition and treatment being provided.

Those expenses that will or can be covered as qualifying health care costs are defined as broadly as defined by the statute. Prior approval is required only for very costly items, items that involve major construction, and/or out of the ordinary expenses. Such prior approval requirements are similar to the prior approval requirements of various Medicaid waiver programs and to commercial insurance prior approval requirements for certain items and/or services.

Reviews of denials of claims and denials of requests for prior approval will provide enrollees with full due process and prompt decisions. Enrollees are entitled to a conference with the Fund Administrator or his or her designee and a hearing before a Department of Health hearing officer. The hearing officer will make a recommendation regarding the issue and the Commissioner or his designee will make the final determination. An expedited review procedure has also been developed for urgent situations.

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 December 11, 2011.

Text of rule and any required statements and analyses may be obtained from: Katherine Ceroalo, DOH, Bureau of House Counsel, Reg. Affairs Unit, Room 2438, ESP Tower Building, Albany, NY 12237, (518) 473-7488, email: regsqa@health.state.ny.us

Regulatory Impact Statement

Statutory Authority:

Section 2999-j (15) of the Public Health Law (PHL) specifically states that the Commissioner of Health, in consultation with the Superintendent of Financial Services (the Superintendent of Insurance until October 3, 2011), "shall promulgate. . . all rules and regulations necessary for the proper administration of the fund in accordance with the provisions of this section, including, but not limited to those concerning the payment of claims and concerning the actuarial calculations necessary to determine, annually, the total amount to be paid into the fund as otherwise needed to implement this title."

Legislative Objectives:

The Legislature delegated the details of the Fund's operation to the two State agencies that have the appropriate expertise to develop, implement and enforce all aspects of the Fund's operations. Those two agencies are the Department of Health and the Insurance Department (the Insurance Department will merge with into a new agency, the New York State Department of Financial Services, on October 3, 2011). These proposed regulations reflect the collaboration of both agencies in providing the administrative details for the manner in which the Fund will operate.

Needs and Benefits:

The regulations have the goal of establishing a process to provide that persons who have obtained a settlement or a judgment based on having sustained a birth-related neurological injury as the result of medical malpractice will have lifetime medical coverage.

Costs:

Regulated Parties:

There are no costs imposed on regulated parties by these regulations. Qualified plaintiffs will not incur any costs in connection with applying for enrollment in the Fund or coverage by the Fund.

Costs to the Administering Agencies, the State, and Local Governments:

Costs associated with the Fund will be covered by applicable appropriations. The Department of Health will also seek Federal Financial Participation for the health care costs of qualified plaintiffs that otherwise would be covered by Medicaid. No costs are expected to local governments.

Local Government Mandates:

None.

Paperwork:

The proposed regulations impose no reporting requirements on any regulated parties.

Duplication:

There are no other State or Federal requirements that duplicate, overlap, or conflict with the statute and the proposed regulations. Although some of the services to be provided by the Fund are the same as those available under certain Medicaid waivers, the waivers have limited slots. Coordination of benefits will be one of the responsibilities of the Fund Administrator. Health care services, equipment, medications or other items that are available to qualified plaintiffs through commercial insurance coverage they may have or through other State or Federal programs such as the Early Intervention Program or as part of an Individualized Education Plan will not be covered by the Fund.

Alternatives:

Given the statute's directive, there are no alternatives to promulgating the proposed regulations.

Federal Standards:

There are no minimum Federal standards regarding this subject.

Compliance Schedule:

The Fund must be operational by October 1, 2011.

Regulatory Flexibility Analysis

Effect of Rule:

For 2009, of the 135 general hospitals in New York State that provided maternity services, only ten had less than two hundred deliveries that year.

Compliance Requirements:

The regulations impose no new reporting or recordkeeping obligations.

Professional Services:

None.

Compliance Costs:

There are no costs imposed by these regulations on regulated businesses or local governments.

Economic and Technological Feasibility:

The proposed regulations should not create any economic or technological issues for any hospitals or other health care providers. Manual billing will be permitted for those providers that do not have electronic billing capacity.

Minimizing Adverse Impact:

There will be no adverse impact on small businesses and local governments.

Small Business and Local Government Participation:

For purposes of the regulation drafting process, input was sought from hospital associations, provider associations and advocacy organizations throughout the State as well as the Consumer Advisory Committee required by the statute.

Rural Area Flexibility Analysis

Types and Estimated Number of Rural Areas:

The New York State Medical Indemnity Fund being implemented by these regulations will cover future medical expenses for all qualified plaintiffs throughout New York State who have obtained a judgment or a settlement based on a birth-related neurological impairment on or after April 1, 2011.

Reporting, Recordkeeping and Other Compliance Requirements; and Professional Services:

No reporting, recordkeeping, other compliance requirement or professional services other than the submission of claims are required by the regulations.

Costs:

There are no costs to rural areas associated with these regulations.

Minimizing Adverse Impact:

There will be no adverse impact on rural areas as a result of the proposed regulations.

Rural Area Participations:

For purposes of the regulation drafting process, input was sought from hospital associations, provider associations and advocacy organizations throughout the State as well as the Consumer Advisory Committee required by the statute.

Job Impact Statement

Nature of Impact:

The regulations should have no substantial impact on jobs and employment opportunities.

Categories and Numbers Affected:

None.

Regions of Adverse Impact:

None.

Minimizing Adverse Impact:

None.

Self-Employment Opportunities:

None.

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

Accreditation of General Hospitals and Diagnostic and Treatment Centers

I.D. No. HLT-39-11-00006-P

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

Proposed Action: Amendment of sections 405.1, 700.2, 720.1 and 755.2; renumbering of sections 751.11 to 751.12; and addition of new section 751.11 to Title 10 NYCRR.

Statutory authority: Public Health Law, section 2803

Subject: Accreditation of General Hospitals and Diagnostic and Treatment Centers.

Purpose: To update accreditation provisions for general hospitals and diagnostic and treatment centers.

Text of proposed rule: Paragraph (2) of Subdivision (a) of Section 405.1 of Part 405 is amended to read as follows:

(2) *the commissioner may accept as evidence of compliance with the minimum operational standards of this Part, accreditation by an accreditation agency to which the Centers for Medicare and Medicaid Services has granted deeming status and which the Commissioner has determined has accrediting standards sufficient to assure the Commissioner that hospitals so accredited are in compliance with such operational standards. The Commissioner can choose to enter into collaborative agreements with such accreditation agencies so that the accreditation agency's accreditation survey can be used in lieu of a Departmental survey. A list of accreditation agencies with which the Department has a collaborative agreement will be posted on the department's website.* [h]Hospitals shall notify the commissioner in writing within seven days after receipt of notice of [the accreditation decision or notification of a tentative nonaccreditation by the Joint Commission on Accreditation of Healthcare Organizations or the American Osteopathic Association.] *failure to be accredited, re-accredited or the loss of accreditation by the accreditation agency.*

Subdivision (b) of Section 405.1 of Part 405.1 is amended to read as follows:

(b) The provisions of Parts 700, except for paragraphs (a) (1), (a)(21-22), (b)(25) and (c)(7), (35)-(41) of section 700.2; 702; 703, except for section 703.6; 706; and 707 of Article 1 of this Chapter shall not apply to general hospitals.

Paragraph (1) of Subdivision (a) of Section 700.2 is amended to read as follows:

(1) Accredited hospital or other accredited medical facility, as defined in article 28 of the Public Health Law, shall mean a hospital or facility which has been accredited by [the Joint Commission on Accreditation of Hospitals, or an osteopathic hospital which has been accredited by the Committee of Hospitals of the American Osteopathic Association.] *an accreditation agency to which the Centers for Medicare and Medicaid Services has granted deeming status and which the Commissioner has determined has accrediting standards sufficient to assure the Commissioner that hospitals or facilities so accredited are in compliance with operational standards under this Chapter.*

Section 720.1 is amended to read as follows:

Section 720.1 [Standards of Joint Commission on] *General Hospital Accreditation [of Hospitals or American Osteopathic Association].*

(a) *General [H] hospitals must comply with the operational standards set forth in Part 405 of this Title. The commissioner may[,if he so desires,] accept as evidence of compliance with the minimum operational standards of Part 405 of this Title accreditation by [of the Joint Commission on Accreditation of Hospitals or American Osteopathic Association] an accreditation agency to which the Centers for Medicare and Medicaid Services has granted deeming status and which the Commissioner has determined has accrediting standards sufficient to assure the Commissioner that hospitals so accredited are in compliance with such operational standards. The Commissioner can choose to enter into collaborative agreements with such accreditation agencies so that the accreditation agency's accreditation survey can be used in lieu of a Departmental survey. A list of accreditation agencies with which the Department has a collaborative agreement will be posted on the Department's website. [that such hospitals meet the standards of such organization as set forth in the Accreditation Manual of Hospitals of the Joint Commission on Accreditation of Hospitals, 1976 Edition, as amended or the Accreditation Requirements of the American Osteopathic Association, 11th edition, February 1976, as amended, provided that, in addition to complying with Part 405 of this Title] These provisions shall apply provided that:*

[(1) a copy of the survey report and the certificate of accreditation of the Joint Commission on Accreditation of Hospitals or the certificate of accreditation of the American Osteopathic Association is submitted to the commissioner within seven days of receipt from the hospital;

(2) the Joint Commission on Accreditation of Hospitals' plan of correction and interim self-evaluation or the American Osteopathic Association notice of noncompliances and progress report on correction of noncompliances are submitted to the commissioner simultaneous with the mailing or the receipt as the case may be;]

(1) [(3)] there are no constraints placed upon release of the [Joint Commission on Accreditation of Hospitals] accreditation agency survey report, plan of correction, interim self-evaluation report, [or the American Osteopathic Association] certificate of accreditation, notice on noncompliances, [progress report on correction of noncompliances] or such other material which the commissioner has accepted under this section; [or] and

(2) [(4)] the hospital is at all times subject to a survey for compliance with Part 405 of this Title as deemed necessary by the commissioner.

(b) The hospital shall notify the commissioner [immediately upon receipt of notice] in writing within seven days of failure to be accredited, re-accredited or the loss of accreditation by the [Joint Commission on Accreditation of Hospitals or the American Osteopathic Association] accreditation agency with Centers for Medicare and Medicaid Services deeming status.

[(c) The standards of the Joint Commission on Accreditation of Hospitals as set forth in the Accreditation Manual of Hospitals, 1976 Edition, as amended, or the Accreditation Requirements of the American Osteopathic Association, 11th Edition, February 1976, as amended, shall constitute the maximum standards and procedures for purposes of limiting medical assistance reimbursement.]

Section 751.11 is renumbered Section 751.12 to read as follows:

751.12 [751.11] Validity

If any clause, sentence, paragraph or section of this Part shall be adjudged by any court of competent jurisdiction to be invalid, such judgment shall not affect, impair or invalidate the remainder thereof, but shall be confined in its operation to the clause, sentence, paragraph or section thereof directly involved in the controversy in which such judgment shall have been rendered.

A new section 751.11 is added to read as follows:

751.11 Center Accreditation.

(a) Centers must comply with the operational standards set forth in this Article 6 of Subchapter C of Chapter V of this Title. The commissioner may accept as evidence of compliance with the minimum operational standards of this Article 6 of Subchapter C of Chapter V of this Title, accreditation by an accreditation agency to which the Centers for Medicare and Medicaid Services has granted deeming status and which the Commissioner has determined has accrediting standards sufficient to assure the Commissioner that centers so accredited are in compliance with such operational standards. The Commissioner can choose to enter into collaborative agreements with such accreditation agencies so that the accreditation agency's accreditation survey can be used in lieu of a Departmental survey. A list of accreditation agencies with which the Department has a collaborative agreement will be posted on the Department's website. These provisions shall apply provided that:

(1) there are no constraints placed upon release of the accreditation agency survey report, plan of correction, interim self-evaluation report, certificate of accreditation, notice on noncompliances, or such other material which the commissioner has accepted under this section; and

(2) the center is at all times subject to a survey for compliance with Article 6 of Subchapter C of Chapter V of this Title as deemed necessary by the commissioner.

(b) The center shall notify the commissioner in writing within seven days of failure to be accredited, re-accredited or the loss of accreditation by the accreditation agency.

Subdivision (f) of Section 755.2 is amended to read as follows:

When ambulatory surgery services are provided, the operator shall ensure that:

* * *

(f) evidence of compliance with operational standards, as set forth in Section 751.11 of this Title, shall apply. [accreditation is obtained from either the Accreditation Association for Ambulatory Health Care (AAAHC) or the Joint Commission on Accreditation of Healthcare Organizations (JCAHO).] New facilities shall obtain accreditation from an accreditation agency to which the Centers for Medicare and Medicaid Services has granted deeming status and which the Commissioner has determined has accrediting standards sufficient to assure the Commissioner that ambulatory surgery services so accredited are in compliance with ambulatory surgery services operational standards under this Chapter within two full years of operation. [Facilities operational upon the effective date hereof shall obtain accreditation within one full year of such effective date.]

Text of proposed rule and any required statements and analyses may be obtained from: Katherine Ceroalo, DOH, Bureau of House Counsel, Regulatory Affairs Unit, Room 2438, ESP, Tower Building, Albany, NY 12237, (518) 473-7488, email: regsqna@health.state.ny.us

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

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

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

Regulatory Impact Statement

Statutory Authority:

The authority for the promulgation of these regulations is contained in Sections 2800 and 2803(2) of the Public Health Law (PHL). Section 2800 of PHL Article 28 (Hospitals) specifies that "Hospital and related services including health-related service of the highest quality, efficiently provided and properly utilized at a reasonable cost, are of vital concern to the public health. In order to provide for the protection and promotion of the health of the inhabitants of the state, pursuant to section three of article seventeen of the constitution, the department of health shall have the central, comprehensive responsibility for the development and administration of the state's policy with respect to hospital and related services, and all public and private institutions, whether state, county, municipal, incorporated or not incorporated, serving principally as facilities for the prevention, diagnosis or treatment of human disease, pain, injury, deformity or physical condition or for the rendering of health-related service shall be subject to the provisions of this article."

PHL Section 2803(2) authorizes the Public Health and Health Planning Council (PHHPC) to adopt and amend rules and regulations, subject to the approval of the Commissioner, to implement the purposes and provisions of PHL Article 28, and to establish minimum standards governing the operation of health care facilities.

Legislative Objectives:

The legislative objective of PHL Article 28 includes the protection of the health of the residents of the State by assuring the efficient provision and proper utilization of health services, of the highest quality at a reasonable cost.

Needs and Benefits:

Section 720.1 of 10 NYCRR specifically requires hospitals to comply with operational standards set forth in Part 405 of 10 NYCRR and specifies that such hospitals are at all times subject to a survey for compliance with Part 405. Section 720.1 currently authorizes the Commissioner to accept as evidence of compliance with the minimum operational standards of Part 405, accreditation of The Joint Commission (TJC) or the American Osteopathic Association (AOA). Sections 405.1 and 700.2 of 10 NYCRR also refer to The Joint Commission and to the American Osteopathic Association as the national accreditation organizations that are authorized to issue certificates of accreditation to facilities certifying compliance with operational standards. Diagnostic and Treatment Centers (DT&Cs), whose provisions are set forth in 10 NYCRR Subchapter C, Article 6, are, like general hospitals, also Public Health Law Article 28 facilities that are surveyed for compliance with their operational standards. In addition to the TJC, Section 755.2 specifies that accreditation can be obtained for Free-Standing and Off-Site Hospital Based Ambulatory Surgery Centers from the Accreditation Association for Ambulatory Health Care (AAAHC).

Although the TJC and the AOA have been the 2 accrediting organizations predominantly used over the years, and in the case of Free-Standing and Off-Site Hospital Based Ambulatory Surgery Centers, also the AAAHC, additional accrediting organizations have come into existence and have been granted deeming status by the federal Centers for Medicare and Medicaid Services (CMS). Newer accrediting agencies are being utilized by hospitals and other facilities more and more, and recognized by CMS for federal surveillance purposes. At the same time more facilities are dropping their affiliation with the TJC, and various sections of Title 10 NYCRR limit the accreditation agencies for purposes of compliance with Department regulations to just the TJC, AOA, or the AAAHC. The Department of Health enters into collaborative agreements with approved accrediting agencies with the intent to reduce duplication of surveys.

Costs for the Implementation of and Continuing Compliance with these Regulations to the Regulated Entity:

This proposal is intended to reduce duplicative surveys, resulting in costs savings to the regulated parties. The regulated parties will also need to devote less staff time to the survey process.

Cost to State and Local Government:

The regulatory changes being sought could actually produce a cost savings for state and local governments. Any state or local government Article 28 general hospital or diagnostic and treatment center that chooses to be accredited by an accreditation agency with CMS deeming status for Medicare compliance would have the ability to select a more cost efficient

option for accreditation with the expansion of approved agencies. Currently, when a facility drops its accreditation to TJC or AOA the state must perform routine surveys for that facility. This regulation may reduce the need for such surveys by the State because it broadens the number of accredited agencies for which the Department may accept accreditation as compliance with Department regulations.

Cost to the Department of Health:

These regulatory changes will be a cost savings as they will allow the Department to reduce duplicative surveys which require additional staff and resources.

Local Government Mandates:

None. The provisions do not add any additional mandates to local governments.

Paperwork:

No additional new paperwork will be required.

Duplication:

This proposal is intended to reduce duplicative surveys, saving costs and staff time for the Department and the regulated parties. These sought after regulatory changes for hospitals would eliminate the need for hospitals to notify the Department when successfully obtaining accreditation or re-accreditation from a CMS approved agency. The revised regulations will require diagnostic and treatment centers to notify the Department of any adverse accreditation decisions in order to bring consistency to the accreditation notification process for both hospitals and centers.

Alternative Approaches:

There are no other viable alternative approaches. Current provisions limit the accreditation agencies with which the State can enter into collaborative agreements. This proposal would allow for additional accreditation agencies whose accreditation would be acceptable evidence of compliance with Department standards. The proposed regulation would require such agencies to have CMS deeming status for Medicare compliance and be acceptable to the Commissioner. Agencies that meet those requirements will no longer be prohibited from being utilized by hospitals and diagnostic and treatment centers in lieu of State routine surveys and the Commissioner can choose to enter into additional collaborative agreements which will reduce duplicative surveys. A list of accreditation agencies with which the Department has a collaborative agreement will be posted on the Department's website.

Federal Requirements:

This regulatory amendment does not exceed any minimum standards of the federal government for the same or similar subject areas. This proposal is intended to reduce duplicative surveys, saving costs and staff time for the Department and the regulated parties.

Compliance Schedule:

This proposal will go into effect upon publication of a Notice of Adoption in the *New York State Register*.

Regulatory Flexibility Analysis

Effect of Rule:

General hospitals and diagnostic and treatment centers (DT&Cs) would be affected by this rule. Small businesses (defined as 100 employees or less), independently owned and operated, affected by this rule would include: 3 hospitals and 234 diagnostic and treatment centers.

Compliance Requirements:

There will be no additional requirements for general hospitals. Centers must now notify the Department of accreditation decisions consistent with requirements for hospitals.

Professional Services:

This proposal does not require any additional professional services.

Compliance Costs:

There are no additional costs required to comply with this measure. It would reduce the cost of duplicative routine surveys for both the Department and the regulated parties. Staff time would also be saved.

Economic and Technological Feasibility:

This proposal is economically and technically feasible. As said above, it will eliminate the cost of duplicate surveys to determine compliance with operational standards. Facility and Department staff time will also be saved.

