

RULE MAKING ACTIVITIES

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

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

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

Banking Department

PROPOSED RULE MAKING NO HEARING(S) SCHEDULED

Licensed Check Cashers

I.D. No. BNK-47-06-00009-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 400.5(a) of Title 3 NYCRR.

Statutory authority: Banking Law, section 371

Subject: Permissible banking institutions with which licensed check cashers may maintain deposit accounts.

Purpose: To permit licensed check cashers to maintain bank accounts with banking institutions or their branches located inside or outside this State.

Text of proposed rule: Section 400.5(a) of the Superintendent's Regulations is hereby amended to read as follows:

§ 400.5 Depositing of checks, etc.

(1) Except as hereinafter stated all checks, drafts and money orders must be deposited in the licensee's bank account in [the banking institution in this State] *a branch or principal office of a bank, savings bank, savings and loan association, trust company, national bank, federal savings bank, or federal savings and loan association or any other duly chartered depository institution that is insured by the Federal Deposit Insurance Corporation, regardless of whether the branch and/or principal office of the fore-*

going banking institution is located within or without this State (collectively, "banking institution"), not later than the first business day following the day on which they were cashed. Such items must be deposited during the regular business hours of such [bank] banking institution so as to enable it to credit the deposits to the licensee's account on that business day.

(2) *Any account maintained by a licensee for the deposit of checks, drafts or money orders in a banking institution shall be subject to a written account agreement between the licensee and the banking institution that expressly provides for the personal and in rem jurisdiction over the parties and the account, respectively, of state and federal courts located in the State of New York and the agreement shall be governed by the laws of the State of New York, except that this requirement shall not apply (a) with respect to an account maintained in New York or in a State of New York-chartered bank prior to November 1, 2005, unless or until such existing account agreement is amended subsequent to November 1, 2005, or (b) if this requirement is waived in the Superintendent's discretion. Every licensee or applicant for a license shall provide to the Superintendent a copy of any such account agreement within 15 days of establishing any such account or any amendment thereto relating to the items required by this subsection. Every licensee shall maintain a copy of such account agreement as part of its records available for examination by the Superintendent.*

(3) *Prior to depositing any checks, drafts or money orders in an account at a banking institution, the licensee shall cause such banking institution to give the Superintendent written authorization to conduct any such examination of all books, records, documents and materials, including those in electronic form, as they relate to such account and any checks, drafts, or money orders placed on deposit in such account, as the Superintendent in his/her discretion deems necessary, except that this written authorization requirement shall not apply (a) with respect to an account maintained in New York or in a State of New York-chartered bank prior to November 1, 2005, unless or until such existing account agreement is amended subsequent to November 1, 2005, or (b) if this requirement is waived in the Superintendent's discretion. The licensee shall pay the cost of any such examination.*

(4) [(2)] When the number of payroll checks cashed at a limited station amount to 50 or more, the licensee may present those checks to the drawee bank or the maker of the checks and receive in exchange a single draft, provided full details of the transaction are recorded in a manner satisfactory to the superintendent.

Text of proposed rule and any required statements and analyses may be obtained from: Sam L. Abram, Secretary to the Banking Board, Banking Department, One State St., New York, NY 10004-1417, (212) 709-1658, e-mail: sam.abram@banking.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. Section 371 of the Banking Law authorizes the Superintendent of Banks to adopt such rules and regulations as are necessary to ensure the proper conduct of the business of check cashing. Pursuant to section 400.5(a) of Title 3 NYCRR, the Superintendent requires licensed check cashers to deposit checks, drafts and money orders (hereafter "instruments") in a banking institution located in this state no later than the first business day after the date on which the instruments were cashed for the customers.

2. Legislative objectives. The Legislature, when enacting and periodically amending Article 9-A of the Banking Law, which requires regulatory supervision of the business of check cashing, has stated as matter of legislative intent that such businesses provide an important and vital service to New York citizens. The regulatory regime applicable to such industry is intended to ensure the consumer confidence in such business is maintained and the public interest is protected. The regulatory requirements addressed in this rule making are necessary to maintain the financial stability of the licensees, thus maintaining the public confidence in their operations.

3. Needs and benefits. The section 400.5(a) requirement is intended to maintain timely liquidity of check cashers' operating funds, thus protecting their financial viability and stability. The deposit of such instruments in a location generally where the check cashing business is conducted facilitates the clearing process of such instruments through the banking system. In addition, if a check casher experiences financial difficulty and there is a need for the Superintendent to intervene, the location of the licensee's banking institution in this state permits the Superintendent to more readily obtain control of the licensee's assets through the judicial process, if this step proved necessary. However, due to the decision of various in-state banking institutions not to provide further deposit account services to money services industries, such as checking cashing businesses and money transmitters, it is necessary to expand the pool of potential banking institutions that may be willing to provide such services. Permitting check cashers to open and maintain deposit accounts with banks or branches located out of state should assist in addressing this problem. While doing business with banks located out of state may present certain logistical problems for check cashers in meeting the one-business day deposit requirement, there are mechanisms available within the banking system which should make such arrangements workable.

The ancillary regulatory requirements of the proposed rule attendant to a check casher establishing a deposit account relationship with a bank will ensure the Superintendent's supervisory oversight of the casher's banking relationship remains the same, regardless of where the bank is headquartered and whether the federal or a state government has chartered the institution. Such requirements necessitate that (i) the licensee's account agreement provide for the personal and in rem jurisdiction by federal and state courts located in New York over the parties and the account and that the agreement be governed by the laws of New York State; and (ii) prior to making any deposit in such account, the licensee obtain the written authorization by the bank enabling the Superintendent to examine any records and related documents and materials, in whatever form, pertaining to the deposits and the account. This is a timely revision of the rule, given the current rule was adopted prior to the advent of interstate branch banking and the Comptroller of the Currency's recent preemption ruling prohibiting any state bank regulator from exercising visitation authority over national banks.

4. Costs. Presumably, the proposed rule will require a banking institution and a regulated entity to devote additional time and resources when revising an existing deposit account agreement or opening a new account that meets the new requirements and providing the written agreement that authorizes the Superintendent to examine any records, documents and deposited checks relating to a licensee's account. Presumably, the revision of the account agreement and the development of a written Superintendent's authorization would be a one-time expense by a banking institution and such documents thereafter would serve as the template forms for any additional account relationships with licensed check cashers.

If the Superintendent has need to examine such an account, the cost of doing so is borne by the licensee pursuant to the proposed rule. However, such a cost would also be incurred under the current rule if the Superintendent examined the account and any related documents.

The proposed rule imposes no additional costs upon the Banking Department, other state agencies, or any other unit of government.

5. Local government mandates. The proposed rule imposes no mandates or costs upon any type of governmental unit. The regulatory provisions apply only to licensed entities, and such entities are private business enterprises.

6. Paperwork. The proposed rule provides that a check cashers' deposit account shall be subject to a written account agreement between the licensee and the banking institution, and that a copy of any new or amended agreement will be provided to the Superintendent within fifteen days of establishing the account or amendment. Every licensee is required to maintain a copy of the written agreement as part of its records which will be available for examination by the Superintendent. The licensee shall cause the banking institution to give the Superintendent written authoriza-

tion to conduct any examination of its books and records relating to the deposit account which the Superintendent deems necessary.

7. Duplication. None.

8. Alternatives. There are few alternatives to address the present situation other than to increase the pool of potential banks with which licensed check cashers may do business. One alternative is the creation of a bank, either under private or public auspices, that specializes in servicing money services businesses. However, this would be a long-term solution, and not an alternative that may be developed in the short-term given that in-state banks are currently terminating their deposit account relationships with these businesses.

9. Federal standards. There are no federal standards that apply to the daily operational aspects of the business of check cashing. The federal government does not license check cashers nor directly regulate the primary transaction activity of check cashers. When regulated, states are the sole supervisory regulators of the check cashing industry.

10. Compliance schedule. The new requirements applicable to any licensee's new deposit account, or modification of an existing account agreement, will take effect on or after October 1, 2005.

Regulatory Flexibility Analysis

1. Effect of rule: The proposed rule facilitates the conduct of business by and the financial stability of licensed check cashers, which are private businesses.

The rule expands the potential universe of banking institutions with which such licensed entities may maintain a deposit account agreement and thereby meet the current requirements of section 400.5(a)(1) that all cashed customer checks be deposited in a licensee's bank account not later than one business day following the date on which the checks were cashed.

2. Compliance requirements: The proposed rule requires a licensed check casher and a banking institution, when entering into a new account agreement or modifying an existing account agreement, to expressly provide in such agreement for the personal and in rem jurisdiction over the parties to the agreement and the account, respectively, of state and federal courts located in the State of New York and to also be subject to the laws of the State of New York. A copy of the agreement must be submitted to the Superintendent and a copy must be retained on file in the records of the licensee. Further, the proposed rule also requires the licensee to obtain from the banking institution and provide to the Superintendent a written agreement that permits the Superintendent to examine the records of such account, any related documents and deposited checks as the Superintendent deems necessary.

These additional requirements will enable the Superintendent to properly regulate licensed check cashers that may choose to open accounts in out-of-state locations and also in federally chartered banking institutions regardless of where located.

3. Professional services: No professional services are required in order for regulated parties to comply with the proposed rule. Any revision of an account agreement by a banking institution and the development of a template agreement authorizing the Superintendent to examine an account and related documents presumably would at least require review by the banking institution's legal counsel.

4. Compliance costs: Any compliance costs would be associated with the additional time and resources that a banking institution and a regulated entity devoted to revising a deposit account agreement to meet the new requirements and obtaining the written agreement that authorizes the Superintendent to examine any records, documents and deposited checks relating to a licensee's account. The revision of the account agreement and the development of a written template Superintendent's authorization by the banking institution in order to meet the new required standards presumably would be a one-time expense.

If the Superintendent has need to examine such an account, the cost of doing so is borne by the licensee pursuant to the proposed rule. However, such a cost would also be incurred under the current rule if the Superintendent examined the account and any related documents.

5. Economic and technological feasibility: The proposed rule imposes no economic or technological burden upon regulated entities or their customers.

6. Minimizing adverse economic impact: The proposed rule creates no adverse economic impact upon regulated entities. In fact, the proposed rule ensures the economic well being of licensed check cashers by increasing the potential universe of banking institutions with which they may establish a deposit account relationship. Absent an account relationship with a banking institution, a licensed check casher would be unable to conduct business by recouping funds paid out to customers through the deposit and clearing of the customers' checks.

7. Small business participation and local government participation: The Department has determined that the proposed rule has no impact upon other private businesses, or any unit of local government.