Minimizing Adverse Impact:

There will be no adverse impact to small businesses or local governments from this regulation. The revisions merely allow the Commissioner to accept as evidence of compliance with minimum operational standards, a facility's accreditation from a Centers for Medicare and Medicaid Services (CMS) approved accreditation agency. Current regulations specify that such accreditation must be from TJC, AOA or the AAAHC in order to show evidence of compliance. This rule will allow other accreditation agencies to be utilized as long as they are CMS approved. Many facilities choose such other agencies for their accreditation and these regulatory changes recognize CMS expansion of approved agencies.

Small Business and Local Government Participation:

Outreach to the affected parties is being conducted. They include gen-

eral hospitals, diagnostic and treatment centers and accreditation agencies. Organizations representing the affected parties can access notice of this proposal on the Department's website by its inclusion on the agenda of the Codes and Regulations Committee of the Public Health and Health Planning Council (PHHPC). The public, including any affected party, is invited to comment during the PHHPC Codes and Regulations Committee meeting.

Rural Area Flexibility Analysis

Pursuant to section 202-bb of the State Administrative Procedure Act (SAPA), a rural area flexibility analysis is not required. These provisions apply uniformly throughout New York State, including all rural areas.

The proposed rule will not impose an adverse economic impact on rural facilities defined within PHL Articles 28, nor will it impose any additional reporting, record keeping or other compliance requirements on public or private entities in rural areas.

Job Impact Statement

A Job Impact Statement is not included in accordance with Section 201-a (2) of the State Administrative Procedure Act (SAPA), because it will not have a substantial adverse effect on jobs and employment opportunities.

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

Medicaid Benefit Limits for Enteral Formula, Prescription Footwear, and Compression Stockings

I.D. No. HLT-39-11-00007-P

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

Proposed Action: Amendment of Parts 505 and 513 of Title 18 NYCRR.

Statutory authority: Public Health Law, sections 201 and 206; and Social Services Law, sections 363-a and 365-a(2)

Subject: Medicaid Benefit Limits for Enteral Formula, Prescription Footwear, and Compression Stockings.

Purpose: Establishes Medicaid benefit limitations on coverage of enteral formula, prescription footwear, and compression stockings.

Text of proposed rule: Paragraph (2) of subdivision (b) of section 505.1 is amended, and a new paragraph (3) is added to read as follows:

(2) the identification card on its face:

(i) restricts an individual recipient to a single provider; or

(ii) requires prior authorization for all ambulatory medical services and supplies except emergency care [.] ; or

(3) *the service exceeds benefit limitations as established by the department.*

The opening language of paragraph (4) of subdivision (a) of section 505.5 is amended to read as follows:

(4) Orthopedic footwear means shoes, shoe modifications, or shoe additions which are used *as follows: in the treatment of children, to correct, accommodate or prevent a physical deformity or range of motion malfunction in a diseased or injured part of the ankle or foot; in the treatment of children, to support a weak or deformed structure of the ankle or foot; as a component of a comprehensive diabetic treatment plan to treat amputation, ulceration, pre-ulcerative calluses, peripheral neuropathy with evidence of callus formation, a foot deformity or poor circulation; or to form an integral part of an orthotic brace.* Orthopedic shoes must have, at a minimum, the following features:

Subparagraph (ii) of paragraph (4) of subdivision (b) of section 505.5 is amended to read as follows:

(ii) The maximum number of refills permitted for medical/surgical supplies is found in the fee schedule for durable medical equipment, medical/surgical supplies, orthotic and prosthetic appliances and orthopedic footwear. The fee schedule for such equipment and supplies is available *free of charge* from the [department] *Medicaid fiscal agent's website.* [and is also contained in the department's Medicaid Management Information System (MMIS) provider Manual (Durable Medical Equipment, Medical and Surgical Supplies, Prosthetic and Orthotic Appliances). Copies of the manual may be obtained by writing Computer Sciences Corporation, Health and Administrative Services Division, 800 North Pearl St., Albany, NY 12204. Copies may also be obtained from the Department of Social Services, 40 North Pearl St., Albany, NY 12243. The manuals are provided free of charge to every provider of durable medical equipment, medical/surgical supplies, orthotic and prosthetic appliances and orthopedic footwear at the time of enrollment in the MA program.]

Subparagraph (vi) of paragraph (1) of subdivision (d) of section 505.5 is amended to read as follows:

(vi) [All items not listed in the department's fee schedule for dura-

ble medical equipment, medical/surgical supplies, prosthetic and orthotic appliances and orthopedic footwear require prior approval from the New York State Department of Health. The fee schedule for such equipment and supplies is available from the department and is also contained in the department’s MMIS Provider Manual (Durable Medical Equipment, Medical/Surgical Supplies, Prosthetic and Orthotic Appliances). Copies of the manual may be obtained by writing Computer Sciences Corporation, Health and Administrative Services Division, 800 North Pearl St., Albany, NY 12204. Copies may also be obtained from the Department of Social Services, 40 North Pearl St., Albany, NY 12243. The manuals are provided free of charge to every provider of durable medical equipment, medical/surgical supplies, orthotic and prosthetic appliances and orthopedic footwear at the time of enrollment in the MA program.] Reimbursement amounts for unlisted items are determined by the New York State Department of Health and must not exceed the lower of: (a) the acquisition cost to the provider plus 50 percent; or (b) the usual and customary price charged to the general public.

Subparagraph (iii) of paragraph (4) of subdivision (d) of Section 505.5 is amended to read as follows:

(iii) The fee schedule for orthotic and prosthetic appliances and devices is available *free of charge* from the Medicaid [department and is also contained in the department’s MMIS Provider Manual (Durable Medical Equipment, Medical and Surgical Supplies, Prosthetic and Orthotic Appliances). Copies of the manual may be obtained by writing Computer Sciences Corporation, Health and Administrative Services Division, 800 North Pearl St., Albany, NY 12204. Copies may also be obtained from the Department of Social Services, 40 North Pearl St., Albany, NY 12243. The manuals are provided free of charge to every provider of durable medical equipment, medical/surgical supplies, orthotic and prosthetic appliances and orthopedic footwear at the time of enrollment in the MA program] *fiscal agent’s website*.

Subparagraph (i) of paragraph (5) of subdivision (d) of section 505.5 is amended to read as follows:

(i) Payment for orthopedic footwear must not exceed the lower of:

(a) [the acquisition cost to the provider plus 50%] *the maximum reimbursable amount as shown in the fee schedule for durable medical equipment, medical/surgical supplies, orthotics and prosthetic appliances and orthopedic footwear; the maximum reimbursable amount will be determined for each item of footwear based on an average cost of products representative of that item; or*

(b) the usual and customary price charged to the general public for the same or similar products.

Paragraph (1) of subdivision (e) of section 505.5 is amended to read as follows:

(1) [The following items] *Items of durable medical equipment, medical/surgical supplies, orthotic and prosthetic appliances and devices, and orthopedic footwear are limited in their amount and frequency and may require prior authorization. Service limits and prior authorization requirements are listed in the provider manual at the Medicaid fiscal agent’s website.*

[ITEM	LIMIT
Cane	1 every 3 yrs.
Cane, Quad or three prong	1 every 3 yrs.
Flare heels (each)	2 pair per yr.
Cork lifts	2 pair per yr.
Steindler heel corrections	2 pair per yr.
Spenco Insert	2 pair per yr. per child
Heel wedge	2 pair per yr.
Foot, insert, removable, molded to patient model, longitudinal arch support, each	2 per yr. per adult
Foot, insert, removable, molded to patient model, longitudinal/metatarsal support, each	2 per yr. per adult
Foot, arch support, removable, premolded, longitudinal, each	2 per yr. per adult
Foot, arch support, removable, premolded, longitudinal/metatarsal, each	2 per yr. per adult
Longitudinal arch support	1 pair per yr. per adult
Foot, arch support	2 pair per yr. per adult
Removable mold/Levi mold	1 pair per yr. per adult
Elastic stocking/below knee medium wt.	4 pair per yr.

Elastic stocking/below knee heavy wt.	4 pair per yr.
Elastic stocking/above knee medium wt.	4 pair per yr.
Elastic stocking/above knee heavy wt.	4 pair per yr.
Elastic stocking/full length medium wt.	4 pair per yr.
Elastic stocking/full length heavy wt.	4 pair per yr.
Elastic stocking/leotards	4 pair per yr.
Elastic stocking/garter belt	4 pair per yr.
Surgical stocking/below knee	4 pair per yr.
Surgical stocking/thigh length	4 pair per yr.
Surgical stocking/full length	4 pair per yr.
Corset, Sacroiliac 2 per yr. Corset, Lumbar	2 per yr.
Handheld shower head	1 every 3 yrs.
Bed pan, fracture	1 every 3 yrs.
Urinary suspensory	1 every 5 yrs.
Emesis basin	1 every 5 yrs.
Sitz bath	1 every 5 yrs.
Urinal, female, any material	1 every 5 yrs.
Urinal, male, any material	1 every 5 yrs.
Commode pad	1 every 5 yrs.
Flotation pad	1 per yr.
Humidifier, cold air	1 every 3 yrs.
Vaporizer, room type	1 every 3 yrs.
Standard adult wheelchair	1 every 3 yrs.
Electric heating pad standard	1 every 3 yrs.
Hot fomentation heating pads	1 every 3 yrs.
Orthopedic shoes	2 pair per yr.]

A new subdivision (g) of section 505.5 is added to read as follows:

(g) *Benefit limitations. The department shall establish defined benefit limits for certain Medicaid services as part of its Medicaid State Plan. The department shall not allow exceptions to defined benefit limitations. The department has established defined benefit limits on the following services:*

(1) *Compression and surgical stockings are limited to coverage during pregnancy and for venous stasis ulcers.*

(2) *Orthopedic footwear is limited to coverage in the treatment of children to correct, accommodate or prevent a physical deformity or range of motion malfunction in a diseased or injured part of the ankle or foot; in the treatment of children to support a weak or deformed structure of the ankle or foot; as a component of a comprehensive diabetic treatment plan to treat amputation, ulceration, pre-ulcerative calluses, peripheral neuropathy with evidence of callus formation, a foot deformity or poor circulation; or to form an integral part of an orthotic brace.*

(3) *Enteral nutritional formulas are limited to coverage for tube-fed individuals who cannot chew or swallow food and must obtain nutrition through formula via tube; individuals with rare inborn metabolic disorders requiring specific medical formulas to provide essential nutrients not available through any other means; and for children under age 21 when caloric and dietary nutrients from food cannot be absorbed or metabolized.*

Paragraph (1) of subdivision (b) of section 513.0 is amended to read as follows:

(1) The department, as the single State agency supervising the administration of the MA program, has entered into an interagency agreement with the Department of Health whereby that department will review and approve selected medical, dental and remedial care, services and supplies prior to their being furnished. The purpose of this process is to assure that: the requested medical, dental and remedial care, services or supplies are medically necessary and appropriate for the individual recipient’s medical needs; other adequate and less expensive alternatives have been explored and, where appropriate and cost effective, are approved; *the request does not exceed benefit limitations as promulgated by the department; and the medical, dental and remedial care, services or supplies to be provided conform to accepted professional standards. The department shall not allow exceptions to defined benefit limitations.*

A new subdivision (h) of section 513.1 is added to read as follows:

(h) *Benefit limits means specified Medicaid coverage limits which cannot be exceeded by obtaining prior approval or authorizations and for which no exceptions are allowed.*

Paragraph (1) of subdivision (a) of section 513.6 is amended to read as follows:

(1) the specific statutory and regulatory standards *and benefit limits* governing the furnishing of the requested care, services, or supplies;

Text of proposed rule and any required statements and analyses may be obtained from: Katherine Ceroalo, DOH, Bureau of House Counsel, Regulatory Affairs Unit, Room 2438, ESP, Tower Building, Albany, NY 12237, (518) 473-7488, email: regsqa@health.state.ny.us

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

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

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

Regulatory Impact Statement

Statutory Authority:

Social Services Law (SSL) section 363-a and Public Health Law section 201(1)(v) provide that the Department is the single state agency responsible for supervising the administration of the State's medical assistance ("Medicaid") program and for adopting such regulations, not inconsistent with law, as may be necessary to implement the State's Medicaid program.

Legislative Objective:

The legislative objective, expressed through SSL section 365-a(2)(g), is to impose benefit limitations on Medicaid coverage of enteral formula, prescription footwear, and compression stockings.

Needs and Benefits:

Enteral formula. Enterals are ordered by practitioners and dispensed by pharmacy or durable medical equipment providers. Medicaid reimburses the cost of enteral formulas for administration via tube or as a liquid oral nutritional therapy when there is a documented diagnostic condition where caloric and dietary nutrients from food cannot be absorbed or metabolized. When prescribed for oral supplementation in adults who can chew and swallow their food, it is objectively difficult to assess medical necessity for the enteral formula and to prevent such reimbursement when used strictly as a convenient food supplement and not due to medical necessity to treat a clinical condition. In the Medicare program enterals are covered for tube-fed individuals only.

Medicaid has attempted to put controls into place such as Card Swipe Prior Authorization and Automated Telephone Prior Authorization. Medicaid has also continued to monitor (through reporting systems) and correct provider prescribing and dispensing activity. In 2004, the enteral pricing methodology was changed, resulting in a 10-20 percent reduction in fees. Despite these measures, total yearly Medicaid utilization and expenditures for enteral nutrition have risen from less than \$11 million per year in 1997 to over \$70 million using the current coverage guidelines and procedures.

By limiting the benefit to specific medical necessity criteria for tube-fed individuals who cannot chew or swallow food, and must obtain nutrition through formula via tube, for individuals with rare inborn metabolic disorders requiring specific medical formulas to provide essential nutrients not available through any other means, and for children when there is a documented diagnostic condition where caloric and dietary nutrients from food cannot be absorbed or metabolized, the regulation will help reduce Medicaid costs by \$15.4 million state and local share annually while continuing to meet intensive medical needs of individual beneficiaries with serious medical conditions.

Orthopedic footwear. Orthopedic footwear is ordered by practitioners and dispensed by durable medical equipment providers. Medicaid currently reimburses the cost of footwear for treatment of any physical deformity, range of motion malfunction, or foot or ankle weakness. A significant portion of utilization under the current benefit is for individuals whose needs can be met with off the shelf footwear. When prescribed for these less serious purposes, it is objectively difficult to assess medical necessity for the footwear and to prevent such reimbursement. Medicare reimburses footwear only for treatment of diabetes complications. Additionally, footwear is currently manually priced at invoice cost plus 50 percent, resulting in paper claims.

By limiting the benefit based on medical necessity criteria and adopting the new reimbursement methodology, the regulation will reduce Medicaid costs by \$7.35 million state and local share in State Fiscal Year 2011-12 while continuing to meet intensive medical needs of individual beneficiaries with serious medical conditions.

Compression stockings. Compression stockings are ordered by practitioners and dispensed by pharmacy or durable medical equipment providers. Medicaid currently reimburses the costs of stockings for treatment of clinically significant medical conditions such as open wounds, and complications in pregnancy. Medicaid also currently reimburses the cost of stockings that have been prescribed for relatively less serious purposes such as circulatory improvement and wound prevention. When

prescribed for these less serious purposes, it is objectively difficult to assess medical necessity for the stockings and to prevent their reimbursement when used strictly for comfort or convenience instead of medically necessary treatment for a clinical condition. Medicare reimburses for stockings only for treatment of open wounds.

By limiting the benefit based on diagnoses of pregnancy or open wounds, the regulation will help reduce Medicaid costs while continuing to meet intensive medical needs of individual beneficiaries with serious medical conditions.

In addition to the changes described above, the regulation amends sections 513.0, 513.1 and 513.6 to clarify that the new benefit limitations are not subject to exception through prior approval. Also, the regulation updates outdated language in section 505.5 regarding how durable medical equipment providers could obtain a hard copy of the Medicaid Provider Manual; such Manual is currently made available to providers online.

COSTS:

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

This amendment will not increase costs to the regulated parties. It will reduce revenues to the extent providers are furnishing enteral formula, prescription footwear, or compression stockings beyond the scope of the benefit limit.

Costs to State and Local Government:

This amendment will not increase costs to the State or local governments. Savings to the Medicaid Program will be achieved by establishing these benefit limits.

Costs to the Department of Health:

There will be no additional costs to the Department.

Local Government Mandates:

This amendment will not impose any program, service, duty, additional cost, or responsibility on any county, city, town, village, school district, fire district, or other special district.

Paperwork:

This amendment will not impose any additional paperwork for providers of enteral formula, prescription footwear, or compression stockings.

Duplication:

There are no duplicative or conflicting rules identified.

Alternatives:

The benefit limits on enteral formula, prescription footwear, and compression stockings are mandated by section 365-a(2)(g) of the SSL. No alternatives were considered.

Federal Standards:

The proposed regulations do not exceed any minimum federal standards.

Compliance Schedule:

Social services districts and fiscal intermediaries should be able to comply with the proposed regulations when they become effective.

Regulatory Flexibility Analysis

Effect of Rule:

This amendment affects the 3,123 pharmacies and 369 durable medical equipment providers enrolled in the Medicaid program who actively bill Medicaid for enteral formula. The amendment will limit the enteral benefit, which will reduce Medicaid utilization and billable claims to these businesses, some of which are small. The Department is anticipating a \$15.40 million reduction in enteral expenditures in State Fiscal Year (SFY) 2011-12 and thereafter.

This amendment affects the 955 durable medical equipment providers enrolled in the Medicaid program who actively bill Medicaid for footwear. The amendment will limit the footwear benefit, which will reduce Medicaid utilization and billable claims to these businesses, some of which are small. The Department is anticipating a \$7.35 million reduction in footwear expenditures in SFY 2011-12 and \$16 million annually thereafter.

This amendment affects the 1196 pharmacies and 441 durable medical equipment providers enrolled in the Medicaid program who actively bill Medicaid for stockings. The amendment will limit the stocking benefit, which will reduce Medicaid utilization and billable claims to these businesses, some of which are small. The Department is anticipating a \$1.07 million reduction in stocking expenditures in SFY 2011-12 and thereafter.

The fifty-eight local social services districts share in the costs of services provided to eligible beneficiaries who receive Medicaid through their districts.

Compliance Requirements:

This amendment does not impose new reporting, recordkeeping or other compliance requirements on small businesses or local governments.

Professional Services:

No new professional services are required as a result of this amendment.

Compliance Costs:

There are no direct costs of compliance with this amendment. However, affected providers will realize reduced Medicaid billings for enteral formula, prescription footwear, and compression stockings. Local social

service districts will experience decreased costs in their share of medical expenses for these items as a result of overall decreases in utilization.

Economic and Technological Feasibility:

The amendment will not change the way providers bill for services or affect the way the local districts contribute their local share of Medicaid expenses for enteral formula, prescription footwear, or compression stockings. Therefore, there should be no technological difficulties associated with compliance with the proposed regulation.

Minimizing Adverse Impact:

SSL section 365-a(2)(g) requires a benefit limit on the coverage of enteral formula, prescription footwear, and compression stockings. These limits will affect providers by reducing payable Medicaid claims for such items. This impact cannot be avoided given the statutory mandate.

Small Business and Local Government Participation:

Local government officials have consistently urged the Department to implement Medicaid cost savings programs. The Department also meets on a regular basis with provider groups such as the New York Medical Equipment Providers (NYMEP). NYMEP has been informed of the proposed changes and has indicated its concerns regarding adequate notice to beneficiaries and practitioners on the revised benefits. Upon promulgating the regulation, the Department will inform the industry of the changes and assist as necessary with the transition to the new benefit limits.

Rural Area Flexibility Analysis

Types and Estimated Number of Rural Areas:

The benefit limit on enteral formula will apply to 3123 pharmacies and 369 durable medical equipment providers in New York State. The benefit limit on prescription footwear will apply to 955 durable medical equipment providers in New York State. The benefit limit on compression stockings will apply to 1196 pharmacies and 441 durable medical equipment providers in New York State. These businesses are located in rural, as well as suburban and metropolitan areas of the State.

Reporting, Recordkeeping and Other Compliance Requirements and Professional Services:

No new reporting, recordkeeping or other compliance requirements and professional services are needed in a rural area to comply with the proposed rule.

Costs:

There are no direct costs associated with compliance. However, affected providers will realize reduced Medicaid billable claims for enteral formula, prescription footwear, and compression stockings.

Minimizing Adverse Impact:

The Department considered the approaches in Section 202-bb(2)(b) of the State Administrative Procedure Act and found them to be inappropriate given the legislative objective.

Rural Area Participation:

The Department meets on a regular basis with provider groups such as the New York Medical Equipment Providers (NYMEP), who represents some rural providers, to discuss reimbursement issues. NYMEP has indicated its concerns regarding adequate notice to beneficiaries and practitioners on the revised benefits. Upon promulgating the regulation, the Department will inform the industry of the changes and assist as necessary with the transition to the new benefit limits.

Job Impact Statement

Nature of Impact:

This rule will result in decreased Medicaid billable claims for providers of enteral formula, prescription footwear, and compression stockings. This decreased revenue will not likely have an adverse impact on jobs and employment opportunities within these businesses as they offer a wide variety of services which are reimbursed by Medicaid.

Categories and Numbers Affected:

This rule, which decreases Medicaid revenue, will not likely affect employment opportunities within providers who provide enteral formula, prescription footwear, and compression stockings.

The dispensing of enteral formula and compression stockings requires store clerk level staff, not licensed professionals.

The dispensing of prescription footwear requires staff certification from a national orthotic and prosthetic accreditation and training body. Support staff require no special training.

Regions of Adverse Impact:

This rule will affect all regions within the State and businesses out of New York State that are enrolled in the Medicaid Program to provide enteral formula, prescription footwear, and compression stockings.

Minimizing Adverse Impact:

SSL section 365-a(2)(g) requires a benefit limit on the coverage of enteral formula, prescription footwear, and compression stockings. These limits will affect providers by reducing payable Medicaid claims for such items. This impact cannot be avoided given the statutory mandate.

Self-Employment Opportunities:

The rule is expected to have minimal impact on self-employment opportunities since the majority of providers that will be affected by the rule are not small businesses or sole proprietorships whose sole business is dispensing enteral formula, prescription footwear, or compression stockings.

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

Observation Unit Operating Standards

I.D. No. HLT-39-11-00008-P

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

Proposed Action: Amendment of section 405.19 of Title 10 NYCRR.

Statutory authority: Public Health Law, section 2803

Subject: Observation Unit Operating Standards.

Purpose: To provide operating standards for observation units.

Text of proposed rule: Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by section 2803 of the Public Health Law, Part 405 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

405.19 Emergency services

* * *

(e) Patient care. (1) The hospital shall assure that all persons arriving at the emergency service for treatment receive emergency health care that meets generally accepted standards of medical care.

(2) Every person arriving at the emergency service for care shall be promptly examined, diagnosed and appropriately treated in accordance with triage and transfer policies and protocols adopted by the emergency service and approved by the hospital. Such protocols must include written agreements with local emergency medical services (EMS) in accordance with subparagraph (b)(1)(i) of this section. All patient care services shall be provided under the direction and control of the emergency services director or attending physician. In no event shall a patient be discharged or transferred to another facility, unless evaluated, initially managed, and treated as necessary by an appropriately privileged physician, physician assistant, or nurse practitioner. *No later than eight hours after presenting in the emergency service, every person shall be admitted to the hospital, or assigned to an observation unit in accordance with subdivision (g) of this section, or transferred to another hospital in accordance with paragraph (6) of this subdivision, or discharged to self-care or the care of a physician or other appropriate follow-up service.* Hospitals which elect to use physician assistants or nurse practitioners shall develop and implement written policies and treatment protocols subject to approval by the governing body that specify patient conditions that may be treated by a registered physician assistant or nurse practitioner without direct visual supervision of the emergency services attending physician.

* * *

(5) [Where observation beds are used, they shall be for observation and stabilization and they shall not be used for longer than eight hours duration. Patients in these beds shall be cared for by sufficient staff assigned to meet the patients' needs. At the end of eight hours observation or treatment the patient must be admitted to the inpatient service, be transferred in accordance with paragraph (6) of this subdivision, or be discharged to self-care or the care of a physician or other appropriate follow-up service.] Reserved.

* * *

(g) *Observation units. Observation units shall be under the direction and control of the emergency service and, unless a contrary requirement is specified in this subdivision, observation units shall be subject to all requirements of this section applicable to emergency services.*

(1) *Patient Care: An observation unit shall be used only for observation, diagnosis and stabilization of those patients for whom diagnosis and a determination concerning admission, discharge, or transfer cannot be accomplished within eight hours, but can reasonably be expected within twenty-four hours. Patients shall be assigned to the observation unit by physician order and within twenty-four hours of the issuance of an order assigning the patient to an observation unit, the patient must be admitted to the inpatient service, be transferred in accordance with paragraph (6) of subdivision (e) of this section, or be discharged to self-care or the care of a physician or other appropriate follow-up service.*

(2) Physical Space:

(i) *The total number of dedicated observation unit beds in a hospital shall be limited to five percent of the hospital's certified bed capacity, and shall not exceed forty, provided that in a hospital with less than 100 certified beds, an observation unit may have up to five beds.*

(ii) *The observation unit shall be located within a distinct physical space, except in a hospital designated as a critical access hospital pursuant to subpart F of part 485 of Title 42 of the Code of Federal Regulations or a sole community hospital pursuant to section 412.92 of Title 42 of the Code of Federal Regulations or any successor provisions.*

(iii) *The observation unit shall comply with the applicable provisions of Parts 711 and 712-2 and section 712-2.4 of this Title for construction projects approved or completed after January 1, 2011.*

(iv) *Observation unit beds shall not be counted within the state certified bed capacity of the hospital and shall be exempt from the public need provisions of Part 709.*

(v) *The observation unit shall be marked with a clear and conspicuous sign that states: "This is an observation unit for visits of up to 24 hours. Patients in this unit are not admitted for inpatient services."*

(3) Staffing.

(i) *Patients in an observation unit shall be cared for, pursuant to a defined staffing plan, by staff, appropriately trained and in sufficient numbers to meet the needs of patients in the observation unit.*

(ii) *At a minimum, a physician, nurse practitioner, or physician assistant shall be responsible for oversight of the medical care of the patients assigned to the observation unit. Such physician, nurse practitioner, or physician assistant assigned to oversee the observation unit shall be immediately available to meet the needs of patients in the observation unit and shall not be assigned concurrent duties that will interfere with such availability.*

(4) *Organization. The medical staff shall develop and implement written policies and procedures approved by the governing body for the observation unit that shall include, but not be limited to:*

(i) *the integration of the observation unit and its services with the emergency service and other related services of the hospital; and*

(ii) *appropriate use of the observation unit, including documentation of the clinical reasons and indications that warrant the period of observation, rather than admission or discharge, consistent with section 405.10 of this Part.*

(5) Opening and Closure.

(i) *Any hospital seeking to establish an observation unit shall:*

(A) *if no construction, as defined in subdivision 5 of section 2801 of the Public Health Law, will be needed, and no service will be eliminated:*

(I) *submit a written notice to the Department on a form developed by the Department, not less than 90 days prior to opening the unit, indicating the hospital's intent to establish such a unit; the number of beds to be located in the unit; the location of the unit within the facility, and such other information as the Department may require; and*

(II) *submit a certification from a licensed architect or engineer, in the form specified by the Department, that the space complies with the applicable provisions of Parts 711 and 712-2 and section 712-2.4 of this Title for construction projects approved or completed after January 1, 2011; or*

(B) *if construction, as defined in subdivision 5 of section 2801 of the Public Health Law, will be needed or a service will be eliminated:*

(I) *comply with Part 710 of this Title, provided that for purposes of Part 710, a construction project involving only the creation of an observation unit and the addition of observation unit beds shall not be subject to review under paragraph (2) or (3) of subdivision (c) of section 710.1 of this title, unless the total project cost exceeds \$15 million or \$6 million respectively; and*

(II) *comply with the applicable provisions of Parts 711 and 712-2 and section 712-2.4 of this Title for construction projects approved or completed after January 1, 2011.*

(ii) *No hospital may discontinue operation of an observation unit without providing written notification to the Department of the impending closure not less than 90 days prior to the closure.*

(6) *Transition. A hospital operating an observation unit pursuant to a waiver granted by the Department shall be required to comply with the provisions of this subdivision within 24 months of its effective date.*

Text of proposed rule and any required statements and analyses may be obtained from: Katherine Ceroalo, DOH, Bureau of House Counsel, Regulatory Affairs Unit, Room 2438, ESP, Tower Building, Albany, NY 12237, (518) 473-7488, email: regsqna@health.state.ny.us

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

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

Regulatory Impact Statement**Statutory Authority:**

The authority for the proposed revision to Title 10 NYCRR Part 405 is section 2803 of the Public Health Law (PHL), which authorizes the Public Health and Health Planning Council (PHHPC) to adopt and amend rules and regulations, subject to the approval of the Commissioner of Health, to effectuate the provisions and purposes of Article 28 of the PHL with respect to minimum standards for hospitals.

Legislative Objectives:

In March 2011, Governor Cuomo's Medicaid Re-Design Team (MRT) voted to approve certain regulatory reforms to support improvements in the quality of care and assist health care facilities to operate more efficiently. The creation of a regulatory framework for observation units and a Medicaid rate for observation services was one of several reforms adopted by the MRT.

The Department proposes to allow hospitals to create observation units to be used for patient assessment, including diagnostic testing, and stabilization for a period of up to twenty-four hours from the time the patient is assigned to the observation unit, after which time, the patient will either be admitted, transferred, or discharged. Observation unit beds in a facility will be limited to a total of five percent of the hospital's certified bed capacity, and up to a maximum of forty beds, provided that in a hospital with less than 100 certified beds, an observation unit may have up to five beds.

It is important for state regulations governing hospitals to safeguard and promote patient safety, while also allowing hospitals to operate efficiently. The Department's goal is to keep pace with the health care environment, while assuring patient safety and quality of care. The intent of this regulation is to avoid unnecessary inpatient admissions, premature discharges from the emergency department, and repeated emergency department visits, and to improve the quality and experience of care received by patients seeking emergency services. Observation units can also help to improve the efficiency of emergency services and relieve emergency service overcrowding.

Current Requirements:

Current regulations require that after eight hours in the emergency department, hospitals must either discharge or admit the patient. In some circumstances, eight hours may not be enough time to stabilize a patient and complete the diagnostic tests required to assess the patient properly. Even patients who have been stabilized may remain in the emergency department while they await test results, occupying emergency service space that could be used by other patients who may require more immediate services. Hospitals have identified observation services as a means of improving patient care and relieving overcrowding in emergency departments by increasing efficiency and patient through-put.

The Department has granted waivers for the use of observation services to approximately 22 hospitals. Observations services in a unit under the auspices of the emergency service, allow hospitals to provide focused assessment and treatment as needed, beyond the 8 hours permitted for emergency services. When properly utilized, observation services can prevent inappropriate admissions and premature discharges from the emergency service.

Needs and Benefits:

State regulations governing hospitals should safeguard and promote high-quality care and patient safety, while also allowing hospitals to operate efficiently and maintain access to services. Regulations should also keep pace with the advances in health care technology, best practices, and models of care.

This proposed regulation creates operating standards for observation units under the auspices of the emergency service. Patients will be permitted to stay in observation units for up to twenty-four hours from assignment to the observation unit from the emergency service. After this time patients must be discharged, admitted as an inpatient or transferred to another hospital. Observation services provided in these units will be eligible for Medicaid reimbursement, provided that payment requirements are met. This regulatory change will support improvements in emergency service efficiency and reductions in unnecessary inpatient admissions and in premature discharges from the emergency service that can lead to poor outcomes. These provisions will also improve the patient's experience of care by preventing prolonged stays in crowded emergency departments and relieve emergency department overcrowding.

COSTS**Costs to Private Regulated Parties:**

As the creation of an observation unit is optional, this regulation creates no additional burdens or costs to regulated parties. It will eliminate the need for the cumbersome waiver process that is currently used to autho-

alize the operation of observation units. A few providers that are currently operating observation units pursuant to waivers approved by the Department may have to make modifications to the observation unit space. Costs associated with these modifications should be minimal, and those providers will, for the first time, be able to bill Medicaid for services provided in the unit.

Costs to Local Government:

There are no costs to local government.

Costs to the Department of Health:

The proposed amendment would impose no new costs on the Department.

Costs to Other State Agencies:

There are no costs to other State agencies or offices of State government.

Local Government Mandates:

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

Paperwork:

This regulation will eliminate the paperwork associated with a cumbersome waiver application process. The regulation does not require a certificate of need or other application in order to establish an observation unit unless construction is necessary or a service is to be eliminated. Instead, it imposes a notice requirement.

Duplication:

There are no relevant State regulations which duplicate, overlap or conflict with the proposed amendment. Federal Medicare payment rules set forth standards for reimbursement of observation services. These proposed regulations provide a clear and consistent process for creating observation units and operating standards for such units. The regulations do not conflict with Medicare payment rules.

Alternatives:

The Department considered allowing providers to use undesignated emergency service beds as observation beds, instead of creating a distinct unit. Based on the literature, the Department determined that this arrangement would not achieve the goals of the regulation. It would merely prolong emergency service visits without altering the model of care, relieving overcrowding, or improving quality and the patient experience of care.

Federal Standards:

The proposed amendment does not exceed any minimum operating standards for health care facilities imposed by the Federal government.

Compliance Schedule:

The proposed amendment will be effective upon publication of a Notice of Adoption in the New York State Register. Facilities operating observation units pursuant to a waiver approved by the Department will have 24 months to comply with these regulations.

Regulatory Flexibility Analysis

No regulatory flexibility analysis is required pursuant to section 202-(b)(3)(a) of the State Administrative Procedure Act. The proposed amendment does not impose an adverse economic impact on small businesses or local governments, and it does not impose reporting, record keeping or other compliance requirements on small businesses or local governments.

Rural Area Flexibility Analysis

No rural area flexibility analysis is required pursuant to section 202-bb(4)(a) of the State Administrative Procedure Act. The proposed amendment does not impose an adverse impact on facilities in rural areas, and it does not impose reporting, record keeping or other compliance requirements on facilities in rural areas. The regulation includes an exemption from the requirement of a discrete physical space for critical access hospitals and sole community hospitals.

Job Impact Statement

No Job Impact Statement is required pursuant to section 201 a(2)(a) of the State Administrative Procedure Act. It is apparent, from the nature of the proposed amendment, that it will not have an adverse impact on jobs and employment opportunities.

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

Chemical Analyses of Blood, Urine, Breath or Saliva for Alcoholic Content

I.D. No. HLT-39-11-00012-P

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

Proposed Action: Amendment of Part 59 of Title 10 NYCRR.

Statutory authority: Vehicle and Traffic Law, sections 1194(4)(c) and 1198(6); and Environmental Conservation Law, section 11-1205(6)

Subject: Chemical Analyses of Blood, Urine, Breath or Saliva for Alcoholic Content.

Purpose: Update technical standards for blood and breath alcohol testing conducted by law enforcement.

Substance of proposed rule (Full text is posted at the following State website: www.health.state.ny.us): This proposed amendment to Part 59 updates standards, reflects changes in nomenclature and technology, and provides clarification of provisions pertinent to alcohol determinations of breath, blood and other body fluids, and certification of ignition interlock devices used for enforcement of Vehicle and Traffic Law.

The Section 59.1 definition for the term techniques and methods is amended to include saliva, which itself is defined in a new subdivision (k). The definition of testing laboratory is revised to clarify the Department's requirements. A definition for calibration is added. Section 59.2 is modified to introduce current terminology, specifically blood alcohol concentration (BAC). The rule clarifies that urine may be used as a specimen, and its analysis requires controls and blanks similar to those used for analyses of blood. This amendment removes the list of persons authorized to draw blood and eliminates technical specifications not required for analytical accuracy. Section 59.2 is further modified to revise the acceptable range for the alcohol reference standard used for calibration verification of instruments for both breath and blood analysis. This section and others now provide for a 0.08 grams/100 ml (w/v) reference standard. This proposal also requires that units for alcohol determinations of blood and urine be expressed as blood alcohol concentration (BAC), meaning percent weight per volume, rather than the outdated terminology of grams percent.

Section 59.3 is modified in several places to address saliva as a potential specimen. The proficiency testing performance criteria for renewal of a permit for the chemical analysis of blood, urine and saliva are clarified. "Competence" is replaced with "proficiency" throughout the section. In Section 59.4, outdated NYS-specific criteria for breath testing instruments are replaced with documentation that the model has been accepted by the U.S. Department of Transportation/National Highway Traffic Safety Administration (NHTSA) as an evidential breath alcohol measurement device. The proposed amendment includes the list of NHTSA-approved breath measurement instruments published in the Federal Register on March 11, 2010 to remove any possible ambiguity about the fact that devices listed therein, including the Alcotest 9510 manufactured by Draeger Safety, Inc., are fully approved by the Department of Health. The training agencies' responsibilities for instrument maintenance, including the establishment of a calibration cycle, and records retention are clarified.

The Section 59.5 two-hour time frame for specimen collection is eliminated, and the requirement for certain techniques and methods to be a component of each training agency's curriculum and to be put to use by the analyst is clarified. The requirement for observation of a subject prior to collection of a breath sample has been clarified. Minor technical changes have been made to Section 59.6.

This proposal would reduce the hours spent in initial training for a breath analyst permit as specified in Section 59.7, from 32 hours required to 24 hours, and require training agencies to develop learning objectives. The minimum time for hands-on training with breath analysis instruments is reduced from ten to six hours. Revised Section 59.7 establishes an application window of 120 calendar days preceding the permit's expiration date. The Section also clarifies that a permit expires and is void when not renewed, but that the Commissioner of Health may extend the permit expiration date for 30 calendar days, during which period the permit remains valid. The amendment makes clear that failure to renew in accordance with time frames established in the regulation results in the permit becoming void, which then requires the analyst to participate in the 24-hour initial/comprehensive training course. Section 59.7, as revised, requires training agencies to submit information on training sessions and participant lists to the Department of Health in a format designated by the Commissioner.

Section 59.9, as amended, provides for an effective period of four years for technical supervisor certification, an increase of two years. The responsibilities of a technical supervisor have been modified to reflect current practice. Notably, the duty to conduct field inspections has been eliminated, as has the responsibility to provide expert

testimony, since the recognition of expertise is a role of the court. Revised Section 59.9 clarifies that a technical supervisor may delegate certain tasks, including instrument maintenance and preparation of chemicals used in testing, to a person not qualified as a supervisor, provided the work product is reviewed and found acceptable. A new sentence at the end of the section codifies long-standing Department policy that suspension or revocation of an operator's permit held by a supervisor triggers suspension or revocation of the person's certification as a technical supervisor.