Rural Area Flexibility Analysis

The Department has determined the proposed rule has virtually no impact upon private businesses or units of local government situated in rural areas. Licensed check cashers are predominantly located in metropolitan and urban areas of this state. To the extent there are licensed check cashers in any rural locations, the proposed rule will facilitate the conduct of business by and the financial stability of such businesses. The proposed rule will have the same effect upon regulated entities, regardless of where located.

Job Impact Statement

The proposed rule is intended to facilitate the conduct of business by and the financial stability of check cashing businesses. Without deposit account relationships with banking institutions, licensed check cashers could not function. Therefore, the Department has determined the proposed rule has no adverse impact upon employment in the check cashing industry.

Office of Children and Family Services

EMERGENCY RULE MAKING

Regulatory Standards for the Operation of a Mother/Baby Facility

I.D. No. CFS-47-06-00003-E

Filing No. 1326

Filing date: Nov. 3, 2006

Effective date: Nov. 3, 2006

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

Action taken: Amendment of section 442.25(a) of Title 18 NYCRR.

Statutory authority: Social Services Law, sections 20(3)(d), 34(3)(f) and 462(1)

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

Specific reasons underlying the finding of necessity: To prevent the disruption of the placement of infants with their mothers. Because of the imminent closing of a previously available facility caring for mothers with their infants, existing regulation 18 NYCRR 442.25 must be amended to grant to the Office of Children and Family Services the authority to grant exceptions for the operation of mother/baby residential facilities pursuant to 18 NYCRR 442.17. Should the Office of Children and Family Services not have the authority to grant exceptions for the opening of a new otherwise suitable program to receive the mothers and infants from the imminent closing program, the mothers and infants will not have a suitable program available to them. This will result in a further disruption in placement and services to the detriment of the mothers and their infants.

Subject: Regulatory standards for the operation of a mother/baby facility.

Purpose: To amend 18 NYCRR, section 442.25 to grant to the Office of Children and Family Services the authority to grant to authorized agencies an exception to the regulatory standards for the operation of mother/baby facilities in accordance with 18 NYCRR, section 442.17. In order for an authorized agency to receive an exception, the authorized agency must make a written request to the Office of Children and Family Services. The authorized agency must demonstrate that the residential program is in substantial compliance with the regulations of the Office of Children and Family Services in regard to the operation of a child care institution, with the exception of the standards that are the subject to the request for the exception. The authorized agency must also demonstrate that the granting of the exception will not create any hazardous conditions which could impact the health or safety of children in the residential program. The Office of Children and Family Services may impose on the requesting authorized agency alternative requirements the Office of Children and Family Services considers necessary for the protection of the health or safety of the children.

The Office of Children and Family Services has been informed by the authorized agency that operates the current mother/baby program that is caring for these mothers and their infants that the program will be closing on Nov. 3, 2006 and that all of the current residents must vacate the premises by that date. The authorized agency is proposing to open an alternative residential program for these mothers and infants at another location. For this location to open, the Office of Children and Family Services must grant the new program certain exceptions to the current mother/baby standards set forth in 18 NYCRR, section 442.17. At this time, the Office of Children and Family Services does not have the legal authority to grant exceptions to these regulatory standards. The Office of Children and Family Services has been informed by the New York City Administration for Children's Services, which has legal responsibility for these residents, that the failure to enact the rule on an emergency basis would have a severe negative impact on the mothers and babies who currently receive foster care services in the current mother/baby program that is closing on Nov. 3, 2006 in that their placement and services will be disrupted. In addition, there are no other comparable placements available for these mothers with their babies upon the closing of the current program.

Text of emergency rule: Subdivision (a) of section 442.25 is amended to read as follows:

(a) The [department] *Office of Children and Family Services* may grant an exception to compliance with one or more of the provisions of section 442.4, 442.5, [or] 442.15 and 442.17 of this Part upon finding that compliance will result in undue hardship upon an institution. The authorized agency applying for the exception must demonstrate that, aside from the exception, the facility is in substantial compliance with the provisions of this Part and that granting the exception will not create any hazardous conditions which could impair the health or safety of the children. An institution must comply with any alternative requirements the [department] *Office of Children and Family Services* may consider necessary for the protection of the health or safety of the children. All exceptions must be requested by the authorized agency in writing and approved by the [department] *Office of Children and Family Services* in writing.

This notice is intended to serve only as a notice of emergency adoption. This agency intends to adopt this emergency rule as a permanent rule and will publish a notice of proposed rule making in the *State Register* at some future date. The emergency rule will expire January 31, 2007.

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

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

A Regulatory Impact Statement, Regulatory Flexibility Analysis, Rural Area Flexibility Analysis and Job Impact Statement are not submitted, but will be published in the *Register* within 30 days of the rule's effective date.

Education Department

EMERGENCY RULE MAKING

The Practice of Physical Therapy without a Referral

I.D. No. EDU-47-06-00018-E

Filing No. 1334

Filing date: Nov. 7, 2006

Effective date: Nov. 23, 2006

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

Action taken: Addition of sections 29.17 and 77.9 to Title 8 NYCRR.

Statutory authority: Education Law, sections 207 (not subdivided), 6504 (not subdivided), 6506(1), 6507(2)(a), 6509(9) and 6731(d)

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

Specific reasons underlying the finding of necessity: Chapter 298 of the Laws of 2006, which was signed by the Governor on July 26, 2006, adds a new section 6731(d) to the Education Law to permit licensed physical

therapists who have practiced physical therapy on a full-time basis equivalent to not less than three years to provide treatment to patients without a referral from a physician, dentist, podiatrist or nurse practitioner. This statute directs the Commissioner of Education to prescribe a form that physical therapists must distribute to a patient prior to treatment, advising the patient that any treatment provided without a referral may not be an expense covered by the patient's health care plan or insurer.

The proposed amendment implements the requirements of Chapter 298 by defining the experience requirement that a licensed physical therapist must meet to provide treatment without a referral, clarifying the content of the notice of advice provided to a patient prior to treatment by a licensed physical therapist without a referral, and establishing a definition of unprofessional conduct relating to such practice. The effective date of Chapter 298 of the Laws of 2006 is November 23, 2006. These requirements must be in place by that date to advise licensed physical therapists of the requirements that they must meet to provide treatment without a referral and to provide uniformity and consistency in the information that must be contained in the written notice provided to a patient. At the present time, about 17,500 physical therapists are licensed and registered to practice in New York State. Consequently, a significant number of individuals will be affected by the proposed amendment.

The recommended action is proposed as an emergency measure because such action is necessary to preserve the public health and safety in order to establish necessary regulatory standards to implement on a timely basis the requirements of Chapter 298 of the Laws of 2006 concerning requirements that licensed physical therapists must meet to provide treatment without a referral from specified health care professionals, thereby helping to ensure that licensed physical therapists are qualified to provide such treatment and that patients receive adequate notice relating to such treatment. An emergency action is necessary to ensure that the requirements are in place on November 23, 2006, when the law becomes effective.

It is anticipated that the proposed amendment will be presented to the Board of Regents for adoption as a permanent rule at its January 2007 meeting.

Subject: The practice of physical therapy without a referral.

Purpose: To implement the requirements of section 6731(d) of the Education Law by defining the experience requirement that a licensed physical therapist must meet to provide treatment without a referral; clarifying the content of the notice of advice provided to a patient prior to treatment by a physical therapist without a referral; and establishing a definition of unprofessional conduct relating to such practice.

Text of emergency rule: 1. Section 29.17 of the Rules of the Board of Regents is added, effective November 23, 2006, as follows:

29.17 Special provisions for the profession of physical therapy.

Unprofessional conduct in the practice of physical therapy shall include conduct prohibited by sections 29.1 and 29.2 of this Part. In addition, unprofessional conduct in the practice of physical therapy shall include failing to meet the requirements of subdivision (d) of section 6731 of the Education Law and/or section 77.9 of this Title, when providing treatment in the practice of physical therapy without a referral from a physician, dentist, podiatrist, or nurse practitioner.

2. Section 77.9 of the Regulations of the Commissioner of Education is added, effective November 23, 2006, as follows:

77.9 Providing treatment in the practice of physical therapy without referral.

(a) In accordance with Education Law section 6731(d), a licensed physical therapist may provide a patient with treatment in the practice of physical therapy without a referral from a physician, dentist, podiatrist, or nurse practitioner, for 10 visits or 30 days whichever occurs first, provided the licensed physical therapist meets the following requirements:

(1) the licensed physical therapist has practiced physical therapy on a full-time basis equivalent to not less than three years prior to beginning such treatment, meaning the licensed physical therapist has completed at least 4,320 clock hours of physical therapy practice over a minimum of 36 months anytime prior to beginning such treatment; and

(2) the licensed physical therapist meets all requirements of subdivision (b) of this section relating to the notice of advice.

(b) Notice of advice. A physical therapist providing treatment in the practice of physical therapy without a referral from a physician, dentist, podiatrist, or nurse practitioner, in accordance with Education Law section 6731(d) and the requirements of this section, shall advise the patient in writing prior to beginning treatment of the possibility that treatment may not be covered by the patient's health care plan or insurer without a referral from a physician, dentist, podiatrist, or nurse practitioner and that

treatment may be a covered expense if rendered pursuant to such referral. This notice of advice shall be provided on a form, a copy of which shall be kept on file by the licensed physical therapist as a patient record and a copy of which shall be given to the patient. The notice of advice form shall include the following information:

(1) a statement of such advice and a statement attesting that the patient has read the notice of advice;

(2) the date treatment will begin;

(3) the patient's name and address;

(4) the patient's signature and date the patient signed the form;

(5) the treating physical therapist's name and address; and

(6) the treating physical therapist's signature and the date the physical therapist signed the form.

This notice is intended to serve only as a notice of emergency adoption. This agency intends to adopt the provisions of this emergency rule as a permanent rule, having previously published a notice of proposed rule making, I.D. No. EDU-43-06-00009-P, Issue of October 25, 2006. The emergency rule will expire January 31, 2007.

Text of emergency rule and any required statements and analyses may be obtained from: Anne Marie Koschnick, Legal Assistant, Office of Counsel, Education Department, State Education Bldg., Rm. 148, Albany, NY 12234, (518) 473-8296, e-mail: 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.

Section 6504 of the Education Law authorizes the Board of Regents to supervise the admission to and regulation of the practice of the professions.

Subdivision (1) of section 6506 of the Education Law authorizes the Board of Regents to promulgate rules.

Paragraph (a) of subdivision (2) of section 6507 of the Education Law authorizes the Commissioner of Education to promulgate regulations in administering the admission to and the practice of the professions.

Subdivision (9) of section 6509 authorized the Board of Regents to define in its rules unprofessional conduct subject to professional discipline.

Paragraph (d) of section 6731 of the Education Law, as added by Chapter 298 of the Laws of 2006, authorizes the Commissioner of Education to promulgate regulations relating to the process for physical therapists to treat patients without a referral.

2. LEGISLATIVE OBJECTIVES:

The proposed amendment to the Rules of the Board of Regents and Regulations of the Commissioner of Education carries out the intent of the aforementioned statutes in that the proposed amendment establishes requirements for physical therapists to provide treatment to a patient without a referral, and the proposed rule defines unprofessional conduct for the practice of physical therapy relating to such practice.

3. NEEDS AND BENEFITS:

Chapter 298 of the Laws of 2006, which was signed by the Governor on July 26, 2006, added a new section 6731(d) to the Education Law to permit licensed physical therapists who have practiced physical therapy on a full-time basis equivalent to not less than three years to provide treatment to patients without a referral from a physician, dentist, podiatrist or nurse practitioner. This statute directs the Commissioner of Education to prescribe a form that physical therapists must distribute to a patient prior to treatment advising the patient of the possibility that any treatment provided without a referral may not be an expense covered by the patient's health care plan or insurer.

The proposed amendment implements the requirements of section 6731(d) of the Education Law by defining the experience requirement that a licensed physical therapist must meet to provide treatment without a referral, clarifying the content of the notice of advice provided to a patient prior to treatment without a referral, and establishing a definition of unprofessional conduct relating to such practice.

The amendment is needed to advise licensed physical therapists of the requirements that they must meet in order to provide treatment without a referral and to provide uniformity and consistency in the information that must be contained in the written notice provided to a patient. At the present time, about 17,500 physical therapists are licensed and registered to practice in New York State. Consequently, a significant number of individuals will be affected by the proposed amendment.

The amendment establishes an additional definition of unprofessional practice in the practice of physical therapy: failing to meet the requirements of subdivision (d) of section 6731 of the Education Law and/or

section 77.9 of the Commissioner's Regulations. This will provide a way for the State Education Department to enforce the requirements that licensed physical therapists must meet to provide treatment without a referral.

4. COSTS:

(a) Costs to State government. The proposed amendment implements statutory requirements and establishes standards as directed by statute. It will not impose any additional costs on State government, including the State Education Department, beyond those imposed by the statute. The Department will utilize existing personnel and resources to implement these requirements.

(b) Costs to local government: None.

(c) Cost to private regulated parties. The proposed amendment does not impose additional costs beyond those imposed by the statute, which requires licensed physical therapists to provide a notice of advice to patients prior to treatment.

(d) Cost to the regulatory agency: As stated above in "Costs to State government", the proposed amendment does not impose additional costs on State Government, including the State Education Department.

5. LOCAL GOVERNMENT MANDATES:

The proposed amendment implements the requirements of section 6731(d) of the Education Law, relating to requirements that must be met by licensed physical therapists to provide treatment to their patients without a referral from a physician, dentist, podiatrist or nurse practitioner. The amendment does not impose any program, service, duty, or responsibility upon local governments.

6. PAPERWORK:

Education Law section 6731(b) requires licensed physical therapists to provide a written notice of advice to patients prior to providing treatment without a referral. Consistent with this statute, the proposed amendment requires the notice of advice form to include the following information: (1) a statement of such advice and a statement attesting that the patient has read the notice of advice; (2) the date treatment will begin; (3) the patient's name and address; (4) the patient's signature and date the patient signed the form; (5) the treating physical therapist's name and address; and (6) the treating physical therapist's signature and the date the physical therapist signed the form.

7. DUPLICATION:

The proposed amendment does not duplicate any existing State or Federal requirements.

8. ALTERNATIVES:

There are no viable alternatives to the proposed amendment, and none were considered. The amendment implements statutory requirements.

9. FEDERAL STANDARDS:

There are no Federal standards that establish requirements that licensed physical therapists must meet to provide treatment without a referral from a physician, dentist, podiatrist or nurse practitioner.

10. COMPLIANCE SCHEDULE:

Licensees will be required to comply with the proposed amendment on its stated effective date in order to comply with section 6731(d) of the Education Law, as added by Chapter 298 of the Laws of 2006. No additional period of time is needed to enable regulated parties to comply.

Regulatory Flexibility Analysis

(a) Small Businesses:

1. EFFECT OF RULE:

The proposed amendment to the Rules of the Board of Regents and Regulations of the Commissioner of Education applies to licensed and registered physical therapists in New York State. All 17,639 licensed physical therapists registered to practice in New York would be subject to the requirements of the proposed amendment once they have practiced physical therapy on a full-time basis for three years, or the equivalent, and if they choose to provide treatment in the practice of physical therapy without a referral.

2. COMPLIANCE REQUIREMENTS:

The proposed amendment defines an experience requirement that individuals who are licensed physical therapists must meet in order to provide treatment to patients without a referral from specified health care professionals. This requirement does not pertain to small businesses but are requirements that individual licensees must meet.

Education Law section 6731(d) directs the Commissioner of Education to prescribe a form that licensed physical therapists must distribute to a patient prior to treatment advising the patient of the possibility that any treatment provided without a referral may not be an expense covered by the patient's health care plan or insurer. The proposed amendment implements this requirement by clarifying what must be included in the notice of

advice provided to a patient prior to treatment by a licensed physical therapist without a referral. Consistent with this statute, the proposed amendment requires the notice of advice form to include the following information: (1) a statement of such advice and a statement attesting that the patient has read the notice of advice; (2) the date treatment will begin; (3) the patient's name and address; (4) the patient's signature and date the patient signed the form; (5) the treating physical therapist's name and address; and (6) the treating physical therapist's signature and the date the physical therapist signed the form. These content requirements will affect the practice of physical therapy, including such practice in small businesses.

3. PROFESSIONAL SERVICES:

No professional services are expected to be required by small businesses to comply with the proposed amendment.

4. COMPLIANCE COSTS:

The proposed amendment will not impose costs beyond those required to comply with the statutory requirements.

5. ECONOMIC AND TECHNOLOGICAL FEASIBILITY:

The proposed amendment will not impose any special technological requirements on regulated parties. As stated above in "Compliance Costs," the amendment will not result in additional costs to regulated parties.

6. MINIMIZING ADVERSE IMPACT:

The amendment implements a statutory requirement which make no exception for licensed physical therapists who are employed in small businesses. The statute requires licensed physical therapists that provide treatment without a referral from specified health care professionals to provide the patient with written notice of the possibility that such treatment may not be an expense covered by the patient's health care plan or insurer. Because of the nature of the proposed amendment, establishing different standards for licensed physical therapist based upon the size of the physical therapist's employer is inappropriate. The amendment establishes a uniform content requirement for this notice. The Department believes that uniform standards are required, regardless of the size of the business, in order to ensure that all patients who receive such treatment have this consumer protection.

7. SMALL BUSINESS PARTICIPATION:

Members of the State Board for Physical Therapy, many of whom have experience in a small business environment, provided input during the development of the proposed amendment. In addition, staff of the State Education Department have worked with the statewide and national professional associations and councils that represent physical therapists by disseminating information concerning the proposed amendment to these organizations and seeking their input. These organizations include membership who own and operate small businesses or are employed by small businesses.

(b) Local Governments:

The proposed amendment establishes requirements that licensed physical therapists must meet to provide treatment to patients without a referral from a physician, dentist, podiatrist or nurse practitioner, and clarifies the content of a written notice to patients prior to their receiving such treatment. The proposed amendment will not impose an adverse economic impact or reporting, recordkeeping, or other compliance requirements on local governments. Because it is evident from the nature of the proposed rule that it does not affect local governments, no further steps were needed to ascertain that fact and none were taken. Accordingly, a regulatory flexibility analysis for local governments is not required and one has not been prepared.

Rural Area Flexibility Analysis

1. TYPES AND ESTIMATED NUMBER OF RURAL AREAS:

The proposed amendment to the Rules of the Board of Regents and Regulations of the Commissioner of Education applies to licensed and registered physical therapists in the 44 rural counties with less than 200,000 inhabitants and the 71 towns in urban counties with a population density of 150 per square mile or less. All 17,639 licensed physical therapists registered to practice in New York would be subject to the requirements of the proposed amendment once they have practiced physical therapy on a full-time basis for three years, or the equivalent, and if they choose to practice without a referral. Of these, 2,331 reported that their permanent address of record is in a rural county of New York State.

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

Chapter 298 of the Laws of 2006, which was signed by the Governor on July 26, 2006, added a new section 6731(d) to the Education Law to permit licensed physical therapists, including those located in rural areas, who have practiced physical therapy on a full-time basis equivalent to not less

than three years to provide treatment to patients without a referral from a physician, dentist, podiatrist or nurse practitioner. This statute directs the Commissioner of Education to prescribe a form that physical therapists must distribute to a patient prior to treatment advising the patient of the possibility that any treatment provided without a referral may not be an expense covered by the patient's health care plan or insurer.

The proposed amendment implements the requirements of section 6731(d) of the Education Law by defining the experience requirement that a licensed physical therapist must meet to provide treatment without a referral, clarifying the content of the notice of advice provided to a patient prior to treatment without a referral, and establishing a definition of unprofessional conduct relating to such practice.

Education Law section 6731(b) requires licensed physical therapists, including those living or working in rural areas, to provide a notice of advice to patients prior to providing treatment without a referral. Consistent with this statute, the proposed amendment requires the notice of advice form to include the following information: (1) a statement of such advice and a statement attesting that the patient has read the notice of advice; (2) the date treatment will begin; (3) the patient's name and address; (4) the patient's signature and date the patient signed the form; (5) the treating physical therapist's name and address; and (6) the treating physical therapist's signature and the date the physical therapist signed the form.

The proposed amendment will not require licensed physical therapists to hire professional services in order to comply.

3. COSTS:

The proposed amendment does not impose additional costs on licensed physical therapists, including those that are located in rural areas, beyond those imposed by the statute.

4. MINIMIZING ADVERSE IMPACT:

The proposed amendment makes no exception for licensed physical therapists who are located in rural areas. The amendment implements statutory requirements which make no exception for licensed physical therapists who live or work in rural areas. In any event, consistent practice requirements should apply no matter the geographic origin of the licensee to ensure a uniform high standard of competency across the State. Because of the nature of the proposed amendment, establishing different standards for licensed physical therapist located in rural areas of New York State is inappropriate.

5. RURAL AREA PARTICIPATION:

Comments on the proposed amendment were solicited from statewide organizations representing parties having an interest in the practice of physical therapy. The State Board for Physical Therapy and professional associations representing the physical therapy profession were included. These groups have members who live or work in rural areas of New York State. Each organization has been provided notice of the proposed rule making and an opportunity to comment.