Existing Sections 59.10 and 59.11 are repealed, and replaced with two new sections that provide criteria, respectively, for certification for ignition interlock devices and for testing of such devices by independent laboratories. The existing reference to a seven-county pilot study of ignition interlock devices is removed, and outdated performance standards for devices are replaced with NHTSA standards. Existing provisions for the application process, manufacturer interaction with testing laboratories, and discontinuance of certification remain in effect. New Section 59.10 requires the manufacturer to provide contact information, including identification of a person to respond to Department inquiries, and requires the manufacturer to furnish a certificate stating that the company issuing the requisite liability coverage will notify the Department at least 30 days prior to cancellation of the policy before the expiration date. Section 59.10 also makes clear the Department's requirement that the manufacturer must demonstrate, through arrangements with a testing laboratory, that the device meets the NHTSA model specifications when calibrated to a set point of 0.025% BAC; and stipulates that only devices that employ fuel cell technology or another technology with demonstrated comparable accuracy and specificity are eligible for certification.

New Section 59.11 specifies the minimal elements of a testing laboratory report and requires such report to be submitted directly to the Department. In both new sections, a reference to "circumvention" has been added with each occurrence of the word "tampering," to recognize that these are both prohibited in Vehicle and Traffic Law Section 1198.

Existing Section 59.12 is repealed. New Section 59.12 establishes requirements for continued ignition interlock certification. New Section 59.12 requires a manufacturer to notify the Department of any operational modification to a certified device, and to obtain express approval for its continued use, as modified, under the existing certification. The definition of operational modification and the process for reporting modifications has been moved from Section 59.10 to Section 59.12. A new requirement is added that the manufacturer notify the Department of each renewal of insurance coverage, each change of issuing company, and each change in liability limits. The section requires manufacturers to supply to installation/service providers a sufficient number of labels with text that conforms to the text mandated by statute. The vast majority of the section's other requirements, including reporting and labeling requirements and manufacturer-service provider interactions, have been eliminated from Section 59.12; most have been incorporated into a new 9 NYCRR Part 358 being promulgated by the Division of Probation and Correctional Alternatives (DPCA) contemporaneously with this regulation in response to the anticipated August 2010 implementation of the ignition interlock provisions of Leandra's Law (L. 2009, Ch. 496). New Section 59.12 establishes a process for periodic renewal to ensure that information on file with the Department is current. The application form has been removed from the regulation, as it will be available electronically.

Text of proposed rule and any required statements and analyses may be obtained from: Katherine Ceroalo, DOH, Bureau of House Counsel, Regulatory Affairs Unit, Room 2438, ESP, Tower Building, Albany, NY 12237, (518) 473-7488, email: regsqna@health.state.ny.us

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

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

Summary of Regulatory Impact Statement

Statutory Authority:

The New York State (NYS) Vehicle and Traffic Law, Section 1194(4)(c), and Department of Environmental Conservation Law, Sec-

tion 11-1205(6), authorize the Commissioner of Health to adopt regulations concerning methods of testing breath and body fluids for alcohol content. NYS Vehicle and Traffic Law, Section 1198(6) authorizes the Commissioner of Health to promulgate regulations setting standards for use of ignition interlock devices.

Legislative Objectives:

This amendment is consistent with the legislative objective of ensuring effective enforcement of laws against driving while intoxicated (DWI). This proposal is consistent with Chapter 669 of the Laws of 2007, which authorized statewide use of ignition interlock devices, and Chapter 496 of the Laws of 2009 (Leandra's Law), which mandates that every person sentenced for any DWI offense, must have an ignition interlock device installed as a requirement for conditional discharge or probation.

Needs and Benefits:

Part 59 establishes standards for chemical tests on blood, breath, and urine for the presence of alcohol, for purposes of detecting unacceptable levels of alcohol in persons. Courts rely on Part 59 provisions daily in adjudicating alcohol-related offenses; the State's correctional alternatives program relies on effective operation of ignition interlock devices to prevent repeat offenders from driving while impaired by alcohol. The existing regulation must be updated, as it is inconsistent with existing DWI statutes, as well as current and anticipated usage of ignition interlock devices.

The specificity of Section 59.2 standards for collecting, handling and analyzing a specimen for blood alcohol analysis has prevented convictions even though the defendant was driving while intoxicated. This amendment would delete the list of persons authorized to draw blood, as the listing could present a legal conflict with similar provisions in Vehicle and Traffic Law Section 1194(4)(a) and Public Health Law Section 3703. This amendment would eliminate technical specifications for the collection of blood within a two-hour timeframe, and use of a clean and sterile syringe and anticoagulant, and require that alcohol units be expressed as blood alcohol concentration, rather than the outdated terminology of grams percent. The reference standard for calibration verification of breath and blood analysis instruments has been changed to a standard greater than or equal to 0.08 grams/100 ml, consistent with the Vehicle and Traffic Law provision that sets 0.08% weight per volume (w/v) alcohol in blood as the threshold for certain DWI sanctions. The amendment describes criteria for revocation or nonrenewal of a blood alcohol analysis permit based on unsuccessful proficiency testing (PT) performance or failure to participate in PT challenges.

Section 59.4 affords training agencies the flexibility of establishing retention times for records, as these may vary by record type and potential use in a legal proceeding; delegation of recordkeeping activities is authorized. Section 59.4, as revised, stipulates the commissioner's approval of breath measurement devices for use in NYS provided the device has been accepted by the National Highway Traffic Safety Administration (NHTSA). The revised section includes the list of NHTSA-approved breath measurement instruments published in the Federal Register on March 11, 2010 to remove any possible ambiguity about the fact that devices listed therein, including the Alcotest 9510 manufactured by Draeger Safety Inc., are fully approved by the Department of Health. The requirement in Section 59.5 for conducting breath analysis within two hours of arrest or a positive breath alcohol screening test has been removed. The requisite for test subject observation prior to testing has been clarified, as the existing provision for continuous observation carries the risk of unintended and unnecessarily specific interpretation, thus jeopardizing successful DWI prosecution. The reference to operational checklists, which are no longer used, has been eliminated. The requirement for certain techniques and methods to be a component of each training agency's curriculum and to be put into use by analysts is clarified.

This proposal would reduce from 32 to 24 hours the time trainees must spend in initial training. The reduction from 10 to six hours in hands-on use of instruments is reasonable given the decreasing complexity of instrumentation overall, and the trend towards use of one device model within a jurisdiction. Training agencies would be required to identify learning objectives and design examinations in

keeping with objectives. The outdated term equilibrators has been deleted, as breath analyzers no longer need to counter a matrix effect from use of simulator solutions. As modified, the rule requires retraining to renew a BTO permit take place via a course designed to refresh applicants' recall of formal training material, such as including mechanisms to assess proficiency and measure retained knowledge. The proposal stipulates that retraining must occur within the 120 days prior to permit expiration, to eliminate overlap within the two-year BTO cycle. This amendment would afford, at the Commissioner's discretion, a 30-day extension in permit expiration date, in an effort to avoid the potential legal dilemma of administrative permit lapses due to paperwork processing delays. Operators whose permits are voided are required to participate successfully in another initial certification course before a new BTO permit may be issued, to demonstrate that recall and competency have been maintained.

The effective period for a technical supervisor's certification has been increased from two to four years. Supervisor responsibilities have been detailed; and supervisors are permitted to delegate certain tasks, provided they review the work product to ensure the designee's performance meets expectations. A reference to field inspection of instruments by supervisors has been modified to reflect the current practice of remote calibration checks. Provision of expert testimony has also been deleted from the list of supervisor's responsibilities, since the process of qualifying subject matter experts rests with the court.

Existing Section 59.10 is repealed. New Section 59.10 retains many existing ignition interlock certification criteria, rearranged for ease of comprehension. The reference to a seven-county pilot study for ignition interlock devices has been eliminated, as Chapter 669 of the Laws of 2007 amended the Vehicle and Traffic Law to expand the study into a statewide program. New Section 59.10 requires the manufacturer to identify a person to respond to Department inquiries, and requires the manufacturer to furnish a certificate stating that the company issuing the requisite liability coverage will notify the Department at least 30 days prior to cancelling a policy before the expiration date. New Section 59.10 also makes clear that the manufacturer must demonstrate, through arrangements with a testing laboratory, that the device meets the NHTSA model specifications when calibrated to a set point of 0.025% BAC; and stipulates that only devices that employ fuel cell technology or another technology with demonstrated comparable accuracy and specificity are eligible for certification, thus ensuring deployment of state-of-the-art equipment.

Existing Section 59.11 is repealed. New Section 59.11 replaces New York State-specific criteria for certification of interlock devices with NHTSA standards, as the NYS standards, codified in 1990, are less encompassing than federal standards. Submission of testing agency credentials with each application for device approval is no longer required. New Section 59.11 details requirements for certification of the testing laboratory, the laboratory's responsibilities in the device approval process, and the minimum components of a testing laboratory report. In both new Section 59.10 and 59.11 a reference to "circumvention" has been added with each occurrence of the word "tampering," to recognize that these are distinct Vehicle and Traffic Law violations.

Existing Section 59.12 is repealed. New Section 59.12 establishes requirements for continued ignition interlock certification. New Section 59.12 requires a manufacturer to notify the Department of any operational modification to a certified device, and to obtain approval for continued use, as modified, under the existing certification. The definition of operational modification and the process for reporting modifications has been moved to Section 59.12. The amendment codifies a currently implicit requirement that manufacturers notify the Department of changes to insurance coverage. The text required for the warning label is revised to conform to the text mandated by statute. The section requires the manufacturers to supply a sufficient number of labels to installation/service providers. The vast majority of the section's other requirements, including reporting and labeling requirements and manufacturer-service provider interactions, have been eliminated from Section 59.12; most have been incorporated into a new 9 NYCRR Part 358 being promulgated by the Division of Probation and Correctional Alternatives (DPCA) to implement the ignition

interlock provisions of Leandra's Law. New Section 59.12 establishes a process for periodic renewal to ensure that information on file with the Department is current. The application form for device certification has been removed from the regulation, and will be available electronically.

COSTS:

Costs to Private Regulated Parties:

The requirements of this regulation applicable to ignition interlock manufacturers and installation/service providers impose no new costs on these private regulated parties. The newly codified requirement that manufacturers notify the Department of changes to insurance coverage may be accomplished electronically at no cost to the manufacturer. The renewal of certification form/attestation may be electronically submitted.

Costs to State Government:

Affected State agencies other than the Department of Health, i.e., the State Police, the Division of Criminal Justice Services (DCJS), and DPCA, would incur minimal additional costs as a result of adoption of this amendment, as the amendment relaxes, clarifies or codifies practices already implemented. The State Police and DCJS, as training agencies, may realize cost savings from the proposed reduced duration of the breath analyst certification course, from 32 to 24 hours.

Costs to Local Government:

The Nassau County, Suffolk County and New York City Police Departments, which are local-government training agencies, would incur either no to minimal additional costs as a result of this amendment's adoption, as the amendment relaxes, clarifies or codifies processes already in place. These training agencies may realize cost savings from the proposed reduced duration of the breath analyst certification course, from 32 to 24 hours, which represents one full day that officers need not be absent from the work pool.

Prosecutorial units of local government may experience cost savings resulting from this amendment's deletion of specific requirements for specimen collection that, historically, have been challenged successfully by defense attorneys.

Costs to the Department of Health:

Adoption of this regulation would impose minimal additional costs on the Department. Implementation of a renewal process for the six manufacturers that currently hold ignition interlock certifications will use existing resources and result in minimal additional work load. Regulated parties will be provided with the text of the final adopted rule by electronic mail.

Local Government Mandates:

This regulation does not impose any new mandate on any county, city, town, village, school district, fire district or other special district.

Paperwork:

The proposal to extend, from two to four years, the effective period of breath analyzer supervisor permits will reduce paperwork, as will deletion of the requirement for quarterly reporting to multiple agencies of ignition interlock use data. This amendment's emphasis on learning goals rather than course structure would allow for paperwork reduction, as recertification courses would be adaptable to online distance learning modules. Manufacturers are encouraged to utilize electronic means of communication for required notifications and certificate renewals.

Duplication:

Part 59 as amended would be consistent with, but not duplicate, federal standards for approval of breath alcohol evidentiary devices as promulgated by the NHTSA.

Alternative Approaches:

At the present time, there are no acceptable alternatives to pursuing adoption of the amendment as written. The major stakeholders have reached agreement that inability to move forward with the changes as proposed would likely impede DWI enforcement and prosecutorial activities in NYS. The clarifications and updates in this amendment are required to keep the regulation current with law enforcement practices and changes to laws governing ignition interlock programs and evidence-gathering protocols related to DWI prosecutions, as well as technological advances in the devices themselves.

Federal Standards:

The proposed rule does not exceed any minimum standards of the federal government; it references sources for information on federally approved devices, and is consistent with federal standards for ignition interlock and breathalyzer device approval.

Compliance Schedule:

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

Regulatory Flexibility Analysis

No Regulatory Flexibility Analysis is required pursuant to Section 202-b (3)(b) of the State Administrative Procedure Act. The proposed amendment does not impose any adverse economic impact on small businesses or local governments, and does not impose reporting, recordkeeping or other compliance requirements on small businesses or local governments.

Rural Area Flexibility Analysis

No Rural Area Flexibility Analysis is required pursuant to Section 202-bb (4)(a) of the State Administrative Procedure Act. The proposed amendment does not impose any adverse impact on facilities in rural areas, and does not impose any reporting, recordkeeping or other compliance requirements on regulated parties in rural areas.

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.

PROPOSED RULE MAKING NO HEARING(S) SCHEDULED

NYS Newborn Screening Panel

I.D. No. HLT-39-11-00018-P

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

Proposed Action: Amendment of section 69-1.2 of Title 10 NYCRR.

Statutory authority: Public Health Law, section 2500-a

Subject: NYS Newborn Screening Panel.

Purpose: Adds Severe Combined Immunodeficiency (SCID) and eliminates testing for hyperammonemia/ornithinemia/citrullinemia (HHH).

Text of proposed rule: Section 69-1.2(b) is amended as follows:

(b) Diseases and conditions to be tested for shall include:

argininemia (ARG);

* * * *

3-hydroxy-3-methylglutaryl-CoA lyase deficiency (HMG);

[hyperammonemia/ornithinemia/citrullinemia (HHH);]

hypermethioninemia (HMET);

* * * *

propionic acidemia (PA);

severe combined immunodeficiency and other inherited T-cell deficiencies (SCID)

short-chain acyl-CoA dehydrogenase deficiency (SCADD);

tyrosinemia (TYR); and

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

Text of proposed rule and any required statements and analyses may be obtained from: Katherine Ceroalo, DOH, Bureau of House Counsel, Regulatory Affairs Unit, Room 2438, ESP, Tower Building, Albany, NY 12237, (518) 473-7488, email: regsqna@health.state.ny.us

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

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

Summary of Regulatory Impact Statement

Statutory Authority:

Public Health Law (PHL) Section 2500-a (a) provides statutory authority for the Commissioner of Health to designate in regulation 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. Emerging medical treatments and the complexity of genetic testing require periodic reassessments of the benefits of newborn screening. These reassessments ensure that the New York State's Newborn Screening Program (the NYS Program) meets the legislative intent of preventing childhood diseases and disorders by early detection. This proposal, which would modify the newborn screening panel currently in regulation by adding severe combined immunodeficiency (SCID), and by deleting hyperammonemia/ornithinemia/citrullinemia (HHH), 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:

Severe Combined Immunodeficiency (SCID) is a primary immune deficiency, which results in the infant's failure to develop a normal immune system. The defining characteristic for SCID is a severe defect in the production and function of T-cells and/or B-cells. Affected infants are susceptible to a wide range of infections that are typically controlled by a normal immune system. If undetected and untreated, SCID typically leads to death in the first year of life. It is noteworthy that, in May of 2010, the U.S. Department of Health and Human Services (DHHS) Secretary Kathleen Sebelius added SCID to the core newborn screening panel that represents a national standard 30-test panel that states are encouraged to adopt.

The pediatric immunology community now recognizes this once-fatal disease is a disorder that can be treated and most likely cured at a reasonable cost. Early detection through screening is critical to successful treatment. Current estimates suggest that one in every 50,000 to 100,000 newborns may be affected; however, since many infants may succumb to infection before being diagnosed, the true incidence of SCID and related forms of T-cell immune deficiency may be higher. A DNA-based test for immune deficiency has been recently modified for accurate, high-throughput analyses, making possible its use for newborn screening. This test detects T-cell Receptor Gene Excision Circles or TRECs, which are produced during normal T-cell maturation but are absent or severely reduced in infants with SCID.

Immediately after confirming a SCID diagnosis, infants are started on intravenous immunoglobulins (IVIG) and antibiotics, and a donor search is initiated to perform stem cell transplant from donor bone marrow or cord blood. SCID infants and children require IVIG for as long as they lack the ability to produce antibodies - before and often for some time after a transplant. If the transplant proves not totally corrective, IVIG may be needed for life. Alternatively, enzyme replacement therapy with bovine pegademase (PEG-ADA), an injectable medication, can be used to treat the approximately 40-percent of SCID patients with a form of the disorder characterized by a deficiency of the enzyme adenosine deaminase. This treatment is typically used only when the patient is not a candidate for the more conventional bone marrow transplant treatment.

General health care costs attributable to treatment of SCID-confirmed infants, including those related to a stem cell transplant (i.e., use of a surgical suite, stays in the neonatal intensive care unit) cannot be assessed due to large variations in charges for the professional component of specialists' and ancillary providers' services, and the scope of potentially required donor-matching services. However, overall health care costs would be reduced since early diagnosis of SCID provides the opportunity for less expensive treatments, and avoids medical complications, thereby reducing the number and average length of hospital stays, and emergency and intensive care services necessary due to recurrent infections in affected children.

If a matched, related donor cannot be found or a transplant fails, infants diagnosed with SCID typically are initially treated using IVIG as an outpatient procedure. Since IVIG only replaces the missing end product, but does not correct the deficiency in antibody production, the replacement therapy usually becomes necessary for the patient's entire lifespan. The cost of lifetime IVIG replacement therapy is estimated to be approximately \$600,000. Costs for enzyme replacement therapy for one form of SCID with PEG-ADA, which is designated as an orphan drug, are estimated at \$3,800 per injection. PEG-ADA is administered by intramuscular injection twice weekly and once weekly after stabilization is reached, usually in one to three weeks. Costs for a transplant including a 1 year follow-up period are \$300,000, while costs for an unscreened and undiagnosed child who does not receive early treatment can exceed \$600,000.

This amendment also proposes to discontinue newborn screening for hyperammonemia/hyperornithinemia/homocitrullinemia (HHH). HHH syndrome is a rare inherited metabolic disorder that prevents the body from properly processing ammonia due to reduced enzyme activity. HHH syndrome is extremely rare; only about 50 cases are known. In 2008 and 2009, a total of 19 newborns were referred for evaluation/treatment because of elevated ornithine, a biomarker for HHH. None of these cases was confirmed as HHH. The NYS Program has seen no confirmed cases

after four years of testing more than one million specimens. It is now widely recognized that levels of ornithine are not abnormal in children with the disease before five days of age, generally after a newborn screening specimen is collected.

Costs:

Costs to Private Regulated Parties:

Birth facilities would incur no new costs related to collection and submission of blood specimens to the NYS Program, since the dried blood spot specimens now collected would also be tested for SCID. Discontinuation of screening for HHH would have no significant impact on birthing facilities or other regulated parties or stakeholders; costs incurred from referral of SCID-positive infants would be offset by savings from no longer having to arrange for repeat specimens for or pursue referral of infants with high levels of HHH biomarker.

The NYS Program estimates that following implementation of this proposal, 125 newborns would screen positive for SCID annually statewide, with SCID being confirmed in seven of those infants.