Job Impact Statement

The proposed amendment implements the requirements of section 6731(d) of the Education Law by defining the experience requirement that a licensed physical therapist must meet to provide treatment without a referral from specified health care professionals and clarifying the content of the notice of advice provided to a patient prior to treatment by a licensed physical therapist without a referral. The amendment implements statutory requirements and will have no impact on jobs or employment opportunities in the field of physical therapy or any other field. Because it is evident from the nature of this proposed amendment that it will have no impact on jobs or employment opportunities, no further steps were needed to ascertain that fact and none were taken. Accordingly, a job impact statement is not required and one was not prepared.

Department of Environmental Conservation

EMERGENCY RULE MAKING

Architectural and Industrial Maintenance Coatings

I.D. No. ENV-47-06-00010-E

Filing No. 1332

Filing date: Nov. 7, 2006

Effective date: Nov. 7, 2006

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

Action taken: Amendment of Part 205 of Title 6 NYCRR.

Statutory authority: Environmental Conservation Law, sections 1-0101, 3-0301, 3-0303, 19-0103, 19-0105, 19-0301 and 19-0305

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

Specific reasons underlying the finding of necessity: To achieve the reductions of emissions of volatile organic compounds necessary to demonstrate attainment with the ozone national ambient air quality standards. Attainment of this standard is necessary to protect the public health and welfare.

Subject: Architectural and industrial maintenance coatings.

Purpose: To end the small manufacturer exemption on Dec. 31, 2006; and establish a sell-through end date of May 15, 2007 to eliminate the unlimited sell-through of non-complying coatings manufactured before Jan. 1, 2005.

Text of emergency rule: Sections 205.1 through 205.2 remain unchanged.

Section 205.3 (a) is amended to read as follows:

Section 205.3 Standards.

(a) 'VOC content limits.' Except as provided in [subdivision] *subdivisions* (b) and (g) of this section, no person shall manufacture, blend, or repackage for sale within the State of New York, supply, sell, or offer for sale within the State of New York or solicit for application or apply within the State of New York any architectural coating manufactured on or after January 1, 2005 which contains volatile organic compounds in excess of the limits specified in the following Table of Standards. Limits are expressed in grams of VOC per liter of coating thinned to the manufacturer's maximum recommendation, excluding the volume of any water, exempt compounds, or colorant added to tint bases. 'Manufacturer's maximum recommendation' means the maximum recommendation for thinning that is indicated on the label or lid of the coating container.

The remainder of section 205.3(a) remains unchanged.

Sections 205.3(b) through 205.3(f) remain unchanged.

New Section 205.3(g) is added to read as follows:

(g) '*Sell Through of Coatings.*' A coating manufactured prior to January 1, 2005, or previously granted an exemption pursuant to Section 205.7, may be sold, supplied, or offered for sale until May 15, 2007, so long as the coating complied with standards in effect at the time the coating was manufactured.

Sections 205.4 through 205.7(e) remain unchanged.

Section 205.7 (f) is amended to read as follows:

(f) Any exemption granted under subdivision (d) of this section may remain in effect no later than December 31, [2007] 2006.

Section 205.7(g) is deleted.

Section 205.7(h) is renumbered as follows:

[(h)](g) Limited exemptions for small AIM coatings manufacturers as approved by the director, Division of Air Resources, Department of Environmental Conservation under this Part, will be submitted to the EPA as State Implementation Plan revisions for approval.

Section 205.8 remains unchanged.

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 February 4, 2007.

Text of emergency rule and any required statements and analyses may be obtained from: Daniel S. Brinsko, P.E., Department of Environmental

Conservation, Division of Air Resources, 625 Broadway, Albany, NY 12233, (518) 402-8396, e-mail: 205aim@gw.dec.state.ny.us

Additional matter required by statute: Pursuant to Article 8 of the (State Environmental Quality Review Act), a Short Environmental Assessment Form, a Negative Declaration and a Coastal Assessment Form have been prepared and are on file.

Summary of Regulatory Impact Statement

New York faces a significant public health challenge from ground-level ozone, which causes health effects ranging from respiratory disease to death. In response to this public health problem, New York has enacted a series of regulations designed to control ozone and its chemical precursors which include volatile organic compounds (VOCs). Among other regulatory actions, New York has promulgated regulations designed to limit the VOCs emitted by various paints, stains, and sealers also known as architectural and industrial maintenance coatings (AIM coatings).

The Department now proposes to revise Part 205 to implement two rule changes. First, the Department proposes to modify the provision in section 205.7 whereby small manufacturers could apply for and obtain an exemption from VOC content limits through December 31, 2007, with the option to apply to renew the exemption for an additional three years. This exemption is otherwise known as the small manufacturer's exemption or "SME." The Department proposes to end the SME effective December 31, 2006. Second, the Department proposes to include a "sell-through" end date provision so that products manufactured prior to January 1, 2005, or granted a SME, which do not meet Part 205 VOC content limits, cannot be sold indefinitely. Together, these modifications will ensure that the State achieves the VOC emission reductions from AIM coatings needed to address the emission shortfall identified by EPA for the NYCMA in connection with the one-hour ozone NAAQS and that the State can make immediate progress towards attaining the eight-hour ozone NAAQS statewide.

In 2005, the Department granted SMEs to twenty small manufacturers for specific AIM coatings. The Department has analyzed the information submitted in connection with the SME applications, and has now determined that the SMEs account for approximately 4 tons of VOC emission reductions per ozone season day (tpd) out of the 14 tpd of reductions that were anticipated to be achieved when the VOC content limits in Part 205 took effect in 2005. One of the objectives of this rule making is to recover the 4 tpd of VOC emission reductions that were not achieved as a result of the SMEs. In addition to the VOC emission reductions lost due to the SMEs, the Department is concerned about the VOC emissions lost from the continued sale of AIM coatings produced prior to the January 1, 2005 compliance date in Part 205. The VOC content limits in Part 205 do not apply to products manufactured prior to January 1, 2005, only products manufactured on or after that date. In discussions with AIM coatings manufacturers, the Department has learned that some pre-2005 product is still being sold. The Department proposes to add a "sell-through" end date of May 15, 2007, after which all AIM products sold in New York State must comply with the low VOC content limits in Part 205. By eliminating the SMEs and establishing a "sell-through" end date, the Department will be able to demonstrate progress towards attaining the eight-hour NAAQS for ozone.

The Department is filing an emergency adoption to make these rule revisions effective immediately. Under these revisions, the SMEs will not end until December 31, 2006. Manufacturers will have until May 15, 2007 to sell non-compliant products that were manufactured before January 1, 2005 or were granted a SME. The Department realizes, however, that manufacturers granted one or more SMEs will need time to shift their production to compliant coatings. Both large and small manufacturers who were selling non-compliant coatings manufactured before the new VOC standards took effect need time to liquidate their existing inventories or transfer those inventories to states outside of the Ozone Transport Region with less stringent AIM coatings regulations. The adoption of these revisions on an emergency basis ensures that manufacturers have significant advance notice to react to these rule changes in a timely manner and achieve compliance with Part 205 by the "sell-through" end date.

The promulgation of these Part 205 amendments is authorized by the following sections of the Environmental Conservation Law which, taken together, clearly empower the Department to establish and implement the Program: Section 1-0101; Section 3-0301; Section 19-0103; Section 19-0105; Section 19-0301 and Section 19-0305.

Part 205 currently includes the SME provision that allows the Department to grant an exemption to a small AIM coatings manufacturer in order to allow more time for the manufacturer to acquire the technology to comply with the new VOC content limits. Twenty-two small manufactur-

ers applied for and twenty received SMEs. Revised Part 205 was estimated to achieve VOC emission reductions of 14 tons per ozone season day (tpd) and the Department has determined that as a result of granting the SMEs, 4 tpd of VOC emission reductions that had been anticipated were not realized. These emission reductions are essential to the Department's strategy to bring NYCMA, and the other nonattainment areas of the state into attainment with the eight-hour NAAQS for ozone. In a letter dated January 27, 2006 from Raymond Werner, Chief, Air Programs Branch, USEPA Region 2 Office, to Dave Shaw, Director Division of Air Resources of DEC, EPA requested an accounting of the shortfall measures to meet the 42 tpd VOC emission reduction shortfall. New York cannot make this demonstration unless it is able to take credit for all of the emission reductions anticipated through implementation of the six "shortfall measures", which included the 14 tpd from Part 205, the AIM Coatings rule.

In addition to evaluating the SME provision, the Department also reviewed a provision that was considered during the last rule making but not included in the final adopted rule in 2003. Part 205 currently does not contain a "sell-through" end date for sales of AIM coatings manufactured before January 1, 2005 and thus allows the sale of AIM coatings manufactured before 2005 to continue indefinitely. Because the Department believed that AIM coatings moved quickly through the market (based upon discussions with industry during the rule making process), it was believed that there was not a need for a cut-off date. Since adoption of the final rule in 2003, the Department has discovered that some of these products do have long shelf lives and have remained in the market for periods sometimes exceeding two years. Moreover, the Department has also been advised that some manufacturers stockpiled AIM coatings manufactured prior to the rule implementation date of January 1, 2005 to ensure that they could continue to sell 2004 formulations after the revised rule took effect. As a result, it is important to establish a "sell-through" end date to ensure that the entire 14 tpd of VOC emission reductions are realized as soon as possible. The Department now concludes that if a "sell-through" end date is not invoked then noncompliant products will continue to be sold for a long time, and New York State will not realize the full potential of the VOC emission reductions expected during the rule making process. The Department's selection of May 15, 2007 as a "sell-through" end date effectively provides the regulated community with a "sell-through" period nearly two and a half years. Also, May 15th corresponds to the beginning of the ozone season, so removing these higher VOC products from the market before the start of the ozone season will improve New York's ability to attain the ozone NAAQS.

There are two types of ozone, stratospheric and ground level ozone. Ozone in the stratosphere is naturally occurring and is desirable because it shields the earth from harmful ultraviolet rays from the sun which may cause skin cancer. Ozone at ground level causes throat irritation, congestion, chest pains, nausea and labored breathing. It aggravates respiratory conditions like chronic lung and heart diseases, allergies and asthma. Ozone damages the lungs and may contribute to lung disease. Even exercising healthy adults can experience 15 percent to 20 percent reductions in lung function from exposure to low levels of ozone over several hours. Children are most at risk from exposure to ozone. Because their respiratory systems are still developing, they are more susceptible than adults. This problem is exacerbated because ozone is a summertime phenomenon. Children are outside playing and exercising more often during the summer which results in children being exposed to ozone more than adults. Outdoor workers are also more susceptible to lung damage because of their increased exposure to ozone.

Implementation of the Part 205 revisions will, in concert with similar regulations adopted by other States and other measures undertaken by New York, lower levels of ozone in New York State and will decrease the adverse public health and welfare effects described above.

The cost of the proposed regulations will mostly affect the twenty SME manufacturers to whom the Department granted a SME. There may be some cost to other manufacturers that still have supplies of AIM coatings manufactured before January 1, 2005, but Department staff expects this to be minor. Large manufacturers who have existing inventories of product manufactured prior to January 1, 2005 will have to ensure that the product is sold before the "sell-through" end date or moved out of New York State for sale in other states which do not have an AIM coatings rule.

Small manufacturers may have increased costs associated with the production of compliant AIM coatings and may experience a reduction in profits to the extent that their sales increased during the SME as a result of their ability to make and sell higher VOC products. These manufacturers must now make and sell complying coatings and accordingly their production costs may increase slightly and they may sell less product. Since

compliant formulations are available for all coating categories, however, the Department expects that the financial effects of this rule are beneficial to the overall market since all manufacturers must meet the same VOC content limits.

It should be noted that the impact to consumers is expected to be minimal since there are already a large amount of complying coatings on store shelves (produced by manufacturers that did not receive a SME). Competition from these existing complying coatings will likely constrain any price increases as manufacturers will not be able to pass on all of their costs to the consumers. This is likely to control any actual retail price increases.

The Department evaluated several alternatives and determined that the most preferable alternative is to end the SME in December 2006 and the "sell-through" in May 2007. This option provides time for the manufacturers who have products granted a SME or products manufactured prior to January 1, 2005 to "sell-through" any remaining inventory. In particular, ending the "sell-through" by May 15, 2007 allows manufacturers time to liquidate inventory while ensuring that sale of non-complying products is curtailed by the 2007 ozone season. This is the preferred option because it ensures New York can realize the necessary VOC emission reductions.

EPA approved Part 205 into New York's State Implementation Plan on December 13, 2004. As a result of EPA's action, the VOC content limits in Part 205 represent the Federal standards for AIM coatings in New York. EPA has asked New York to demonstrate compliance with the ozone NAAQS. To do this, the Department needs to demonstrate 42 tpd of VOC emission reductions identified by EPA as the shortfall. In order to achieve the 42 tpd of shortfall reductions, the Department adopted six VOC control measures including the Part 205 AIM coatings rule. The AIM coatings rule was expected to produce 14 tpd of the VOC shortfall emission reductions but because of the SME and the unlimited sell-through provisions the Department is not able to make its shortfall demonstration to EPA. These revisions will allow the Department to comply with that federal mandate.

Regulatory Flexibility Analysis

New York faces a significant public health challenge from ground-level ozone, which causes health effects ranging from respiratory disease to death. In response to this public health problem, New York has enacted a series of regulations designed to control ozone and its chemical precursors which include volatile organic compounds (VOCs). Among other regulatory actions, New York has promulgated regulations designed to limit the VOCs emitted by various paints, stains, and sealers also known as architectural and industrial maintenance coatings (AIM coatings).

On July 18, 1997 the EPA promulgated the eight-hour ozone national ambient air quality standard (NAAQS). EPA has designated several areas within New York State to be in nonattainment with the eight-hour NAAQS. Previously, New York State had been subject to the one-hour ambient air quality standard for ozone, which remained in effect until June 2005. New York State is required to develop and implement enforceable strategies to get those areas into attainment by 2009. Attainment is measured over a three year average, so NOx and VOC emission reductions are needed before the ozone season (May through October) of 2007 in order to have the best chance of measuring attainment.

The Department of Environmental Conservation (the Department) proposes to revise Part 205 to implement two rule changes. First, the Department proposes to modify the provision in section 205.7 whereby small manufacturers could apply for and obtain an exemption from VOC content limits through December 31, 2007, with the option to apply to renew the exemption for an additional three years. This exemption is otherwise known as the small manufacturer's exemption or "SME." The Department proposes to end the SME effective December 31, 2006. Second, the Department proposes to include a "sell-through" provision so that products manufactured prior to January 1, 2005, or granted a SME, and which do not meet Part 205 VOC content limits cannot be sold indefinitely. Together, these modifications will ensure that the State achieves the VOC emission reductions from AIM coatings needed to address the emission shortfall identified by EPA for the NYCMA in connection with the one-hour ozone NAAQS and that the State can make immediate progress towards attaining the eight-hour ozone NAAQS statewide.

In 2005, the Department granted a SME to twenty small manufacturers for specific AIM coatings. The Department has analyzed the information submitted in connection with the SME applications, and has now determined that the SMEs account for 4 tons per ozone season day (tpd) out of the 14 tpd of VOC emission reductions that were anticipated to be achieved when the VOC content limits in Part 205 took effect in 2005. One of the objectives of this rule making is to recover the 4 tpd of VOC emission reductions that were not achieved as a result of the SMEs. In

addition to the VOC emission reductions lost due to the SMEs, the Department is concerned about the VOC emissions lost from AIM coatings produced prior to the January 1, 2005 compliance date in Part 205. The VOC content limits in Part 205 do not apply to products manufactured prior to January 1, 2005, only products manufactured on or after that date. In discussions with AIM coatings manufacturers, the Department has learned that some pre 2005 product is still being sold. The Department proposes to add a "sell-through" end date of May 15, 2007 which would require that only VOC compliant coatings be sold after that date. By eliminating the SMEs and establishing a "sell-through" end date, the Department will be able to demonstrate progress in its efforts to attain the eight-hour NAAQS for ozone.

The Department is filing an emergency adoption to make these rule revisions effective immediately. Under these revisions, the SMEs will not end until December 31, 2006. Manufacturers will have until May 15, 2007 to sell non-compliant products that were manufactured before January 1, 2005 or were granted a SME. The Department realizes, however, that manufacturers granted one or more SMEs will need time to shift their production to compliant coatings. Both large and small manufacturers who were selling non-compliant coatings manufactured before the new VOC standards took effect need time to liquidate their existing inventories or transfer those inventories to states outside of the OTR with less stringent AIM coatings regulations. The adoption of these revisions on an emergency basis ensures that manufacturers have significant advance notice to react to these rule changes in a timely manner and achieve compliance with Part 205 by the "sell-through" end date.

1. Effects on Small Businesses and Local Governments. No local governments will be directly affected by the revisions to 6 NYCRR Part 205, the Architectural and Industrial Maintenance (AIM) Coatings regulation. Small businesses that manufacture AIM coatings for sale pursuant to a small manufacturer exemption (SME) provision for certain products under section 205.7 had a three year exemption that would have ended on December 31, 2007. With these rule revisions, the SME will end on December 31, 2006. In addition, as a result of the new sell through provision, AIM coatings manufacturers will have until May 15, 2007 to sell products which were grandfathered or received a SME.

2. Compliance Requirements. Local governments are not directly affected by the revisions to 6 NYCRR Part 205. Small businesses which were not granted a SME will face no additional requirements. Manufacturers who were granted a SME will have to comply with the low VOC content limits of Part 205, which may involve reformulating some of their coatings. Contractors and retailers who use or sell AIM simply need to continue to purchase compliant coatings.

3. Professional Services. Local governments are not directly affected by the revisions to 6 NYCRR Part 205. It is not anticipated that small businesses that manufacture architectural coatings will need to contract out for professional services to comply with this regulation. In the few cases where small manufacturers do not already have compliant formulations to replace those SME products complying formulations are available at little or no cost from both the solvent and the raw material suppliers to this industry. See Chemidex.com on the web.

4. Compliance Costs. There are no additional compliance costs for small businesses and local governments as a result of this rule except for the 11 New York State manufacturers granted a SME. Since there are compliant coatings now available in all AIM categories, small businesses and local governments that previously purchased AIM coatings that received a SME, they are not expected to see a price increase for the purchase of compliant AIM coatings.

There may be some cost to other manufacturers that still have supplies of AIM coatings manufactured before January 1, 2005, but the Department expects this to be minor. Manufacturers that have existing inventories of product manufactured before January 1, 2005 will need to ensure that the product is sold before the "sell-through" end date or moved out of New York State for sale in other states which do not have an AIM coatings rule.

The proposed regulations will mostly affect the eleven New York urban/suburban businesses that received an SME for certain products. Some of manufacturers may have increased costs associated with the production of compliant AIM coatings. The Department is aware of some small manufacturers who, after having been granted a SME, were able to increase sales and market share of their products. These manufacturers will now be required to produce compliant coatings which will have to compete in the market place with the compliant coatings of other manufacturers. Consequently, they might experience reduced profits to the extent they cannot maintain the same level of sales with compliant VOC coatings as they did with their higher VOC content coatings. Compliant formulations

are available for all coating categories, however, so all manufacturers should be able to access that technology going forward. Department staff believe that the financial effects of this rule are beneficial to the overall market since this rule would no longer provide a market advantage to those companies that received the SMEs or had large inventories of products manufactured before January 2005.

It should be noted that the impact to consumers is expected to be minimal since there are already large amounts of complying coatings on store shelves (produced by manufacturers that did not receive a SME). Competition from these existing complying coatings will likely constrain any price increases as manufacturers will not be able to pass on all of their costs to the consumers. This is likely to control any actual retail price increases.

5. **Minimizing Adverse Impact.** Local governments are not directly affected by the revisions to 6 NYCRR Part 205. The emergency adoption of these revisions ensures that manufacturers have significant advance notice to react to these rule changes in a timely manner and achieve compliance with Part 205 by the "sell-through" end date. The Department is providing four months advance notice of the end of the SME and almost nine months notice of the sell through end date. This will provide manufacturers time to liquidate their existing inventories, or transfer those inventories to non-OTR states.

6. **Small Business and Local Government Participation.** Since local governments are not directly affected by this regulation, the Department did not contact local governments directly. On September 21, 2005 the Department notified all the manufacturers who had been granted a SME of its intent to end the SME by December 31, 2006, with no extensions. Only two (one New York company) of the twenty companies with SMEs responded and also that those responses were many months after the initial notification. While the one New York company indicated that they would like to see the SME provision remain as well as the ability to sell non-complying manufactured before January 1, 2005, indications are that they now have the ability to reformulate their products to comply with Part 205. The Department will also be giving official notice of this rule making to each of the twenty companies with SMEs.