Birth facilities would likely incur minimal additional costs related to fulfilling their responsibilities for referral of screen-positive infants; such costs would be limited to human resources costs for less than 0.5 person-hour. Any birthing facility can calculate its specific cost impact based on its annual number of births and related expenses, and a referral rate of one infant per 2,100 births. The Department estimates that on average specialized care facilities would receive referrals of fewer than two infants per month for clinical assessment and additional testing to confirm or refute screening results.

Annual cost for arranging for SCID-related referrals for a facility at which 2,000 babies are delivered each year would range from ½ of \$40 to ½ of \$100, depending on whether clerical staff or nursing staff arranged for the referral, or specifically \$20-50 a year. Larger birthing facilities (i.e., those with the resources to perform transplants) would not incur even these minimal costs for referral to another facility.

Cost savings from eliminating referral and follow-up to obtain repeat specimens for infants with high biomarker levels for HHH would offset approximately 10% of the costs for referral activities in response to a SCID-positive infant.

Costs for Implementation and Administration of the Rule:

Costs to State Government:

State-operated facilities providing birthing services and infant follow-up and medical care would incur costs and savings as described above for private regulated parties.

State Medicaid costs will not increase with regard to referral costs, as such costs are included in rates for delivery-related services, and are not separately reimbursed. Costs associated with treatment for SCIDS for Medicaid-eligible infants would generally be borne by the State, as most counties have already reached their cap for Medicaid liability. However, there would likely be a net savings to Medicaid since early diagnosis provides the opportunity for less expensive treatment, (on the order of \$300,000) and avoids medical complications, thereby reducing the number and average length of hospital stays, and emergency and intensive care services necessary due to recurrent infections (which can exceed \$600,000).

Costs to the Department:

Costs incurred by the Department's Wadsworth Center for performing SCID screening tests, providing short- and long-term follow-up, and supporting continuing research in neonatal and genetic diseases will be covered by State budget appropriations. The Program expects minimal to no additional laboratory instrumentation costs related to this proposal, since the necessary technology has already been purchased.

The Department will incur minimal administrative costs for notifying all New York State-licensed physicians, hospital chief executive officers (CEOs) and their designees, and other affected parties, by letter informing them of a newborn screening panel expansion or, on an ongoing basis, of information regarding positive SCID screening results.

Costs to Local Government:

Local government-operated facilities providing birthing services and medical care to affected infants would incur the costs and savings described above for private regulated parties.

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. 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 of infants with abnormal screening results. Educational materials for parents and health care professionals and forms will be updated to include information on SCID at minimal costs at the next printing.

Duplication:

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

Alternative Approaches:

Potential delays in detection of SCID until onset of clinical symptoms would result in increased infant morbidity and mortality, and are therefore unacceptable. Given the recent recommendation by DHHS, which takes into account that treatment is available to ameliorate adverse clinical outcomes in affected infants, the Department has determined that there are no alternatives to requiring newborn screening for this condition.

Federal Standards:

The DHHS has recommended a core newborn screening panel that represents a national standard 30-test panel that states are encouraged to adopt. This core panel does not include HHH. A DHHS-commissioned Advisory Committee on Heritable Disorders of Newborns and Children recently recommended that states' newborn screening programs amend their test panels to include SCID. With the addition of SCID to its panel, the NYS Program would include all the DHHS-recommended tests.

Compliance Schedule:

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 to other affected parties.

The infrastructure and mechanisms for making the necessary referrals is already in place in birthing facilities. 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 one new condition - an immunodeficiency disorder known as severe combined immunodeficiency (SCID) to, and to delete one condition, an inherited metabolic disorder known as hyperammonemia/ornithinemia/homocitrullinemia (HHH) from, the list of 44 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. No facility recognized as having medical expertise in clinical assessment and treatment of SCID is operated as a small business. Local governments, including the New York City Health and Hospitals Corporation, operate 21 hospitals. 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 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 test proposed by this amendment. Discontinuation of screening for HHH would have no adverse impact on birthing facilities or other regulated parties or stakeholders.

Birth facilities and at-home birth attendants (i.e., licensed midwives) would be required to follow up infants screening positive for SCID, and assume some responsibility for referral for medical evaluation and additional testing as they do for other conditions. The anticipated increased burden is expected to have a 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 one to two per month in the number of infants requiring referral.

On average, each birthing facility can expect to refer no more than one additional infant per year for clinical assessment and confirmatory testing as a result of this amendment's proposal to add SCID screening to the existing newborn screening panel. This increase is expected to have minimal effect on a birthing facility's workload since at present approximately 30 infants, on average, are referred by birthing facilities statewide; with the addition of SCID this number would increase by an

average of one infant. Therefore, no additional staff would be required for these institutions to comply with this proposal.

The Department anticipates that more than 95 percent of approximately 125 referred infants will ultimately be found not to be afflicted with SCID, based on clinical assessment and laboratory tests. Cost savings from eliminating the need to arrange for repeat specimens and referral for infants with high biomarker levels for HHH would offset costs for referral activities in response to a SCID screen-positive infant.

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. Birthing facilities' existing professional staff are expected to be able to assume any increase in workload resulting from the Program's newborn screening for SCID and identification of screen-positive infants. Infants with positive screening tests for SCID would be referred to a facility employing a physician and other medical professionals with expertise in SCID.

Compliance Costs:

Birthing facilities operated as small businesses and by local governments, and practitioners who are small business owners (e.g., 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 test 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 SCID, primarily because the testing proposed under this regulation is expected to result in, on average, fewer than one referral per year at each of the 11 birthing facilities that are small businesses.

The NYS Program estimates that following implementation of this proposal, 125 newborns would screen positive for SCID annually statewide. Since timing is crucial, i.e., treatment must commence early to be effective, newborns who screen positive will require immediate referral to a facility with the requisite expertise for clinical assessment and laboratory testing. The Department estimates that on average such a facility would receive referrals of fewer than one infant per month for clinical assessment and additional testing to confirm or refute screening results. Cost figures that follow are based on 125 as a high-end estimate for the maximum number of infants statewide needing immediate referral.

Communicating the need for and/or arranging referral for medical evaluation of an identified infant would require less than 0.5 person-hour; no additional staff would be required. Annual cost for arranging for SCID-related referrals for a facility at which 2,000 babies are delivered each year would range from ½ of \$40 to ½ of \$100, depending on whether clerical staff or nursing staff arranged for the referral, or specifically \$20-50 a year. Larger birthing facilities (i.e., those with the resources to perform transplants) would not incur even these minimal costs for referral to another facility.

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. The infrastructure for specimen collection and referrals of affected infants are already in place.

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. The addition of SCID to the newborn screening panel will not impose a unique burden on facilities and practitioners that are operated by a local government or as a small business. 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 specimen collection, reporting, follow-up and recordkeeping practices.

Small Business and Local Government Participation:

The Program will notify all New York State-licensed physicians by letter informing them of this newborn screening panel expansion. An informational letter will also be distributed to hospital chief executive officers (CEOs) and their designees responsible for newborn screening, as well as to other affected parties. Regulated parties that are small businesses and local governments are expected to be prepared to participate in screening and follow-up for SCID on the effective date of this amendment because the staff and infrastructure needed for specimen collection and referrals of affected infants are already in place.

Rural Area Flexibility Analysis

Types of Estimated Numbers of Rural Areas:

Rural areas are defined as counties with a population of fewer than

200,000 residents; 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 eliminate one condition - hyperammonemia/ornithinemia/homocitrullinemia (HHH) - and to add one new condition - severe combined immunodeficiency (SCID) - to the list of 44 genetic/congenital disorders and one infectious disease, for which every newborn in the State must be tested, would 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. No facility recognized as having medical expertise in clinical assessment and treatment of SCID 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 birthing 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; 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 test 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 SCID, and assume referral responsibility for medical evaluation and additional testing. Discontinuation of screening for HHH would have no overall impact on birthing facilities or midwives; use of human resources and costs incurred from referral of SCID-positive infants would be offset by savings from no longer having to pursue referral of infants with high levels of HHH biomarker. 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 one to two per month 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. Birthing facilities' existing professional staff are expected to be able to assume any increase in workload resulting from the Program's newborn screening for SCID and identification of screen-positive infants. Infants with a positive screening test for SCID will be referred to a facility employing a physician and other medical professionals with expertise in SCID.

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 test 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, since the proposed added testing is expected to result in no more than one additional referral per month. Communicating the need and/or arranging referral for medical evaluation of one additional identified infant would require less than 0.5 person-hour, and these tasks are expected to be able to be accomplished with existing staff. Annual cost for arranging for SCID-related referrals for a facility at which 2,000 babies are delivered each year would range from ½ of \$40 to ½ of \$100, depending on whether clerical staff or nursing staff arranged for the referral, or specifically \$20-50 a year. Larger birthing facilities (i.e., those with the resources to perform transplants) would not incur even these minimal costs for referral to another facility. The Department estimates that more than 95 percent of infants will be ultimately found not to be afflicted with the target condition, based on clinical assessment and additional testing.

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. The addition of SCID to the newborn screening panel will not impose a unique burden on facilities and practitioners operating in rural areas. These amendments will not have an adverse impact on the ability of regulated parties in rural areas to comply with Department requirements for mandatory newborn screening, as full compliance would entail minimal changes to present collection, reporting, follow-up and record-keeping practices.

Rural Area Participation:

The Program will notify all New York State-licensed physicians by letter informing them of this newborn screening panel expansion. An informational letter will also be distributed to hospital chief executive officers (CEOs) and their designees responsible for newborn screening, as well as to other affected parties. Regulated parties in rural areas are expected to be able to participate in screening and follow-up for SCID on the effective date of this amendment.

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 an immune system disorder, severe combined immunodeficiency (SCID) to, and the deletion of hyperammonemia/ornithinemia/citrullinemia (HHH) from, the scope of newborn screening services provided by the Department. It is expected that no regulated parties will experience other than minimal impact on their workload, and therefore none will need to hire new personnel. Therefore, this proposed amendment carries no adverse implications for job opportunities.

PROPOSED RULE MAKING NO HEARING(S) SCHEDULED

July 2011 Ambulatory Patient Groups (APGs) Payment Methodology

I.D. No. HLT-39-11-00019-P

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

Proposed Action: Amendment of Subpart 86-8 of Title 10 NYCRR.

Statutory authority: Public Health Law, section 2807(2-a)(e)

Subject: July 2011 Ambulatory Patient Groups (APGs) Payment Methodology.

Purpose: To refine the APG payment methodology.

Substance of proposed rule (Full text is posted at the following State website: www.health.state.ny.us): The amendments to Part 86 of Title 10 (Health) NYCRR are required to update the Ambulatory Patient Groups (APGs) methodology, implemented on December 1, 2008, which governs reimbursement for certain ambulatory care fee-for-service (FFS) Medicaid services. APGs group procedures and medical visits that share similar characteristics and resource utilization patterns so as to pay for services based on relative intensity.

86-8.2 - Definitions

The proposed amendment to section 86-8.2 of Title 10 (Health) NYCRR removes subdivision (r), which defined ambulatory surgery permissible procedures.

86-8.7 - APGs and relative weights

The proposed revision to section 86-8.7 of Title 10 (Health) NYCRR repeals all of section 86-8.7 effective July 1, 2011 and replaces it with a new section 86-8.7 that includes revised APG weights, procedure-based weights, and APG fee schedule fees.

86-8.9 Diagnostic coding and rate computation

The proposed revisions to section 86-8.9 of Title 10 (Health) NYCRR removes subdivision (c), which references ambulatory surgery permissible procedures. Additionally, a new subdivision (c) is added to allow for a reduction of reimbursement for drugs purchased through the 340B drug benefit program. Subdivision (d) is amended to add APG 451 Smoking Cessation Treatment.

86-8.10 Exclusions from payment

The proposed revisions to section 86-8.10 of Title 10 (Health) NYCRR amends subdivision (h) to add APG 465 Class XIII Combined Chemotherapy and Pharmacotherapy and subdivision (i) to add APG 490 Incidental to Medical, Significant Procedure or Therapy Visit to the if stand alone do not pay list.

Text of proposed rule and any required statements and analyses may be obtained from: Katherine Ceroalo, DOH, Bureau of House Counsel, Regulatory Affairs Unit, Room 2438, ESP, Tower Building, Albany, NY 12237, (518) 473-7488, email: regsqa@health.state.ny.us

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

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

Regulatory Impact Statement

Statutory Authority:

Authority for the promulgation of these regulations is contained in section 2807(2-a)(e) of the Public Health Law, as amended by Part C of Chapter 58 of the Laws of 2008 and Part C of Chapter 58 of the Laws of 2009, which authorize the Commissioner of Health to adopt and amend rules and regulations, subject to the approval of the State Director of the Budget, establishing an Ambulatory Patient Groups methodology for determining Medicaid rates of payment for diagnostic and treatment center services, free-standing ambulatory surgery services and general hospital outpatient clinics, emergency departments and ambulatory surgery services.

Legislative Objectives:

The Legislature's mandate is to convert, where appropriate, Medicaid reimbursement of ambulatory care services to a system that pays differential amounts based on the resources required for each patient visit, as determined through Ambulatory Patient Groups ("APGs"). The APGs refer to the Enhanced Ambulatory Patient Grouping classification system which is owned and maintained by 3M Health Information Systems. The Enhanced Ambulatory Group classification system and the clinical logic underlying that classification system, the EAPG software, and the Definitions Manual associated with that classification system, are all proprietary to 3M Health Information Systems. APG-based Medicaid Fee For Service payment systems have been implemented in several states including: Massachusetts, New Hampshire, and Maryland.

Needs and Benefits:

The proposed regulations are in conformance with statutory amendments to provisions of Public Health Law section 2807(2-a), which mandated implementation of a new ambulatory care reimbursement methodology based on APGs.

This reimbursement methodology provides greater reimbursement for high intensity services and relatively less reimbursement for low intensity services. It also allows for greater payment homogeneity for comparable services across all ambulatory care settings (i.e., Outpatient Department, Ambulatory Surgery, Emergency Department, and Diagnostic and Treatment Centers). By linking payments to the specific array of services rendered, APGs will make Medicaid reimbursement more transparent. APGs provide strong fiscal incentives for health care providers to improve the quality of, and access to, preventive and primary care services.

These amendments include updated APG and, procedure-based weights, and APG fee schedule fees, which will provide reimbursement precision and specificity. These amendments also remove all reference to ambulatory surgery permissible procedures list, which no longer exists. Additionally, drugs purchased through the 340B drug benefit program will be reimbursed at a reduced rate and APG 490 INCIDENTAL TO MEDICAL, SIGNIFICANT PROCEDURE OR THERAPY VISIT was added to the If Stand Alone do Not Pay list.

COSTS

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

There will be no additional costs to providers as a result of these amendments.

Costs to Local Governments:

There will be no additional costs to local governments as a result of these amendments.

Costs to State Governments:

There will be no additional costs to NYS as a result of these amendments.

Costs to the Department of Health:

There will be no additional costs to the Department of Health as a result of these amendments.

Local Government Mandates:

There are no local government mandates.

Paperwork:

There is no additional paperwork required of providers as a result of these amendments.

Duplication:

This regulation does not duplicate other state or federal regulations.

Alternatives:

These regulations are in conformance with Public Health Law section 2807(2-a)(e). Although the 2009 amendments to PHL 2807 (2-a) authorize the Commissioner to adopt rules to establish alternative payment methodologies or to continue to utilize existing payment methodologies where the APG is not yet appropriate or practical for certain services, the utilization of the APG methodology is in its relative infancy and is otherwise continually monitored, adjusted and evaluated for appropriate-

ness by the Department and the providers. This rulemaking is in response to this continually evaluative process.

Federal Standards:

This amendment does not exceed any minimum standards of the federal government for the same or similar subject areas.

Compliance Schedule:

The proposed amendment will become effective upon publication of the Notice of Adoption in the New York State Register.

Regulatory Flexibility Analysis

Effect on Small Business and Local Governments:

For the purpose of this regulatory flexibility analysis, small businesses were considered to be general hospitals, diagnostic and treatment centers, and free-standing ambulatory surgery centers. Based on recent data extracted from providers' submitted cost reports, seven hospitals and 245 DTCs were identified as employing fewer than 100 employees.

Compliance Requirements:

No new reporting, recordkeeping or other compliance requirements are being imposed as a result of these rules.

Professional Services:

No new or additional professional services are required in order to comply with the proposed amendments.

Compliance Costs:

No initial capital costs will be imposed as a result of this rule, nor is there an annual cost of compliance.

Economic and Technological Feasibility:

Small businesses will be able to comply with the economic and technological aspects of this rule. The proposed amendments are intended to further reform the outpatient/ambulatory care fee-for-service Medicaid payment system, which is intended to benefit health care providers, including those with fewer than 100 employees.

Minimizing Adverse Impact:

The proposed amendments apply to certain services of general hospitals, diagnostic and treatment centers and freestanding ambulatory surgery centers. The Department of Health considered approaches specified in section 202-b (1) of the State Administrative Procedure Act in drafting the proposed amendments and rejected them as inappropriate given that this reimbursement system is mandated in statute.

Small Business and Local Government Participation:

These changes do not affect small businesses and local governments.

Rural Area Flexibility Analysis

Effect on Rural Areas:

Rural areas are defined as counties with a population less than 200,000 and, for counties with a population greater than 200,000, includes towns with population densities of 150 persons or less per square mile. The following 43 counties have a population less than 200,000:

Allegany	Hamilton	Schenectady
Cattaraugus	Herkimer	Schoharie
Cayuga	Jefferson	Schuylar
Chautauqua	Lewis	Seneca
Chemung	Livingston	Steuben
Chenango	Madison	Sullivan
Clinton	Montgomery	Tioga
Columbia	Ontario	Tompkins
Cortland	Orleans	Ulster
Delaware	Oswego	Warren
Essex	Otsego	Washington
Franklin	Putnam	Wayne
Fulton	Rensselaer	Wyoming
Genesee	St. Lawrence	Yates
Greene		

The following 9 counties have certain townships with population densities of 150 persons or less per square mile:

Albany	Erie	Oneida
Broome	Monroe	Onondaga
Dutchess	Niagara	Orange

Compliance Requirements:

No new reporting, recordkeeping, or other compliance requirements are being imposed as a result of this proposal.

Professional Services:

No new additional professional services are required in order for providers in rural areas to comply with the proposed amendments.

Compliance Costs:

No initial capital costs will be imposed as a result of this rule, nor is there an annual cost of compliance.

Minimizing Adverse Impact:

The proposed amendments apply to certain services of general hospitals, diagnostic and treatment centers and freestanding ambulatory surgery centers. The Department of Health considered approaches specified in section 202-bb (2) of the State Administrative Procedure Act in drafting the proposed amendments and rejected them as inappropriate given that the reimbursement system is mandated in statute.

Opportunity for Rural Area Participation:

These changes do not affect rural areas.

Job Impact Statement

A Job Impact Statement is not required pursuant to Section 201-a(2)(a) of the State Administrative Procedure Act. It is apparent, from the nature and purpose of the proposed regulations, that they will not have a substantial adverse impact on jobs or employment opportunities.

Insurance Department

EMERGENCY RULE MAKING

Workers' Compensation Insurance

I.D. No. INS-39-11-00009-E

Filing No. 810

Filing Date: 2011-09-09

Effective Date: 2011-09-09

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

Action taken: Addition of Subpart 151-6 (Regulation 119) to Title 11 NYCRR.