7. **Economic and Technological Feasibility.** Local governments are not directly affected by the revisions to 6 NYCRR Part 205. Compliant products are available in all coating categories statewide to meet all consumer needs. The VOC content limits adopted in 2003 were based in large part on the 2000 California Air Resources Boards (CARB) suggested control measure (SCM) for AIM coatings. The SCM is a model AIM coatings rule that is used as a template by the California Air Districts for their AIM coatings regulations. The SCM is based on a 1998 AIM coatings survey by CARB in which they determined the technical feasibility of VOC content limits for each AIM coating category. In effect, the availability of products in a particular coating category at or below a specific VOC content limit indicated the feasibility of that category establishing a standard at that content limit. Since inception of the SCM VOC content limits into California in 2003, there have been no known complaints by small businesses with regards to compliance with the new AIM coatings standards. Likewise, according to CARB, there have been no known small manufacturers to go out of business as a result of the new AIM coatings regulations. By eliminating the SMEs and invoking a "sell-through" end date, this will keep New York State consistent with California as well as the other OTC states that don't have an SME provision.

Rural Area Flexibility Analysis

New York faces a significant public health challenge from ground-level ozone, which causes health effects ranging from respiratory disease to death. In response to this public health problem, New York has enacted a series of regulations designed to control ozone and its chemical precursors which include volatile organic compounds (VOCs). Among other regulatory actions, New York has promulgated regulations designed to limit the VOCs emitted by various paints, stains, and sealers also known as architectural and industrial maintenance coatings (AIM coatings). See 6 NYCRR Part 205.

On July 18, 1997 the EPA promulgated the eight-hour ozone national ambient air quality standard (NAAQS). EPA has designated several areas within New York State to be in nonattainment with the eight-hour NAAQS. Previously, New York State had been subject to the one-hour ambient air quality standard for ozone, which remained in effect until June 2005. New York State is required to develop and implement enforceable strategies to get those areas into attainment by 2009. Attainment is measured over a three year average, so NO_x and VOC emission reductions are needed before the ozone season (May through October) of 2007 in order to have the best chance of measuring attainment.

The Department of Environmental Conservation (the Department) proposes to revise Part 205 to implement two rule changes. First, the Department proposes to modify the provision in section 205.7 whereby small manufacturers could apply for and obtain an exemption from VOC content limits through December 31, 2007, with the option to apply to renew the exemption for an additional three years. This exemption is otherwise known as the small manufacturer's exemption or "SME." The Department proposes to end the SME effective December 31, 2006. Second, the Department proposes to include a "sell-through" provision so that products manufactured prior to January 1, 2005, or granted a SME, and which do not meet Part 205 VOC content limits cannot be sold indefinitely. Together, these modifications will ensure that the State achieves the VOC emission reductions from AIM coatings needed to address the emission shortfall identified by EPA for the NYCMA in connection with the one-hour ozone NAAQS and that the State can make immediate progress towards attaining the eight-hour ozone NAAQS statewide.

In 2005, the Department granted a SME to twenty small manufacturers for specific AIM coatings. The Department has analyzed the information submitted in connection with the SME applications, and has now determined that the SMEs account for 4 tons per ozone season day (tpd) out of the 14 tpd of VOC emission reductions that were anticipated to be achieved when the VOC content limits in Part 205 took effect in 2005. One of the objectives of this rule making is to recover the 4 tpd of VOC emission reductions that were not achieved as a result of the SMEs. In addition to the VOC emission reductions lost due to the SMEs, the Department is concerned about the VOC emissions lost from AIM coatings produced prior to the January 1, 2005 compliance date in Part 205. The VOC content limits in Part 205 do not apply to products manufactured prior to January 1, 2005, only products manufactured on or after that date. In discussions with AIM coatings manufacturers, the Department has learned that some pre 2005 product is still being sold. The Department proposes to add a "sell-through" end date of May 15, 2007 which would require that only VOC compliant coatings be sold after that date. By eliminating the SMEs and establishing a "sell-through" end date, the Department will be able to demonstrate progress in its efforts to attain the eight-hour NAAQS for ozone.

The Department is filing an emergency adoption to make these rule revisions effective immediately. Under these revisions, the SMEs will not end until December 31, 2006. Manufacturers will have until May 15, 2007 to sell non-compliant products that were manufactured before January 1, 2005 or were granted a SME. The Department realizes, however, that manufacturers granted one or more SMEs will need time to shift their production to compliant coatings. Both large and small manufacturers who were selling non-compliant coatings manufactured before the new VOC standards took effect need time to liquidate their existing inventories or transfer those inventories to states outside of the OTR with less stringent AIM coatings regulations. The adoption of these revisions on an emergency basis ensures that manufacturers have significant advance notice to react to these rule changes in a timely manner and achieve compliance with Part 205 by the "sell-through" end date.

1. **Types and estimated number of rural areas:** Rural areas are not particularly affected by the revisions. Part 205 will continue to apply on a statewide basis. This is due in large part to the fact that only eleven of the twenty manufacturers granted SMEs are located in New York State. Of the eleven, nine manufacturers are located in NYCMA, and the other two are located in upstate New York in urban/suburban communities. None of the eleven manufacturers are located in rural communities. The impact to rural consumers, if any, is expected to be minimal since there is already a large number of compliant AIM coatings available for retail sale throughout the state.

2. **Reporting, recordkeeping and other compliance requirements:** Part 205 will continue to apply on a statewide basis. Rural areas are not particularly affected by the revisions. Reporting, recordkeeping, and labeling requirements are essentially unchanged since January 2005 when the Part 205 revisions went into effect. Eleven of the current twenty SMEs are for businesses located in New York urban or suburban communities. Rural area businesses are not expected to be effected by these revisions. Professional services are not anticipated to be necessary to comply with this rule.

3. **Costs:** The cost of the proposed regulations will mostly affect the eleven New York urban/suburban businesses that received an SME for certain products. There may be some cost to other manufacturers that still have supplies of AIM coatings manufactured before January 1, 2005, but the Department expects this to be minor. Manufacturers that have existing inventories of product manufactured prior to January 1, 2005 will need to ensure that the product is sold before the "sell-through" end date or moved

out of New York State for sale in other states which do not have an AIM coatings rule.

It is expected that the small manufacturers may have increased costs associated with the production of compliant AIM coatings. The Department is aware of some small manufacturers who, after having been granted a SME, were able to increase sales and market share of their products. These manufacturers will now be required to produce compliant coatings which will have to compete in the market place with the compliant coatings of other manufacturers. Consequently, they might experience reduced profits to the extent they cannot maintain the same level of sales with compliant VOC coatings as they did with their higher VOC content coatings. Compliant formulations are available for all coating categories, however, so all manufacturers should be able to access that technology going forward. Department staff believe that the financial effects of this rule are beneficial to the overall market since this rule would no longer provide a market advantage to those companies that received the SMEs or had large inventories of products manufactured before January 2005.

It should be noted that the impact to consumers is expected to be minimal since there are already large amounts of compliant coatings on store shelves (produced by manufacturers that did not receive a SME). Competition from these existing compliant coatings will likely constrain any price increases as manufacturers will not be able to pass on all of their costs to the consumers. This is likely to control any actual retail price increases. Eleven of the current twenty SMEs are for businesses located in New York urban or suburban communities, rural area businesses are not expected to be effected by these revisions.

4. Minimizing adverse impact: Part 205 was not anticipated to have an adverse effect on rural areas when it was promulgated in 2003 and took effect in January 2005. To date, the Department is unaware of any particular adverse impacts experienced by rural areas as a result of the promulgation of Part 205 in 2003. Rather, the rule is intended to create air quality benefits for the entire state, including rural areas, through the reduction of ozone forming pollutants. These revisions are not expected to adversely impact on rural areas since many of the products affected are currently not sold in rural areas and compliant products are available in all coating categories statewide to meet all consumer needs. Ending the SMEs by December 31, 2006 and establishing a May 15, 2007 "sell-through" end date ensures a fair and level playing field for all AIM coatings manufacturers and, more importantly, that the State, as a whole, can achieve compliance with the NAAQS for ozone in a timely manner.

5. Rural area participation: Rural areas are not particularly affected by the revisions. Eleven of the current twenty SMEs were granted to businesses located in New York, all of which are located in urban or suburban communities and non are located in rural areas. Consequently, the Department did not see a need to reach out to rural communities.

Job Impact Statement

1. Nature of impact: The Department of Environmental Conservation (the Department) proposes to revise Part 205 to implement two rule changes. First, the Department proposes to modify the provision in section 205.7 whereby small manufacturers could apply for and obtain an exemption from VOC content limits through December 31, 2007, with the option to apply to renew the exemption for an additional three years. Under the Department's proposal, this exemption, otherwise known as the small manufacturers' exemption or "SME", will now end on December 31, 2006, one year earlier, and cannot be extended thereafter. These businesses must stop manufacturing non-complying products by December 31st and will have to reformulate their AIM coatings to comply with the content limits in Part 205 if they do not already have compliant formulations. The Department is aware that some manufacturers already have compliant formulations and thus will be able to make this transition easily. Second, the Department proposes to include a "sell-through" provision so that products manufactured before January 1, 2005, or granted a SME, and which do not meet Part 205 VOC content limits cannot continue to be sold indefinitely. Companies will have until May 15, 2007 to liquidate their existing inventory or move it out of the State. In most cases, manufacturers have already sold all products manufactured before 2005 or will be able to sell it before May 15, 2007 and will therefore, not be adversely impacted by this rule.

These revisions are not expected to have an adverse impact on jobs and employment opportunities in the State. Part 205 has applied Statewide since it was promulgated in 2003 and it will continue to apply on a statewide basis. Since the VOC content limits went into effect on January 1, 2005, there has been no evidence of an adverse impact on employment as a result of regulating AIM coatings. If anything, these revisions will have a positive economic impact in terms of placing all AIM manufacturers on a level economic playing field.

2. Categories and numbers affected: This rule will affect eleven in-State and nine out-of-State small manufacturers who were granted a SME by the Department. In addition, the rule will affect manufacturers who have remaining inventories of AIM coatings manufactured prior to January 1, 2005 that does not comply with Part 205 VOC content limitations.

3. Regions of adverse impact: The Department does not expect there to be regions of adverse impact in the State. The VOC emission limits in Part 205 have applied state-wide since January 1, 2005, and there has been no resulting adverse impact on any particular region of the State. Of the eleven in-state manufacturers who were granted a SME, nine are located in the New York City Metropolitan Area (NYCMA). The Department, however, expects that these coatings manufacturers will be able to readily reformulate their products through the purchase of commercially available technology and that there will be no adverse impact on employment as a result of this rule making.

4. Minimizing adverse impact: The Department is providing advance notice of these rule revisions to the regulated community so that companies have sufficient time to take the necessary steps to come into compliance with Part 205. These steps include reformulating products and ensuring that existing inventories of non-complying products are sold prior to May 15, 2007, or moved out of the State. Compliant formulations are available for all AIM coating categories and are currently being sold throughout the State. The Department, therefore, does not anticipate any adverse impacts on employment from the adoption of these rule revisions. The Department, moreover, believes that this rule will have a positive economic impact on the AIM coatings market because all manufacturers will be operating on a level playing field. Competition will likely constrain manufacturers from passing on production costs to consumers. In sum, the Department does not expect this regulation to have an adverse effect on employment in the State.

5. Self employment opportunities: Not applicable.

PROPOSED RULE MAKING HEARING(S) SCHEDULED

New Source Review for New Modified Facilities

I.D. No. ENV-47-06-00008-P

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

Proposed action: This is a consensus rule making to amend section 621.4(g)(2)(iii) of Title 6 NYCRR.

Statutory authority: Environmental Conservation Law, sections 70-0107 and 3-0301(2)(m); and State Administrative Procedure Act, section 301(3)

Subject: New source review for new modified facilities.

Purpose: To correct the name of 6 NYCRR, Part 231; and delete the reference to the Federal Prevention of Significant Deterioration (PSD) regulations. Failure to do so will result in regulation implementation difficulties.

Public hearing(s) will be held at: 9:00 a.m., Jan. 9, 2007 at Department of Environmental Conservation, 625 Broadway, Rm. 129B, Albany, NY.

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

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

Text of proposed rule: Section 621.1 through Subparagraph (ii) of section 621.4(g)(2) remains unchanged.

All of Subparagraph (iii) of section 621.4(g)(2) is repealed, a new Subparagraph (iii) of section 621.4(g)(2) is added as follows:

(iii) projects subject to major new source review permitting under Part 231 of this Title (New Source Review for New and Modified Facilities);

Subparagraph (iv) of section 621.4(g)(2) through Section 621.19 remains unchanged

Text of proposed rule and any required statements and analyses may be obtained from: Robert D. Bielawa, P.E., Department of Environmental Conservation, Division of Air Resources, 625 Broadway, Albany, NY 12233, (518) 402-8396, e-mail: airsips@gw.dec.state.ny.us

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

Public comment will be received until: Five days after the last scheduled public hearing required by statute.

Additional matter required by statute: Pursuant to article 8 of the State Environmental Quality Review Act, a Short Environmental Assessment Form, a Negative Declaration and a Coastal Assessment Form have been prepared and are on file.

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

Consensus Rule Making Determination

Currently proposed amendments to 6 NYCRR Part 231, "New Source Review for New and Modified Facilities", necessitate that Subparagraph (iii) of section 621.4(g)(2) be amended to reference the revised title of 6 NYCRR Part 231 and to delete the reference to the federal Prevention of Significant Deterioration (PSD) regulations which the Department is no longer implementing.

6 NYCRR Part 621.4(g)(2)(iii), which currently states that "projects subject to major new source preconstruction permitting under Part 231 of this Title (Nonattainment Areas) or the federal Prevention of Significant Deterioration regulations under 40 CFR 52.21 (Attainment Areas, see Part 200 of this Title)" will be amended to state "projects subject to major new source review permitting under Part 231 of this Title (New Source Review for New and Modified Facilities)".

No person is likely to object to the amendments to Part 621 as proposed. If the Department does not amend 6 NYCRR Part 621.4(g)(2)(iii) to reference Part 231 as currently proposed, there could be implementation difficulties because Part 621 would not conform to the current version of Part 231.

Job Impact Statement

Nature of impact:

Currently proposed amendments to 6 NYCRR Part 231, "New Source Review for New and Modified Facilities", necessitate that Subparagraph (iii) of section 621.4(g)(2) be amended to correct the name of 6 NYCRR Part 231 and to delete the reference to the federal Prevention of Significant Deterioration (PSD) regulations. The amendment to Subparagraph (iii) of section 621.4(g)(2), like the amendments to 6 NYCRR Part 231, will not have any impact on jobs and employment opportunities. The amendment to 6 NYCRR 621.4(g)(2)(iii) needs to be promulgated as soon as possible after the adoption 6 NYCRR Part 231 to avoid implementation difficulties.

Categories and numbers affected:

There are no categories of jobs or employment opportunities affected by the amendment to Subparagraph (iii) of section 621.4(g)(2).

Regions of adverse impact:

There are no adverse impacts associated with the amendment to Subparagraph (iii) of section 621.4(g)(2).

Minimizing adverse impact:

There are no adverse impacts associated with the amendment to Subparagraph (iii) of section 621.4(g)(2).

Self-employment opportunities:

Not applicable.

event of a health crisis to these medically fragile residents. Presently, emergency medication kits are limited as to their content and facilities are not permitted to have certain medications including controlled substances in the emergency kits. Delay in responding to resident needs because a medication is not immediately available in the facility, and has to be secured from the pharmacy, is resulting in needless suffering on the part of nursing home residents.

Subject: Nursing home pharmacy regulations.

Purpose: To make available in nursing homes, emergency medication kits, a wider variety of medications to respond to the needs of residents. Allow verbal orders from a legally authorized practitioner.

Text of emergency rule: Subdivisions (g) and (i) of Section 415.18 are amended to read as follows:

Section 415.18 Pharmacy Services.

* * *

(g) Emergency medications. The facility shall ensure the provision of (an) emergency medication kit(s) as follows:

(1) The contents of each kit shall be approved by the medical director, pharmacist and director of nursing.

(2) [Controlled Substances shall be prohibited in emergency kits.] *Limited supplies of controlled substances for use in emergency situations may be stocked in sealed emergency medication kits.*

(i) *Each such kit may contain up to a 24 hour supply of a maximum of ten different controlled substances in unit dose packaging, three of which may be injectable drugs.*

(ii) *Controlled substances contained in emergency medication kits may be administered by authorized personnel pursuant to an order of an authorized practitioner to meet the immediate need of a resident. Personnel authorized to administer controlled substances shall include registered professional nurses, licensed practical nurses or other practitioners, licensed/registered under Title VIII of the Education Law and authorized to administer controlled substances.*

(iii) *The facility shall maintain all records of controlled substances furnished or transferred from the pharmacy and the disposition of all controlled substances in emergency kits, as required by article 33 of the Public Health Law and corresponding regulations.*

(3) *For medications other than controlled substances [The] the medication contents of each kit shall be limited to injectables except that the kit may also include:*

(i) sublingual nitroglycerine; and

(ii) [up to five] noninjectable[,] prepackaged medications not to exceed a 24-hour supply [; which are the same noninjectable, prepackaged medications in all emergency kits throughout the facility.]. *The total number of noninjectables may not exceed 25 medications for the entire facility.*

(4) Each kit shall be kept and secured within or near the nurses' station.

* * *

(i) Verbal orders. All medications administered to residents shall be ordered in writing by a legally authorized practitioner unless unusual circumstances justify a verbal order, in which case the verbal order shall be given to a licensed nurse, or to a licensed pharmacist, immediately reduced to writing, authenticated by the nurse or registered pharmacist and countersigned by the prescriber within 48 hours. In the event a verbal order is not signed by the prescriber or a *legally designated alternate [physician] practitioner* within 48 hours, the order shall be terminated and the facility shall ensure that the resident's medication needs are promptly evaluated by the medical director or another legally authorized prescribing practitioner.

This notice is intended to serve only as a notice of emergency adoption. This agency intends to adopt the provisions of this emergency rule as a permanent rule, having previously published a notice of proposed rule making, I.D. No. HLT-50-05-00004-P, Issue of December 14, 2005. The emergency rule will expire January 4, 2007.

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

Regulatory Impact Statement

Statutory Authority:

These regulation revisions of 10 NYCRR Section 415.18, Pharmacy Services, in nursing homes, are proposed under the authority granted to the Commissioner of Health under PHL Section 2803. The PHL outlines the responsibility to conduct inspections of health care facilities to determine compliance with statutes and regulations promulgated under the provisions of those statutes and authorizes the commissioner to propose rules, regula-

Department of Health

EMERGENCY RULE MAKING

Nursing Home Pharmacy Regulations

I.D. No. HLT-50-05-00004-E

Filing No. 1331

Filing date: Nov. 6, 2006

Effective date: Nov. 6, 2006

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

Action taken: Amendment of section 415.18(g) and (i) of Title 10 NYCRR.

Statutory authority: Public Health Law, section 2803

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

Specific reasons underlying the finding of necessity: There is an increasing need to have available to nursing home residents a wider number of antibiotic and pain management medications to respond quickly in the

tions and amendments thereto for consideration by the State Hospital Review and Planning Council "the Council". The Council, by a majority vote of its members, shall amend rules and regulations, subject to the approval of the commissioner, to effectuate the provisions and purposes as stated in the PHL.

Legislative Objectives:

The Department of Health possesses the comprehensive responsibility for the development and administration of programs, standards and methods of operation, and all other matters of policy with respect to nursing home services. Furthermore, through the Social Security Act, the federal government authorizes the State to administer programs and services through Medical Assistance (*i.e.*, Medicaid). This includes responsibility for standards of care within those settings, in order to ensure the health needs of recipients are met. These amended regulations will enable nursing homes to respond more quickly and efficiently to the health care needs of residents requiring emergency medications. The regulation will ensure the protection of the nursing home resident and promote the highest quality of care.

Needs and Benefits:

This proposal to amend 10 NYCRR sections 415.18(g) and 415.18(i) responds to the fact that current regulations for nursing home emergency medication kits and verbal orders are outdated and not in keeping with actual practice.

The State's nursing homes provide a variety of clinical services which were not anticipated when the current pharmacy services regulations were promulgated. The Rug-II case mix reimbursement methodology which began in 1986, has allowed nursing homes to open their doors to residents who require resources which were previously unavailable. Currently, nursing homes accept residents whose clinical needs at one time were met in a hospital. In addition, some nursing homes have units that address the unique needs of special populations such as HIV, traumatic brain injury (TBI), or ventilator residents.

The present regulation, section 415.18(g), provides for emergency medication kits but limits the contents to injectables. It also provides for the kit to contain sublingual nitroglycerine and up to five noninjectable prepackaged medications. At the time this regulation was promulgated, the extensive array of oral medications currently available did not exist and emergency medications were primarily viewed in terms of injectable medications. With the greater complexity of clinical conditions often seen in today's nursing home, resident issues of pain management have taken on greater significance. The availability of oral medications for pain and the wide range of antibiotics that did not exist at the time the regulations were written would significantly affect how nursing homes could respond to an emergency need of a resident.