Statutory authority: Insurance Law, sections 201 and 301; and Workers' Compensation Law, sections 15(8)(h)(4) and 151(2)(b)

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

Specific reasons underlying the finding of necessity: Workers' Compensation Law sections 15(8)(h)(4), 25-A(3), and 151(2)(b) require the Workers' Compensation Board ("WCB") to assess insurers and the State Insurance Fund, for the Special Disability Fund, the Fund for Reopened Cases, and the operations of the Workers' WCB, respectively. The assessments are allocated to insurers, self-insurers, group self-insurers, and the State Insurance Fund based upon the total compensation payments made by all such entities. In the case of an insurer, once the assessment amount is determined, the insurer pays the percentage of the allocation based on the total premiums it wrote during the preceding calendar year.

Prior to January 1, 2010, the Workers' Compensation Law required the Workers' Compensation Board to assess insurers on the total "direct premiums" they wrote in the preceding calendar year, whereas the insurers were collecting the assessments from their insureds on the basis of "standard premium," which took into account high deductible policies. As high deductible policies increased in the marketplace, a discrepancy developed between the assessment an insurer collected, and the assessment the insured was required to remit to the Workers' Compensation Board.

Part QQ of Chapter 56 of the Laws of 2009 ("Part QQ") amended Workers' Compensation Law sections 15(8)(h)(4) and 151(2)(b) to change the basis upon which the WCB collects the portion of the allocation from each insurer from "direct premiums" to "standard premium" in order to ensure that insurers are not overcharged or under-charged for the assessment, and to ensure that insureds with high deductible policies are charged the appropriate assessment. Effective January 1, 2010, therefore, each insurer pays a percentage of the allocation based on the total standard premium it wrote during the preceding calendar year. Part QQ requires the Superintendent of Insurance to define "standard premium," for the purposes of setting the assessments, and to set rules, in consultation with the WCB, and New York Compensation Rating Board, for collecting the assessment from insureds.

This regulation was previously promulgated on an emergency basis on December 29, 2009, March 25, 2010, June 24, 2010, September 20, 2010,

December 18, 2010, March 18, 2011, and June 13, 2011. The proposal was sent to the Governor's Office of Regulatory Reform on January 14, 2010 and the Department is awaiting approval to publish the regulation, however because the effective date of the relevant provision of the law is January 1, 2010, and the need that the assessments be calculated and collected in a timely manner, it is essential that this regulation, which establishes procedures that implement provisions of the law, be continued on an emergency basis.

For the reasons cited above, this regulation is being promulgated on an emergency basis for the benefit of the general welfare.

Subject: Workers' Compensation Insurance.

Purpose: This regulation is necessary to standardize the basis upon which the workers' compensation assessments are calculated.

Text of emergency rule: A new subpart 151-6 entitled Workers' Compensation Insurance Assessments is added to read as follows:

Section 151-6.0 Preamble

(a) Workers' Compensation Law sections 15(8)(h)(4), 25-A(3), and 151(2)(b) require the workers compensation board to assess insurers, and the state insurance fund for the special disability fund, the fund for reopened cases, and the operations of the Board, respectively. First, the assessments are allocated to insurers, self-insurers, group self-insurers, and SIF based upon the total compensation payments made by all such entities. In the case of an insurer, once the assessment amount is determined, each pays the percentage of the allocation based on the total premiums it wrote during the preceding calendar year.

(b) Prior to January 1, 2010, each insurer paid a percentage of the allocation based on the total direct written premiums it wrote in the preceding calendar year. However, Part QQ of Chapter 56 of the Laws of 2009 ("Part QQ") amended Workers' Compensation Law sections 15(8)(h)(4), and 151(2)(b) to change the basis upon which the board collects the portion of the allocation from each insurer. Thus, effective January 1, 2010, each insurer pays a percentage of the allocation based on the total standard premium it wrote during the preceding calendar year. Part QQ requires the superintendent of insurance (the "superintendent") to define "standard premium," for the purposes of the assessments, and to set rules, in consultation with the board, and NYCIRB for collecting the assessment from insureds.

Section 151-6.1 Definitions

As used in this Part:

- (a) Board means the New York workers' compensation board.
- (b) Insurer means an insurer authorized to write workers' compensation insurance in this state, except for the SIF.
- (c) NYCIRB means the New York workers compensation rating board.
- (d) SIF means the state insurance fund.
- (e) Standard Premium means
 - (i) the premium determined on the basis of the insurer's approved rates; as modified by:
 - (a) any experience modification or merit rating factor;
 - (b) any applicable territory differential premium;
 - (c) the minimum premium;
 - (d) any Construction Classification Premium Adjustment Program credits;
 - (e) any credit from return to work and / or drug and alcohol prevention programs;
 - (f) any surcharge or credit from a workplace safety program;
 - (g) any credit from independently-filed insurer specialty programs (for example, alternative dispute resolution, drug-free workplace, managed care or preferred provider organization programs);
 - (h) any charge for the waiver of subrogation;
 - (i) any charge for foreign voluntary coverage; and
 - (j) the additional charge for terrorism, and the charge for natural disasters and catastrophic industrial accidents.
 - (ii) For purposes of determining standard premium, the insurer's expense constant, including the expense constant in the minimum premium, the insurer's premium discount, and premium credits for participation in any deductible program shall be excluded from the premium base.
 - (iii) The insurer shall use the definition of standard premium set forth in this Part to report standard premium to the Board.

Section 151-6.2 Collection of assessments

Any assessments required by Workers' Compensation Law sections 15(8)(h)(4), 25-A(3) and 151(2)(b) that are collected by an insurer or SIF from policyholders shall be collected through a surcharge based on standard premium in a percentage to be determined by the superintendent in consultation with NYCIRB and the Board.

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 December 7, 2011.

Text of rule and any required statements and analyses may be obtained from: David Neustadt, New York State Insurance Department, 25 Beaver Street, New York, NY 10004, (212) 480-5265, email: dneustad@ins.state.ny.us

Regulatory Impact Statement

1. Statutory authority: The authority of the Superintendent of Insurance for the promulgation of Part 151-6 of Title 11 of the Official Compilation of Codes, Rules and Regulations of the State of New York (Fifth Amendment to Regulation No. 119) derives from Sections 201 and 301 of the Insurance Law, and Sections 15, 25-A, and 151 of the Workers' Compensation Law.

Sections 201 and 301 of the Insurance Law authorize the Superintendent to effectuate any power accorded to him by the Insurance Law, and to prescribe regulations interpreting the Insurance Law.

Sections 15, 25-A, and 151 of the Workers' Compensation Law, as amended by Part QQ of Chapter 56 of the Laws of 2009 require the Superintendent to define the "standard premium" upon which assessments are made for the Special Disability Fund, the Fund for Reopened Cases, and the operations of the Workers' Compensation Board ("WCB"). Section 15 of the Workers' Compensation Law further requires workers' compensation insurers to collect the assessments from their policyholders through a surcharge based on premiums in accordance with the rules set forth by the Superintendent, in consultation with the New York Workers' Compensation Insurance Rating Board ("NYCIRB"), and the chair of the WCB.

2. Legislative objectives: (a) Workers' Compensation Law sections 15(8)(h)(4), 25-A(3), and 151(2)(b) require the WCB to assess insurers writing workers' compensation insurance and the State Insurance Fund, for the Special Disability Fund, the Fund for Reopened Cases, and the operations of the WCB, respectively. The assessments are allocated to insurers, self-insurers, group self-insurers, and the State Insurance Fund based upon the total compensation payments made by all such entities. In the case of an insurer, once the assessment amount is determined, the insurer pays the percentage of the allocation based on the total premiums it wrote during the preceding calendar year.

Prior to January 1, 2010, the Workers' Compensation Law required the WCB to assess insurers based on the total "direct premiums" they wrote in the preceding calendar year, whereas the insurers collected assessments from their insureds based on the "standard premium," which took into account high deductible policies. As high deductible policies increased in the marketplace, a discrepancy developed between the assessment an insurer collected and the assessment the insurer was required to remit to the WCB.

Therefore, Part QQ of Chapter 56 of the Laws of 2009 ("Part QQ") amended Workers' Compensation Law sections 15(8)(h)(4) and 151(2)(b) to change the basis upon which the Board collects the portion of the allocation from each insurer from "direct premiums" to "standard premium" to ensure that insurers are not overcharged or under-charged for the assessment, and to make certain that insureds with high deductible policies are charged the appropriate assessment. Thus, effective January 1, 2010, each insurer pays a percentage of the allocation based on the total standard premium it wrote during the preceding calendar year. Part QQ requires the Superintendent to define "standard premium," for the purposes of the assessments, and to set rules, in consultation with the WCB and NYCIRB, for collecting assessments from insureds.

3. Needs and benefits: This amendment is necessary, and mandated by the Workers' Compensation Law, to standardize the basis upon which the workers' compensation assessments are calculated to eliminate any discrepancy between the amount that an insurer collects from employers and the amount that an insurer remits to the WCB.

The discrepancy in the assessment calculation and remittance became evident as a result of the proliferation of large deductible policies. In many instances, the "direct premium" paid on a large deductible policy is less than the "standard premium" would be for that policy. Insurers that offered high-deductible policies collected assessments based on the "standard premium," but the Workers' Compensation Law required the WCB to use "direct premiums" to bill insurers. Thus, in some instances, workers' compensation insurers collected from employers more money than they remitted to the WCB.

4. Costs: This amendment standardizes the basis upon which the workers' compensation assessments are calculated to ensure that there is no discrepancy between the amount that an insurer collects from employers, and the amount that an insurer remits to the WCB. Although the amendment itself does not impose new costs, the impact of changing the basis for workers' compensation assessments may increase costs for some insurers, but reduce costs for others. Taken together, the amendment aims to level the playing field for insurers that offer large deductible policies and those that do not.

5. Local government mandates: The amendment does not impose any program, service, duty or responsibility upon a city, town or village, or school or fire district.

6. Paperwork: This amendment requires no new paperwork. Insurers and the State Insurance Fund already collect and remit assessments to the WCB. This regulation only standardizes the basis upon which the assessments are calculated, as required by the Workers' Compensation Law.

7. Duplication: The amendment will not duplicate any existing state or federal rule.

8. Alternatives: No alternatives were considered, because Part QQ requires the Superintendent to define "standard premium" for the purpose of the assessments, and to set rules, in consultation with the WCB and NYCIRB, for collecting the assessment from insureds. Based on discussions with NYCIRB and the WCB, the Superintendent determined that the term "standard premium" should conform to the definition currently used by insurers, and should ensure that the definition accounts for high deductible policies.

NYCIRB has been collecting premium data on a "standard" basis since its inception nearly 100 years ago. The "standard premium" is the premium without regard to credits, deviations, or deductibles. As new credits and types of policies (such as large deductible policies) develop, NYCIRB adjusts the definition to account for the changes. The Insurance Department is merely adopting NYCIRB's current definition.

9. Federal standards: There are no applicable federal standards.

10. Compliance schedule: The effective date of the relevant provision of the law is January 1, 2010. The assessments must be calculated and collected as of January 1, 2010.

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.

This amendment applies to all workers' compensation insurers authorized to do business in New York State, as well as to the State Insurance Fund ("SIF"). It standardizes the basis upon which the workers' compensation assessments are calculated to ensure that there is no discrepancy between the amount that an insurer collects from employers, and the amount that an insurer remits to the Workers' Compensation Board.

The basis for this finding is that this rule is directed at workers' compensation insurers authorized to do business in New York State, none of which falls within the definition of "small business" pursuant to section 102(8) of the State Administrative Procedure Act. The Insurance Department has monitored Annual Statements and Reports on Examination of authorized workers' compensation insurers subject to this rule, and believes that none of the insurers falls within the definition of "small business," because there are none that are both independently owned and have fewer than one hundred employees. Nor does SIF come within the definition of "small business" pursuant to section 102(8) of the State Administrative Procedure Act, because SIF is neither independently owned nor operated, and does not employ one hundred or fewer individuals.

2. Local governments:

The amendment does not impose any impacts, including any adverse impacts, or reporting, recordkeeping, or other compliance requirements on any local governments. This amendment does not affect self-insured local governments, because it applies only to insurers.

Rural Area Flexibility Analysis

1. Types and estimated numbers of rural areas: This amendment applies to all workers' compensation insurers authorized to do business in New York State, as well as the State Insurance Fund ("SIF"). These entities do business throughout New York State, including rural areas as defined in section 102(10) of the State Administrative Procedure Act ("SAPA").

2. Reporting, recordkeeping and other compliance requirements, and professional services: This regulation is not expected to impose any reporting, recordkeeping or other compliance requirements on public or private entities in rural areas. Insurers and SIF already collect and remit assessments to the Workers' Compensation Board ("WCB"). This amendment simply standardizes the basis upon which the assessments are calculated.

3. Costs: This amendment standardizes the basis upon which the workers' compensation assessments are calculated to ensure that there is no discrepancy between the amount that an insurer collects from employers, and the amount that an insurer remits to the WCB. Although the amendment itself does not impose new costs, the impact of changing the basis for workers' compensation assessments may increase costs for some insurers, but reduce costs for others. Taken together, the amendment aims to level the playing field for insurers that offer large deductible policies and those that do not.

4. Minimizing adverse impact: The amendment does not impose any impact unique to rural areas.

5. Rural area participation: This amendment is required by statute. The entities covered by this amendment - workers' compensation insurers authorized to do business in New York State and the State Insurance Fund - do business in every county in this state, including rural areas as defined in section 102(10) of SAPA. This amendment standardizes the basis upon which the workers' compensation assessments are calculated.

Job Impact Statement

This rule will not adversely impact job or employment opportunities in New York. The rule merely standardizes the basis upon which workers' compensation assessments are calculated to ensure that there is no discrepancy between the amount that an insurer collects from employers, and the amount that an insurer remits to the Workers' Compensation Board. An insurer's existing personnel should be able to perform this task. There should be no region in New York that would experience an adverse impact on jobs and employment opportunities. This rule should not have a measurable impact on self-employment opportunities.

Public Service Commission

PROPOSED RULE MAKING NO HEARING(S) SCHEDULED

Approval of a Financing

I.D. No. PSC-39-11-00016-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 a petition from DMP New York, Inc. and Laser Northeast Gathering Company LLC requesting approval of a financing in the amount of a \$290 million credit agreement.

Statutory authority: Public Service Law, section 69

Subject: Approval of a financing.

Purpose: Consideration of approval of a financing.

Substance of proposed rule: The Public Service Commission is considering a petition from DMP New York, Inc. and Laser Northeast Gathering Company LLC requesting approval of a financing in the amount of a \$290 million credit agreement. The debt would be secured by recourse to gas transportation facilities located in New York. The Commission may adopt, reject or modify, in whole or in part, the relief proposed.

Text of proposed rule and any required statements and analyses may be obtained by filing a Document Request Form (F-96) located on our website <http://www.dps.state.ny.us/f96dir.htm>. For questions, contact: Leann Ayer, Public Service Commission, 3 Empire State Plaza, Albany, New York 12223-1350, (518) 486-2655, email: leann_ayer@dps.state.ny.us

Data, views or arguments may be submitted to: Jaclyn A. Brillling, Secretary, Public Service Commission, 3 Empire State Plaza, Albany, New York 12223-1350, (518) 474-6530, email: secretary@dps.state.ny.us

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.

(11-G-0413SP1)

PROPOSED RULE MAKING NO HEARING(S) SCHEDULED

Exclusion of Reliability Reporting Statistics from 2010 Reliability Performance Mechanism (RPM)

I.D. No. PSC-39-11-00017-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 Orange and Rockland Utilities, Inc. (ORU) Petition for Rehearing of Commission's June 23, 2011 Order denying exclusion relating to ORU's 2010 Reliability Performance Mechanism duration target.

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

Subject: Exclusion of reliability reporting statistics from 2010 Reliability Performance Mechanism (RPM).

Purpose: To consider petition for rehearing of denial of exclusion of reliability reporting statistics from 2010 RPM.

Substance of proposed rule: By Petition dated July 22, 2011 Orange and Rockland Utilities, Inc. (ORU) seeks rehearing of the Public Service Commission's (Commission) June 23, 2011 Order denying exclusion of statistics relating to a July 19, 2010 storm from ORU's 2010 Reliability Performance Mechanism duration target. Denial of the exclusion subjects ORU to a 20 basis point negative revenue adjustment. The Commission is considering, whether to approve, deny or modify in whole or in part, ORU's Petition.

Text of proposed rule and any required statements and analyses may be obtained by filing a Document Request Form (F-96) located on our website <http://www.dps.state.ny.us/f96dir.htm>. For questions, contact: Leann Ayer, Public Service Commission, 3 Empire State Plaza, Albany, New York 12223-1350, (518) 486-2655, email: leann_ayer@dps.state.ny.us

Data, views or arguments may be submitted to: Jaelyn A. Brillling, Secretary, Public Service Commission, 3 Empire State Plaza, Albany, New York 12223-1350, (518) 474-6530, email: Secretary@dps.state.ny.us

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.

(07-E-0949SP7)

Workers' Compensation Board

EMERGENCY RULE MAKING

Pharmacy and Durable Medical Equipment Fee Schedules and Requirements for Designated Pharmacies

I.D. No. WCB-39-11-00010-E

Filing No. 811

Filing Date: 2011-09-09

Effective Date: 2011-09-09

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

Action taken: Addition of Parts 440 and 442 to Title 12 NYCRR.

Statutory authority: Workers' Compensation Law, sections 117, 13 and 13-o

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

Specific reasons underlying the finding of necessity: This rule provides pharmacy and durable medical equipment fee schedules, the process for payment of pharmacy bills, and rules for the use of a designated pharmacy or pharmacies. Many times claimants must pay for prescription drugs and medicines themselves. It is unduly burdensome for claimants to pay out-of-pocket for prescription medications as it reduces the amount of benefits available to them to pay for necessities such as food and shelter. Claimants also have to pay out-of-pocket many times for durable medical equipment. Adoption of this rule on an emergency basis, thereby setting pharmacy and durable medical equipment fee schedules will help to alleviate this burden to claimants, effectively maximizing the benefits available to them. Benefits will be maximized as the claimant will only have to pay the fee schedule amount and there reimbursement from the carrier will not be delayed. Further, by setting these fee schedules, pharmacies and other suppliers of durable medical equipment will be more inclined to dispense the prescription drugs or equipment without requiring claimants to pay up front, rather they will bill the carrier. Adoption of this rule further advances pharmacies directly billing by setting forth the requirements for the carrier to designate a pharmacy or network of pharmacies. Once a carrier makes such a designation, when a claimant uses a designated pharmacy he cannot be asked to pay out-of-pocket for causally related prescription medicines. This rule sets forth the payment process for pharmacy bills which along with the set price should eliminate disputes over payment and provide for faster payment to pharmacies. Finally, this rule allows claimants to fill prescriptions by the internet or mail order thus aiding claimants with mobility problems and reducing transportation costs necessary to drive to a pharmacy to fill prescriptions. Accordingly, emergency adoption of this rule is necessary.

Subject: Pharmacy and durable medical equipment fee schedules and requirements for designated pharmacies.

Purpose: To adopt pharmacy and durable medical equipment fee schedules, payment process and requirements for use of designated pharmacies.

Substance of emergency rule: Chapter 6 of the Laws of 2007 added Section 13-o to the Workers' Compensation Law ("WCL") mandating the Chair to adopt a pharmaceutical fee schedule. WCL Section 13(a) mandates that the Chair shall establish a schedule for charges and fees for medical care and treatment. Part of the treatment listed under Section 13(a) includes medical supplies and devices that are classified as durable medical equipment. The proposed rule adopts a pharmaceutical fee schedule and durable medical equipment fee schedule to comply with the mandates. This rule adds a new Part 440 which sets forth the pharmacy fee schedule and procedures and rules for utilization of the pharmacy fee schedule and a new Part 442 which sets forth the durable medical equipment fee schedule.

Section 440.1 sets forth that the pharmacy fee schedule is applicable to prescription drugs or medicines dispensed on or after the most recent effective date of § 440.5 and the reimbursement for drugs dispensed before that is the fee schedule in place on the date dispensed.

Section 440.2 provides the definitions for average wholesale price, brand name drugs, controlled substances, generic drugs, independent pharmacy, pharmacy chain, remote pharmacy, rural area and third party payor.

Section 440.3 provides that a carrier or self-insured employer may designate a pharmacy or pharmacy network which an injured worker must use to fill prescriptions for work related injuries. This section sets forth the requirements applicable to pharmacies that are designated as part of a pharmacy network at which an injured worker must fill prescriptions. This section also sets forth the procedures applicable in circumstances under which an injured worker is not required to use a designated pharmacy or pharmacy network.

Section 440.4 sets forth the requirements for notification to the injured worker that the carrier or self-insured employer has designated a pharmacy or pharmacy network that the injured worker must use to fill prescriptions. This section provides the information that must be provided in the notice to the injured worker including time frames for notice and method of delivery as well as notifications of changes in a pharmacy network.

Section 440.5 sets forth the fee schedule for prescription drugs. The fee schedule in uncontroverted cases is average wholesale price minus twelve percent for brand name drugs and average wholesale price minus twenty percent for generic drugs plus a dispensing fee of five dollars for generic drugs and four dollars for brand name drugs, and in controverted cases is twenty-five percent above the fee schedule for uncontroverted claims plus a dispensing fee of seven dollars and fifty cents for generic drugs and six dollars for brand-name drugs. This section also addresses the fee when a drug is repackaged.

Section 440.6 provides that generic drugs shall be prescribed except as otherwise permitted by law.

Section 440.7 sets forth a transition period for injured workers to transfer prescriptions to a designated pharmacy or pharmacy network. Prescriptions for controlled substances must be transferred when all refills for the prescription are exhausted or after ninety days following notification of a designated pharmacy. Non-controlled substances must be transferred to a designated pharmacy when all refills are exhausted or after 60 days following notification.

Section 440.8 sets forth the procedure for payment of prescription bills or reimbursement. A carrier or self-insured employer is required to pay any undisputed bill or portion of a bill and notify the injured worker by certified mail within 45 days of receipt of the bill of the reasons why the bill or portion of the bill is not being paid, or request documentation to determine the self-insured employer's or carrier's liability for the bill. If objection to a bill or portion of a bill is not received within 45 days, then the self-insured employer or carrier is deemed to have waived any objection to payment of the bill and must pay the bill. This section also provides that a pharmacy shall not charge an injured worker or third party more than the pharmacy fee schedule when the injured worker pays for prescriptions out-of-pocket, and the worker or third party shall be reimbursed at that rate.

Section 440.9 provides that if an injured worker's primary language is other than English, that notices required under this part must be in the injured worker's primary language.

Section 440.10 provides penalties for failing to comply with this Part and that the Chair will enforce the rule by exercising his authority pursuant to Workers' Compensation Law § 111 to request documents.

Part 442 sets forth the fee schedule for durable medical equipment.

Section 442.1 sets for that the fee schedule is applicable to durable medical goods and medical and surgical supplies dispensed on or after July 11, 2007.

Section 442.2 sets forth the fee schedule for durable medical equipment as indexed to the New York State Medicaid fee schedule, except the payment for bone growth stimulators shall be made in one payment. This section also provides for the rate of reimbursement when Medicaid has not established a fee payable for a specific item and for orthopedic footwear. This section also provides for adjustments to the fee schedule by the Chair as deemed appropriate in circumstances where the reimbursement amount is grossly inadequate to meet a pharmacies or providers costs and clarifies that hearing aids are not durable medical equipment for purposes of this rule.

Appendix A provides the form for notifying injured workers that the claim has been contested and that the carrier is not required to reimburse for medications while the claim is being contested.

Appendix B provides the form for notification of injured workers that the self-insured employer or carrier has designated a pharmacy that must be used to fill prescriptions.

This notice is intended to serve only as an emergency adoption, to be valid for 90 days or less. This rule expires December 7, 2011.

Text of rule and any required statements and analyses may be obtained from: Heather MacMaster, Esq., New York State Workers' Compensation Board, 20 Park Street, Office of General Counsel, Albany, New York 12207, (518) 486-9564, email: regulations@wcb.state.ny.us

Summary of Regulatory Impact Statement

Section 1 provides the statutory authority for the Chair to adopt a pharmacy fee schedule pursuant to Workers' Compensation Law Section (WCL) 13-o as added to the WCL by Chapter 6 of the Laws of 2007 which requires the Chair to adopt a pharmaceutical fee schedule. Chapter 6 also amended WCL Section 13(a) to mandate that the Chair establish a schedule for charges and fees for medical care and treatment. Such medical care and treatment includes supplies and devices that are classified as durable medical equipment (hereinafter referred to as DME).

Section 2 sets forth the legislative objectives of the proposed regulations which provide the fee schedules to govern the cost of prescription medicines and DME. This section provides a summary of the overall purpose of the proposed regulation to reduce costs of workers' compensation and the scope of the regulation with regard to process and guidance to implement the rule.

Section 3 explains the needs and benefits of the proposed regulation. This section provides the explanation of the requirement of the Chair to adopt a pharmacy fee schedule as mandated by Chapter 6 of the Laws of 2007. The legislation authorizes carriers and self-insured employers to voluntarily decide to designate a pharmacy or pharmacy network and require claimants to obtain their prescription medicines from the designated pharmacy or network. This section explains how prescriptions were filled prior to the enactment of the legislation and the mechanisms by which prescriptions were reimbursed by carriers and self-insured employers. This section also provides the basis for savings under the proposed regulation. The cost savings realized by using the pharmacy fee schedule will be approximately 12 percent for brand name drugs and 20 percent for generic drugs from the average wholesale price. This section explains the issues with using the Medicaid fee schedule. The substantive requirements are set forth that carriers must follow to notify a claimant of a designated pharmacy or network. This includes the information that must be included in the notification as well as the time frames within which notice must be provided. This section also describes how carriers and self-insured employers will benefit from a set reimbursement fee as provided by the proposed regulation. This section provides a description of the benefits to the Board by explaining how the proposed regulation will reduce the number of hearings previously necessary to determine proper reimbursement of prescription medications by using a set fee schedule.

Section 4 provides an explanation of the costs associated with the proposed regulation. It describes how carriers are liable for the cost of medication if they do not respond to a bill within 45 days as required by statute. This section describes how carriers and self-insured employers which decide to require the use of a designated network will incur costs for sending the required notices, but also describes how the costs can be offset to a certain degree by sending the notices listed in the Appendices to the regulation with other forms. Pharmacies will have costs associated with the proposed regulation due to a lower reimbursement amount, but the costs are offset by the reduction of administrative costs associated with seeking reimbursement from carriers and self-insured employers. Pharmacies will be required to post notice that they are included in a designated network and a listing of carriers that utilize the pharmacy in the network. This section describes how the rule benefits carriers and self-insured employers by allowing them to contract with a pharmacy or network to provide drugs thus allowing them to negotiate for the lowest cost of drugs.

Section 5 describes how the rule will affect local governments. Since a municipality of governmental agency is required to comply with the rules

for prescription drug reimbursement the savings afforded to carriers and self-insured employers will be substantially the same for local governments. If a local government decides to mandate the use of a designated network it will incur some costs from providing the required notice.

Section 6 describes the paperwork requirements that must be met by carriers, employers and pharmacies. Carriers will be required to provide notice to employers of a designated pharmacy or network, and employers in turn will provide such notice to employees so that employees will know to use a designated pharmacy or network for prescription drugs. Pharmacies will be required to post notice that they are part of a designated network and a listing of carriers that utilize the pharmacy within the network. This section also specifies the requirement of a carrier or self-insured employer to respond to a bill within 45 days of receipt. If a response is not given within the time frame, the carrier or self-insured employer is deemed to have waived any objection and must pay the bill. This section sets forth the requirement of carriers to certify to the Board that designated pharmacies within a network meet compliance requirements for inclusion in the network. This section sets forth that employers must post notification of a designated pharmacy or network in the workplace and the procedures for utilizing the designated pharmacy or network. This section also sets forth how the Chair will enforce compliance with the rule by seeking documents pursuant to his authority under WCL § 111 and impose penalties for non-compliance.

Section 7 states that there is no duplication of rules or regulations.

Section 8 describes the alternatives explored by the Board in creating the proposed regulation. This section lists the entities contacted in regard to soliciting comments on the regulation and the entities that were included in the development process. The Board studied fee schedules from other states and the applicability of reimbursement rates to New York State. Alternatives included the Medicaid fee schedule, average wholesale price minus 15% for brand and generic drugs, the Medicare fee schedule and straight average wholesale price.

Section 9 states that there are no applicable Federal Standards to the proposed regulation.

Section 10 provides the compliance schedule for the proposed regulation. It states that compliance is mandatory and that the proposed regulation takes effect upon adoption.

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. As part of the overall rule, these self-insured local governments will be required to file objections to prescription drug bills if they object to any such bills. This process is required by WCL § 13(i)(1) - (2). This rule affects members of self-insured trusts, some of which are small businesses. Typically a self-insured trust utilizes a third party administrator or group administrator to process workers' compensation claims. A third party administrator or group administrator is an entity which must comply with the new rule. These entities will be subject to the new rule in the same manner as any other carrier or employer subject to the rule. Under the rule, objections to a prescription bill must be filed within 45 days of the date of receipt of the bill or the objection is deemed waived and the carrier, third party administrator, or self-insured employer is responsible for payment of the bill. Additionally, affected entities must provide notification to the claimant if they choose to designate a pharmacy network, as well as the procedures necessary to fill prescriptions at the network pharmacy. If a network pharmacy is designated, a certification must be filed with the Board on an annual basis to certify that the all pharmacies in a network comply with the new rule. The new rule will provide savings to small businesses and local governments by reducing the cost of prescription drugs by utilization of a pharmacy fee schedule instead of retail pricing. Litigation costs associated with reimbursement rates for prescription drugs will be substantially reduced or eliminated because the rule sets the price for reimbursement. Additional savings will be realized by utilization of a network pharmacy and a negotiated fee schedule for network prices for prescription drugs.

2. Compliance requirements:

Self-insured municipal employers and self-insured non-municipal employers are required by statute to file objections to prescription drug bills within a forty five day time period if they object to bills; otherwise they will be liable to pay the bills if the objection is not timely filed. If the carrier or self-insured employer decides to require the use of a pharmacy network, notice to the injured worker must be provided outlining that a network pharmacy has been designated and the procedures necessary to fill prescriptions at the network pharmacy. Certification by carriers and self-insured employers must be filed on an annual basis with the Board that all the pharmacies in a network are in compliance with the new rule. Failure to comply with the provisions of the rule will result in requests for information pursuant to the Chair's existing statutory authority and the imposition of penalties.

3. Professional services:

It is believed that no professional services will be needed to comply with this rule.

4. Compliance costs:

This proposal will impose minimal compliance costs on small business or local governments which will be more than offset by the savings afforded by the fee schedule. There are filing and notification requirements that must be met by small business and local governments as well as any other entity that chooses to utilize a pharmacy network. Notices are required to be posted in the workplace informing workers of a designated network pharmacy. Additionally, a certification must be filed with the Board on an annual basis certifying that all pharmacies within a network are in compliance with the rule.

5. Economic and technological feasibility:

There are no additional implementation or technology costs to comply with this rule. The small businesses and local governments are already familiar with average wholesale price and regularly used that information prior to the adoption of the Medicaid fee schedule. Further, some of the reimbursement levels on the Medicaid fee schedule were determined by using the Medicaid discounts off of the average wholesale price. The Red Book is the source for average whole sale prices and it can be obtained for less than \$100.00. Since the Board stores its claim files electronically, it has provided access to case files through its eCase program to parties of interest in workers' compensation claims. Most insurance carriers, self-insured employers and third party administrators have computers and internet access in order to take advantage of the ability to review claim files from their offices.

6. Minimizing adverse impact:

This proposed rule is designed to minimize adverse impacts to all insurance carriers, employers, self-insured employers and claimants. The rule provides a process for reimbursement of prescription drugs as mandated by WCL section 13(i). Further, the notice requirements are to ensure a claimant uses a network pharmacy to maximize savings for the employer as any savings for the carrier can be passed on to the employer. The costs for compliance are minimal and are offset by the savings from the fee schedule. The rule sets the fee schedule as average wholesale price (AWP) minus twelve percent for brand name drugs and AWP minus twenty percent for generic drugs. As of July 1, 2008, the reimbursement for brand name drugs on the Medicaid Fee Schedule was reduced from AWP minus fourteen percent to AWP minus sixteen and a quarter percent. Even before the reduction in reimbursement some pharmacies, especially small ones, were refusing to fill brand name prescriptions because the reimbursement did not cover the cost to the pharmacy to purchase the medication. In addition the Medicaid fee schedule did not cover all drugs, include a number that are commonly prescribed for workers' compensation claims. This presented a problem because WCL § 13-o provides that only drugs on the fee schedule can be reimbursed unless approved by the Chair. The fee schedule adopted by this regulation eliminates this problem. Finally, some pharmacy benefit managers were no longer doing business in New York because the reimbursement level was so low they could not cover costs. Pharmacy benefit managers help to create networks, assist claimants in obtaining first fills without out of pocket costs and provide utilization review. Amending the fee schedule will ensure pharmacy benefit managers can stay in New York and help to ensure access for claimants without out of pocket cost.

7. Small business and local government participation:

The Assembly and Senate as well as the Business Council of New York State and the AFL-CIO provided input on the proposed rule.

Rural Area Flexibility Analysis

1. Types and estimated numbers of rural areas:

This rule applies to all carriers, employers, self-insured employers, third party administrators and pharmacies in rural areas. This includes all municipalities in rural areas.

2. Reporting, recordkeeping and other compliance requirements:

Regulated parties in all areas of the state, including rural areas, will be required to file objections to prescription drug bills within a forty five day time period or will be liable for payment of a bill. If regulated parties fail to comply with the provisions of Part 440 penalties will be imposed and the Chair will request documentation from them to enforce the provision regarding the pharmacy fee schedule. The new requirement is solely to expedite processing of prescription drug bills or durable medical bills under the existing obligation under Section 13 of the WCL. Notice to the injured worker must be provided outlining that a network pharmacy has been designated and the procedures necessary to fill prescriptions at the network pharmacy. Carriers and self-insured employers must file a certification on an annual basis with the Board that all the pharmacies in a network are in compliance with the new rule.

3. Costs:

This proposal will impose minimal compliance costs on carriers and employers across the State, including rural areas, which will be more than

offset by the savings afforded by the fee schedule. There are filing and notification requirements that must be met by all entities subject to this rule. Notices are required to be posted and distributed in the workplace informing workers of a designated network pharmacy and objections to prescription drug bills must be filed within 45 days or the objection to the bill is deemed waived and must be paid without regard to liability for the bill. Additionally, a certification must be filed with the Board on an annual basis certifying that all pharmacies within a network are in compliance with the rule. The rule provides a reimbursement standard for an existing administrative process.

4. Minimizing adverse impact:

This proposed rule is designed to minimize adverse impact for small businesses and local government from imposition of new fee schedules and payment procedures. This rule provides a benefit to small businesses and local governments by providing a uniform pricing standard, thereby providing cost savings reducing disputes involving the proper amount of reimbursement or payment for prescription drugs or durable medical equipment. The rule mitigates the negative impact from the reduction in the Medicaid fee schedule effective July 1, 2008, by setting the fee schedule at Average Wholesale Price (AWP) minus twelve percent for brand name prescription drugs and AWP minus twenty percent for generic prescription drugs. In addition, the Medicaid fee schedule did not cover many drugs that are commonly prescribed for workers' compensation claimants. This fee schedule covers all drugs and addresses the potential issue of repackagers who might try to increase reimbursements.

5. Rural area participation:

Comments were received from the Assembly and the Senate, as well as the Business Council of New York State and the AFL-CIO regarding the impact on rural areas.

Job Impact Statement

The proposed amendment will not have an adverse impact on jobs. This amendment is intended to provide a standard for reimbursement of pharmacy and durable medical equipment bills.

PROPOSED RULE MAKING NO HEARING(S) SCHEDULED

Recording of Hearings

I.D. No. WCB-39-11-00011-P

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

Proposed Action: Amendment of sections 300.7(c), 300.9, 300.13(d), 300.18(f), 325-4.6(c), 326-1.5(b), 326-2.7, 330.4(b), 340.4(b) and 345.4 of Title 12 NYCRR.

Statutory authority: Workers' Compensation Law, sections 117(1), 25(3)(c), 142(5) and 118

Subject: Recording of hearings.

Purpose: To provide flexibility in determining the appropriate means for recording of hearings.

Text of proposed rule: Subdivision (c) of Section 300.7 of Title 12 NYCRR is amended to read as follows:

(c) Individual [b]Board member hearings. When a [case] *claim* is before a panel of the board and the panel deems new or additional evidence is necessary for a determination thereof, the panel may hear and receive such evidence. The panel may, however, designate one of its members to do so, in which event the [stenographic transcript] *record* of such hearing in a *readable, viewable or audible format* shall be made part of the [record] *case file maintained by the Board*, and the determination of the panel shall be based upon the entire [record] *case file maintained by the Board*.

Section 300.9 of Title 12 NYCRR is repealed and a new section 300.9 is adopted to read as follows:

(a) *All hearings and proceedings shall be conducted in an orderly manner in order to ascertain the substantial rights of the parties. All parties and participants in any hearing or proceeding shall maintain a civil, respectful and professional demeanor when appearing before the Board or when conducting depositions relative to a claim and comply with the Standards of Civility adopted by the Board. Parties and participants who are disrespectful or disruptive in any hearing or proceeding, so as to interfere with the orderly conduct of the hearing or proceeding, will be removed so the hearing or proceeding may continue in an orderly manner.*

(b) *All witnesses shall testify under oath (or by affirmation). The Board and Workers' Compensation Law Judges may examine and cross-examine all parties and witnesses at any hearing or proceeding. The Board shall not be bound by common law or statutory rules of evidence or by technical or formal rules of procedure.*

(c) *The Board shall keep a verbatim record of all hearings and*

proceedings. No other record shall be allowed. The Board will maintain in its case file a copy of the verbatim record it prepared in a readable, viewable or audible format. No other record of a hearing or proceeding in a readable, viewable or audible format shall be allowed.

Subsection (d) of Section 300.13 of 12 NYCRR is amended to read as follows:

(d) The [b]Board [file] shall [contain a copy of all stenographic minutes of hearings] *have the verbatim records of all hearings and proceedings placed in the case file it maintains in a readable, viewable or audible format* where the issue or issues raised in the application for review were covered, and the case file shall only be considered by a [b]Board [p]Panel after the [minutes] *verbatim records* covering the disputed issues are inserted in the case file. [The review bureau shall promptly make arrangements for the transcription of all minutes not heretofore inserted in the file, as set forth above, and such minutes shall be inserted in the file.]

Subdivisions (b), (c), (e), (f) and (g) of Section 300.18 of 12 NYCRR are amended to read as follows:

(b) In the event that the appellant wishes additional [minutes] *verbatim records of hearings or proceedings that are not in a viewable or audible format* to be transcribed which heretofore have not been *transcribed and made part of the case file maintained by the Board* [inserted in the file], the board shall make arrangements for the immediate transcription of same, and [a typewritten copy of the minutes] *such transcript* shall be inserted in the case file. [and a photo or typewritten] *A copy of such transcript* shall be furnished to the appellant upon the payment of the fees as required by section 122 of the Workers' Compensation Law.

(c) The designation of portions of the case file made on behalf of the respondent [b]Board shall be made by its general counsel's office with the advice of the Attorney General. [Each respondent, except for the Workers' Compensation Board, shall pay the fee as required by section 122 of the Workers' Compensation Law for the transcribing of any minutes not theretofore transcribed and designated by such respondents, and a typewritten copy of said minutes shall be inserted in the file and a typewritten copy or photocopy furnished to the respondent requesting such minutes.] *In the event that a respondent wishes additional verbatim records of hearing or proceedings that are not in a viewable or audible format to be transcribed which heretofore have not been transcribed and made part of the case file maintained by the Board, the Board shall make arrangements for the immediate transcription of the same, and such transcript shall be inserted in the case file. A copy of such transcript shall be furnished to the respondent upon the payment of the fees as required by section 122 of the Workers' Compensation Law, except that the Board is not required to pay such fee.*

(e) The [b]Board, upon request of any party, shall render a written decision in the event that there is an unresolved dispute as to the record list or the contents of the case file *maintained by the Board*.

(f) Within 30 days after certification of the record list, the [b]Board shall, at the prepaid expense of the respective parties other than the respondent Workers' Compensation Board, make arrangement for and provide each party with copies of the [items] *documents, exclusive of [stenographic minutes] transcripts of hearings or proceedings recorded and transcribed by a Board employed verbatim reporter, requested by each respective party. In the case of [stenographic minutes] transcripts prepared by a Board employed verbatim reporter, the respective parties, except for the Workers' Compensation Board, shall pay for copies of requested minutes directly to the [hearing]verbatim reporter as required by section 122 of the Workers' Compensation Law, and the [b]Board, in the interest of expediency, may in its discretion provide photocopies of the same. Any interested party, as authorized by section 110-a of the Workers' Compensation Law, upon prepayment of the appropriate fee, may request a [photo]copy of the entire [b]Board case file to be furnished to him/her.*

(g) In the event an additional appeal is filed from a denial of an application to reconsider or reopen a case pending on appeal, said additional appeal shall be processed concurrently with the prior appeal and in accordance with the procedures and limitations set forth in this section. The record on appeal in such instances shall consist of the record list previously certified in accordance with the provisions of section 800.18(d) of the rules of the Appellate Division, Third Department (22 NYCRR 800.18(d)), and, in addition thereto, the parties may designate any additional [papers] *documents* in the [b]Board case file that they wish to include in the record list relative to the second appeal being filed.

Subdivision (c) of Section 325-4.6 of 12 NYCRR is amended to read as follows:

(c) At the hearing on such charge or charges, the accused hospital or health maintenance organization shall be entitled to have counsel present and to cross-examine witnesses. A [stenographic] *verbatim* record of the proceedings shall be made, and witnesses shall testify under oath.

Subdivision (b) of section 326-1.5 of 12 NYCRR is amended to read as follows:

(b) At the hearing on such charge or charges, the accused physician,

medical bureau or laboratory shall be entitled to be represented by counsel and to cross-examine witnesses. A [stenographic] *verbatim* record of the proceeding shall be made, and witnesses shall testify under oath.

Section 326-2.7 of 12 NYCRR is amended to read as follows:

If the Medical Appeals Unit shall permit oral argument or the taking of additional testimony, any one or more than one of the members of the Medical Appeals Unit may conduct the hearing. A [stenographic] *verbatim* record of such oral argument, testimony and evidence shall be made and filed with and become part of the record of the case on appeal or review, and thereupon the Medical Appeals Unit shall make its decision and recommendation thereon.

Subdivision (b) of section 330.4 of 12 NYCRR is amended to read as follows:

(b) On the hearing of such charge or charges, the accused psychologist shall be entitled to be represented by counsel and to cross-examine witnesses. Witnesses shall be placed under oath. A [stenographic] *verbatim* record of the proceedings shall be made.

Subdivision (b) of section 340.4 of 12 NYCRR is amended to read as follows:

(b) On the hearing of such charge or charges, the accused podiatrist shall be entitled to be represented by counsel and to cross-examine witnesses. Witnesses shall be placed under oath. A [stenographic] *verbatim* record of the proceedings shall be made.

Subdivision (b) of section 345.4 of 12 NYCRR is amended to read as follows:

(b) On the hearing of such charge or charges, the accused chiropractor shall be entitled to be represented by counsel and to cross-examine witnesses. Witnesses shall be placed under oath. A [stenographic] *verbatim* record of the proceedings shall be made.

Text of proposed rule and any required statements and analyses may be obtained from: Heather MacMaster, Workers' Compensation Board, Office of General Counsel, 20 Park Street, Albany, NY 12207, (518) 486-9564, email: regulations@wcb.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.

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

Regulatory Impact Statement

1. Statutory authority: The Workers' Compensation Board (hereinafter referred to as Board) is authorized to amend 12 NYCRR §§ 300.7(c), 300.9, 300.13(d), 300.18(f), 325-4.6(c), 326-1.5(b), 326-2.7, 330.4(b), 340.4(b) and 345.4(b). Workers' Compensation Law (WCL) § 117(1) authorizes the Board to adopt reasonable rules consistent with and supplemental to the provisions of the WCL and Labor Law. It also authorizes the Chair of the Board (Chair) to make reasonable rules consistent with the provisions of the WCL and Labor Law.

In addition to the general authority to promulgate regulations, the Board is specifically authorized to amend the following regulations: 12 NYCRR § 325-4.6(c) [§ 13-c(3)(h) authorizes the Chair to adopt rules and regulations for the authorization and continued supervision of medical centers, and § 13-c(4)(h) authorizes the Chair to adopt rules and regulations for the authorization and continued supervision of hospitals and health maintenance organizations]; 12 NYCRR §§ 326-1.5(b) and 2.7 [WCL § 13-aa(4) authorizes the medical appeals unit to adopt rules and regulations to govern its own proceedings]; 12 NYCRR § 330.4(b) [WCL § 13-m (2) authorizes the Chair to promulgate rules governing the charges and fees for psychological care, WCL § 13-m (7)(b) authorizes the Board to promulgate rules governing the interest charges due for a psychologist's bill which is due and owing, and WCL § 13-m (9) authorizes the Chair to promulgate rules governing the procedure to be followed by those rendering psychological care]; 12 NYCRR § 340.4(b) [WCL § 13-k (2) authorizes the Chair to promulgate rules governing the charges and fees for podiatry care, WCL § 13-k (6) authorizes the Board to promulgate rules governing the interest charges due for a podiatrist's bill which is due and owing, and WCL § 13-k (8) authorizes the Chair to promulgate rules governing the procedure to be followed by those rendering podiatry care]; and 12 NYCRR § 345.4(b) [WCL § 13-l (2) authorizes the Chair to promulgate rules governing the charges and fees for chiropractic care, WCL § 13-l (6) authorizes the Board to promulgate rules governing the interest charges due for a chiropractor's bill which is due and owing, WCL § 13-l (8) authorizes the Chair to promulgate rules governing the procedure to be followed by those rendering chiropractic care].

2. Legislative objectives: The proposed amendments to 12 NYCRR §§ 300.7(c), 300.9, 300.13(d), 300.18(f), 325-4.6(c), 326-1.5(b), 330.4(b), 340.4(b) and 345.4(b) are in accordance with the legislative purpose of conducting accurate and fair hearings, ensuring that all parties are afforded due process and preserving the integrity of the hearing process. Alternative and additional means of recording hearings, such as

electronic recording devices, will ensure that all parties receive accurate, impartial, timely and fair hearings. In addition, alternative means of recording will assist the Board in ensuring that the hearings are conducted in the utmost professional and ethical manner. This will assist the Board in maintaining the integrity of the hearing process.

3. Needs and benefits: The purposes of the proposed rule are to 1) ensure that future hearings are conducted accurately and expeditiously; 2) ensure that the Board always has reliable means of recording hearings; 3) explore opportunities to use technology to simultaneously record and incorporate the verbatim content of hearings into the Board's electronic files; and 4) enable the Board to better evaluate and monitor the conduct of its hearings and all the parties and participants in that process. The Board would be able to meet its stated objectives if it had the flexibility to determine the appropriate means to record hearings. Presently, 12 NYCRR §§ 300.7(c), 300.9, 325-4.6(c), 326-1.5(b), 326-2.7, 330.4(b), 340.4(b) and 345.4(b) require that all hearings be conducted using stenographic recordings. The Board will become more efficient in conducting hearings and resolving cases if alternative means for recording hearings were permitted.

Currently, the Board utilizes stenographic recordings exclusively in all hearings. Seventy-three percent (73%) of all Board cases require a hearing which in turn requires a verbatim reporter to be present. Of the seventy-three percent (73%) only three and one-half percent (3.5%) require stenographic transcription of the hearing minutes. In other words, nearly seventy percent (70%) of the verbatim reporters' work at hearings is never transcribed. This is an inefficient and expensive way to record hearings. Verbatim reporters spend approximately seventy percent (70%) of their work time transcribing the hearing minutes and performing other job-related duties.

Over the past several years, the Board has had difficulty hiring and retaining qualified verbatim reporters to meet the demand. The shortage of verbatim reporters was so severe that the Department of Civil Service granted the Board the ability to conduct the exam on a decentralized basis. In 2002, verbatim reporters were upgraded and received an increase in salary. Additionally, verbatim reporters are permitted to supplement their state wages by charging parties a per page fee for transcriptions of Board hearings and working for parties on their own time taking depositions of medical witnesses in Board related cases. In spite of all this, verbatim reporters elect to leave the Board for positions at the Office of Court Administration when they have gained the required experience. Due to shortages, the Board has been forced in certain locations to schedule calendars of hearings which are not trials. The purpose of no-trial hearing calendar is that if there is no verbatim reporter available, the Board can more easily cancel the calendar if necessary. The only other alternative is to hold the hearing without a verbatim reporter, but if the decision of the Workers' Compensation Law Judge is appealed, there will be no transcript of the hearing for the Board Panel to review. Currently, conducting a hearing without a means to record it stenographically violates the regulations. Further, such a situation makes it impermissible for the Board Panel to render a decision and will result in delay. Alternative and additional means of recording hearings, such as electronic audio and video devices, would supplement the existing verbatim reporter staff and provide the Board with much needed flexibility in scheduling and conducting hearings. If the Board had the ability to conduct hearings without verbatim reporters being present, there would be no need to cancel hearings or contemplate holding them without verbatim reporters, which necessarily would prevent delays and difficulties in ensuring timely resolution of claims. Further, when cases are cancelled it not only delays the resolution of a case, but it also creates backlogs of cases to be heard. With additional means of recording proceedings, the Board can examine whether proceedings, such as conciliation meetings, should be recorded.

Electronic recording devices will ensure that the hearing record is accurate and complete. Such devices will record each and every word spoken during the course of the hearing, including off-the-record discussions. Electronic recording will ensure that all exhibits have been properly identified and submitted into evidence and all arguments have been recorded, which will benefit the parties, attorneys, representatives and judges, and result in a fair and just hearing.

Electronic recording devices would provide the Board with the opportunity to hear or observe first hand the conduct of the hearings. In the past, the Board has received complaints regarding the proceedings, judges, representatives, attorneys, claimants and witnesses. The Board has encountered difficulties in monitoring and evaluating hearings that utilize a stenographic record. An obvious problem is attempting to gauge the tone and inflection of a hearing participant who has allegedly been disruptive during the hearing. Another problem arises when discussions occur off-the-record that affect the case and the individuals involved have different recollections of what transpired. Unlike a stenographic record, electronic recording devices would afford the Board with the ability to accurately monitor a hearing.

Electronic recording would provide the Board with flexibility in storing and transmitting the hearing record to parties requesting copies. For example, if the Board utilized digital technology to record a hearing, the record could be electronically transmitted to the parties. Such a record could be available almost immediately after the conclusion of the hearing, thereby reducing any delays. Due to the time verbatim reporters spend on calendar, delays in deciding appeals occur because of the time it takes verbatim reporters to transcribe the minutes of the hearing. In cases which are appealed, the Board would have the option to listen or view the electronic recording of the hearing or if necessary request that a transcript of the hearing be prepared from the electronic recording. At the present time, this is not possible because the verbatim reporter's notes of a hearing are only understandable by the verbatim reporters.

4. Costs:

a) There are no projected costs to regulated parties who may be affected by the proposed regulation. However, there may be savings to regulated parties since, depending on the technology used, the cost of the record may be less than the per page fee currently charged by verbatim reporters.

b) It is estimated that the cost of installing electronic recording devices will be \$5,000.00 per unit for each hearing part. At the present time, the Board has not determined the number of electronic recording devices which may be installed or a time frame that the installation will be performed. It is the Board's plan to install alternative means of recording on an as needed basis over time.

c) The Board has based its preliminary estimates on researching products initially through the internet and speaking with vendors.

5. Local government mandates: The proposed regulation does not impose any mandate, duty or responsibility upon any municipality or governmental entity.

6. Paperwork: The proposed regulation does not impose or require any reporting requirements or additional paperwork on regulated parties.

7. Duplication: There is no duplication.

8. Alternatives: The Board considered not making any changes, however, as discussed above the increasing problem in recruiting and maintaining verbatim reporters means that it would neither be prudent nor practical for the Board to continue utilizing stenographic recordings exclusively in all hearings. The other alternative would be to specifically state the new means of recording hearings, however, that would not allow for flexibility and the Board has not decided if there is just one correct or best means of recording hearings.

9. Federal standards: There are no applicable federal standards which address the standards contained in the proposed regulation.

10. Compliance schedule: The proposed regulation does not require compliance by regulated parties. The proposed regulation has a negligible impact on parties appearing before the Board.

Regulatory Flexibility Analysis

1. Effect of rule: Small businesses and local governments whose only involvement with the workers' compensation system is that they are employers and are required to have coverage will not be affected by this rule. Small businesses and local governments are required to maintain workers' compensation coverage, either through an insurance policy or by self-insurance, as either a stand-alone self-insured employer or as a member of a group self-insurance trust. Generally, small businesses cannot afford to meet the requirements to be individually self-insured but rather purchase workers' compensation coverage from the State Insurance Fund or a private insurance carrier authorized to write workers' compensation insurance in New York or join a group self-insured trust. It is the entity providing coverage for the small employer that may be affected by this rulemaking, not the covered employer. Group self-insured trusts and third party administrators hired by private insurance carriers and group self-insured trusts may be small businesses impacted by this regulation. Medical providers authorized by the Chair to treat claimants, some of who may be small businesses, may be affected by this rule. The Chair authorizes over 20,000 medical providers to treat claimants.

The State Insurance Fund and all private insurance carriers are not small businesses, and, therefore, the effect on it is not discussed in this document.

Approximately 2,511 political subdivisions currently participate as municipal employers in self-insured programs for workers' compensation coverage in New York State.

The proposed rule amends §§ 300.7(c), 300.9, 300.13(d), 300.18(f), 325-4.6(c), 326-1.5(b), 326-2.7, 330.4(b), 340.4(b), and 345.4(b) to replace the requirement that stenographic minutes of hearings must be made and kept with a more flexible one that requires the Board to maintain verbatim records of hearings in a readable, viewable, or audible format. The purposes of this change are to 1) ensure that future hearings are conducted accurately and expeditiously; 2) ensure that the Board always has reliable means of recording hearings; 3) to use technology to simultaneously record and incorporate the verbatim content of hearings into the Board's electronic files; and 4) enable the Board to better evaluate and

monitor the conduct of its hearings and all the parties and participants in that process. The rule would affect small businesses and local governments by possibly changing the format in which they receive the record of a hearing.

2. Compliance requirements: The proposed regulation does not require any action whatsoever by small businesses or local governments. The proposed regulation does not impose or require any reporting requirements or additional paperwork on the part of small business or local government.

3. Professional services: Small businesses and local governments will not have to engage any professional services as a result of the proposed regulation.

4. Compliance costs: Small businesses and local governments will not incur any compliance costs as a result of this proposed regulation.

5. Economic and technological feasibility: Small businesses and local governments will not incur any capital costs or annual operating costs or be required to purchase or update technological equipment as a result of the proposed regulation.

6. Minimizing adverse impact: The proposed regulation will have no adverse economic impact on small businesses or local governments. The cost for utilizing alternate means of recording hearings, including installing or updating electronic recording devices, will be borne by the Board.

7. Small business and local government participation: Inasmuch as the proposed regulation does not adversely impact on public or private entities, the Board did not request comment on the proposed regulation. Further, the Board is not eliminating the use of verbatim reporters to record hearings with this proposal. Rather it provides flexibility so the Board can explore all means available to determine and implement the most accurate and cost effective method or methods.

Rural Area Flexibility Analysis

1. Types and estimated numbers of rural areas: The proposed regulation changes provide the Board with flexibility in setting the format of verbatim recordings of hearings. This rule does not impose any requirement or require any action of any individual or entity. However, this rule may result in a change in the format of a transcript of Board hearings for individuals and entities, such as claimants, employers, insurance carriers, and attorneys, who appear before the Board. Individuals and entities, such as claimants, employers, insurance carriers, medical providers, attorneys, and others, are located all across the State including all rural areas of the State.

2. Reporting, recordkeeping and other compliance requirements; and professional services: The proposed regulation does not require any action whatsoever by individuals and entities who appear before the Board in rural areas. The proposed regulation does not impose or require any reporting requirements or additional paperwork and individuals and entities that appear before the Board in rural areas will not have to engage any professional services as a result of the proposed regulation. The only change may be the person/office contacted to receive a record of a hearing and the format in which it is received. The Board would always ensure the format would be one that was common to most entities and will be in full compliance with State Technology Law regarding electronic records.

3. Costs: Individuals and entities located in rural areas who appear before the Board will not incur any capital costs, annual operating costs or any compliance costs as a result of the proposed regulation. The only cost would be for the copy of the record of the hearing, which they already incur. Electronic recordings of hearings may cost less than stenographic records.

4. Minimizing adverse impact: The proposed regulation will have no adverse economic impact on individuals and entities located in rural areas who appear before the Board. The cost for utilizing alternate means for recording hearings, including installation or updating electronic recording devices, will be borne by the Board.

5. Rural area participation: Inasmuch as the proposed regulation does not adversely impact on public or private entities in rural areas, the Board did not request comment from entities in rural areas on the proposed regulation. Further, the Board is not eliminating the use of verbatim reporters to record hearings with this proposal. Rather it provides flexibility so the Board can explore all means available to determine and implement the most accurate and cost effective method or methods.

Job Impact Statement

The proposed rule will not have an adverse impact on existing jobs. Rather than requiring that hearings be recorded by stenographer in §§ 300.7(c), 300.9, 300.13(d), 300.18(f), 325-4.(c), 326-1.5(b), 326-2.7, 330.4(b), 340.4(b), and 345.4(b), the rule allows the Board to maintain the verbatim record in a readable, viewable, or audible format. This change will provide the Board flexibility to use other means of recording hearings, such as audio digital recordings, in addition to using verbatim reporters. The proposed regulation should have little to no affect on the verbatim reporters currently employed by the Board. The Board expects to continue to

use their services to record and transcribe hearings. It is not clear what effect this rule will have on the employment of new verbatim reporters. The implementation of additional means of recording hearings may reduce the need to fill all of the unfilled verbatim reporter positions. As was fully developed at a hearing before the New York State Senate Standing Committee on Labor on October 6, 2009, the Board has had longstanding and intractable difficulties attracting verbatim reporters and retaining verbatim reporters. An important reason why the Board has so many unfilled positions is that verbatim reporters, especially downstate, leave the Board after a few years, four to five, for employment in higher-paying positions with the Office of Court Administration.