The present regulations call for the contents of the emergency medication kits to be identical on every unit throughout the facility. At a time when the needs of residents were similar in terms of clinical management, this made sense. However, with nursing homes providing care to special populations including HIV, TBI and ventilator care, this requirement inhibits the most efficient use of emergency medications kits to best meet the unique clinical needs of special populations. When promulgated, these regulations were seeking to address concerns that facilities would establish "mini" pharmacies by having a wide range of noninjectables in the emergency medication kit and that the presence of a high number of medications may result in administration errors. With safe product packaging that is present today, safety concerns have been significantly reduced. Therefore, the proposed regulation eliminates the cap of up to five noninjectable prepackaged medications per each kit. In addition, the proposed regulation changes would limit the total number of noninjectables that would be available in emergency kits for the entire facility to no more than twenty-five. This would further ensure resident safety and eliminate the concern that nursing homes might stock an unlimited amount of noninjectables in the emergency kits. The proposed revisions would also allow for the presence of controlled substances in nursing home emergency kits. This would allow for the nursing home to respond quickly to pain management concerns that are a major issue for some residents.

Regulations at 415.18 (i) provide that all medications administered to residents shall be ordered in writing by a legally authorized practitioner unless unusual circumstances justify a verbal order. At the time the original regulations were promulgated only physicians could order medications. The proposed changes would insert the phrase designated alternate practitioner in place of designated alternate physician. This change would be reflective of current practices in which other prescribers, such as a nurse practitioner can order medications.

Costs:

Costs to Regulated Parties:

There will be no additional costs to regulated parties.

Costs to State and Local Government:

There will be no additional costs to State or local governments.

Costs to the Department of Health:

There will be no additional costs to the Department.

Local Government Mandates:

The proposed regulation imposes no program, duty, service, or other responsibility upon any city, town, village, school, fire or other special district.

Paperwork:

The regulation imposes no additional reporting requirements, forms or other paperwork.

Duplication:

The regulation does not duplicate any federal or state regulation.

Alternative Approaches:

No alternative approaches were considered, since all nursing homes would be allowed flexibility in determining the contents of the emergency medication kit in their facility.

Federal Standards:

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

Compliance Schedule:

The proposed regulation will be effective upon filing with the Secretary of State.

Regulatory Flexibility Analysis

Effect on Small Business and Local Government:

For the purposes of this Regulatory Flexibility Analysis, small businesses are considered any nursing home within New York State which is independently owned and operated, and employs 100 individuals or less. Approximately 100 nursing homes would therefore be considered "small businesses".

Compliance Requirements:

The regulation would impose no additional recordkeeping or other affirmative acts.

Professional Services:

The regulation would impose no additional professional services.

Compliance Costs:

The regulation would impose no additional costs.

Economic and Technical Feasibility Assessment:

The proposed regulation would impose no compliance requirements which would raise technological or feasibility issues.

Minimizing Adverse Impact:

The agency considered the approaches listed in section 202-b(1) of SAPA and found them inapplicable. The regulation would impose no adverse impact on small businesses or local governments.

Small Business and Local Government Input:

The regulation would have no impact on small businesses and local governments. The regulation is supported by provider and consumer groups and feedback from these groups have been gathered. The proposed revisions have been sent to the Codes and Regulations Committee of the Council and have appeared on the agenda of the Codes and Regulations Committee which is made up of representatives of groups that have as their members representatives of small business and local government.

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 44 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	Saratoga	

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:

The regulation would impose no additional reporting, recordkeeping or other affirmative acts.

Professional Services:

The regulation would not require additional professional services.

Compliance Costs:

The regulation would not impose additional costs.

Minimizing Adverse Impact:

The regulation would not result in any adverse economic impact on providers. The agency considered the approaches listed in section 202-bb(2) of SAPA and found them inapplicable.

Opportunity for Rural Area Participation:

The following groups are in support of the modification of 10 NYCRR 415.18:

- New York Association of Homes and Services for the Aging
- Nursing Home Community Coalition
- New York State Health Facilities Association
- New York State Office for Aging Long Term Care Ombudsman
- Health Facility Association of New York
- New York State Board of Pharmacy

New York Chapter of the American Society of Consulting Pharmacists

The proposed revisions will be sent to the Code Committee of the Council and appear on the agenda of the Code Committee which is made up of representatives of groups that have as their members representatives of rural areas.

Job Impact Statement

A Job Impact Statement is not necessary because it is apparent from the nature and purpose of the proposed regulation that it will not have a substantial adverse impact on jobs or employment opportunities. The proposal simply clarifies what drugs can be stocked in emergency medication kits, as well as who may sign verbal orders.

Assessment of Public Comment

The agency received no public comment.

**EMERGENCY
RULE MAKING**

Controlled Substances in Emergency Kits

I.D. No. HLT-50-05-00005-E

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

Action taken: Amendment of sections 80.11, 80.47, 80.49 and 80.50 of Title 10 NYCRR.

Statutory authority: Public Health Law, section 3308(2)

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

Specific reasons underlying the finding of necessity: We are proposing that these regulations be adopted on an emergency basis because immediate adoption is necessary to protect the public health and safety. Having consulted closely with administrators, nursing personnel and consultant pharmacists of Class 3a health care facilities (nursing homes, and other long-term facilities), the Department has determined that the current Part 80 and Part 400 regulations do not ensure timely access to controlled substances by practitioners and patients when immediate administration is medically necessary. However, for purposes of this emergency justification, Class 3a institutional dispenser, Class 3a facility, and Class 3a health-care facility shall not mean an adult care facility subject to the provisions of Title 18 NYCRR Parts 487, 488 and 490. The proposed regulations exempt such adult care facilities from its provisions.

Current regulations require controlled substances to be administered to patients in Class 3a facilities only pursuant to a prescription. On urgent occasions, such as when a patient suffers a sudden seizure or onset of acute pain, the severity of the situation may make it impossible for a practitioner to first issue a prescription to promptly treat the condition. Even if a practitioner is able to first issue a prescription in an emergency, the prescription may not immediately be dispensed by a pharmacy. In these

situations, a patient is deprived of timely relief from severe symptoms and suffering.

The proposed amendments will allow controlled substances to be maintained in an emergency medication kit in a Class 3a facility and administered to a patient in an emergency situation. To simultaneously protect the public health against the potential for diversion of such drugs, the amendments also specify limitations on their quantities, recordkeeping requirements for their administration, and security requirements for their safeguarding. Immediate adoption of these regulations is necessary to enhance and ensure the quality of health care of every patient in a long-term care facility. Ensuring timely access to controlled substances for immediate administration during medical emergencies will result in substantial benefit to the public health and safety.

Subject: Controlled substances in emergency kits.

Purpose: To allow class 3A facilities to obtain, possess and administer controlled substances in emergency kits.

Text of emergency rule: Paragraph (6) of subdivision (b) of Section 80.11 is amended to read as follows:

(6) [be] not *be*, and not have been, a habitual user of narcotics or any other habit-forming drugs.

Paragraph (6) of subdivision (c), of Section 80.11 is amended to read as follows:

(6) [be] not *be*, and not have been, an habitual user of narcotics or other habit-forming drugs; and

Subdivision (f) of Section 80.11 is amended to read as follows:

(f) Persons conducting distributing activities of controlled substances within the State of New York shall obtain a class 2 license from the department, *except that:*

(1) *Except in an adult care facility subject to the provisions of Title 18 NYCRR Parts 487, 488 and 490, a pharmacy may distribute a controlled substance to a practitioner in a Class 3a institutional dispenser limited solely for stocking in sealed emergency medication kits. Such distribution shall be pursuant only to a written request by the Class 3a facility indicating the name and address of the facility, the name and address of the pharmacy, the date of the request, the type and quantity of the drug requested and the signature of the authorized person making the request. With each distribution, the pharmacy shall provide the Class 3a facility with an itemized list indicating the name and address of the pharmacy, the name and address of the Class 3a facility, the date of the distribution, the type and quantity of the drug distributed, and the signature of the pharmacist.*

Section 80.47 is amended by creating subdivisions (a), (b) and (c) and new subdivision (b) is amended to read as follows:

Section 80.47 Institutional dispenser, limited. (a) Nursing homes, convalescent homes, health-related facilities, *adult care facilities subject to the provisions of Title 18 NYCRR Parts 487, 488 and 490* [homes for the aged], dispensaries or clinics not qualifying as institutional dispensers in license class 3 shall apply for an institutional dispenser, limited license. Such institutional dispensers qualifying for controlled substances privileges shall obtain a class 3a license from the department.

(b) An institutional dispenser licensed in class 3a may administer controlled substances to patients only pursuant to a prescription issued by an authorized physician or other authorized practitioner and filled by a registered pharmacy; except that [an] *controlled substances in emergency medication kits may be administered to patients as provided in Section 80.49(d) of this Part, except in an adult care facility subject to the provisions of Title 18 NYCRR Parts 487, 488 and 490.*

(c) An institutional dispenser, limited, licensed in class 3a, which is operated as an integral and physical part of a facility licensed as a class 3 institutional dispenser may be provided with bulk stocks of controlled substances obtained pursuant to such class 3 institutional dispenser license. Records of distribution and administration of such bulk stocks of controlled substances shall be kept as provided in section 80.48(a) of this Part.

Subdivision (c) of section 80.49 is amended and a new subdivision (d) is added to read as follows:

(c) A separate record shall be maintained of the administration of *prescribed* controlled substances indicating the date and hour of administration, name and quantity of controlled substances, name of the prescriber, patient's name, signature of person administering and the balance of the controlled substances on hand after such administration.

(d) *In an emergency situation, a controlled substance from a sealed emergency medication kit may be administered to a patient by an order of an authorized practitioner. An oral order for such controlled substance shall be immediately reduced to writing and a notation made of the*

condition which required the administration of the drug. Such oral order shall be signed by the practitioner within 48 hours.

(1) For purposes of this subdivision, emergency means that the immediate administration of the drug is necessary and that no alternative treatment is available.

(2) A separate record shall be maintained of the administration of controlled substances from an emergency medication kit. Such record shall indicate the date and hour of administration, name and quantity of controlled substances, name of the practitioner ordering the administration of the controlled substance, patient's name, signature of the person administering and the balance of the controlled substances in the emergency medication kit after such administration.

(3) The institutional dispenser limited shall notify the pharmacy furnishing controlled substances for the emergency medication kit within 24 hours of each time the emergency kit is unsealed, opened, or shows evidence of tampering.

Subdivision (e) of section 80.50 is amended and a new paragraph (1) is added to read as follows:

(e) Except as provided in paragraph (1) of this subdivision, [I]nstitutional dispensers limited may only possess controlled substances prescribed for individual patient use, pursuant to prescriptions filled in a registered pharmacy. These controlled substances shall be safeguarded as provided in subdivision (d) of this section.

(1) Except for adult care facilities subject to the provisions of Title 18 NYCRR Parts 487, 488 and 490, institutional dispensers limited may possess limited supplies of controlled substances in sealed emergency medication kits for use as provided in section 80.49(d) of this Part. Each kit may contain up to a 24-hour supply of a maximum of ten different controlled substances in unit dose packaging, no more than three of which may be in an injectable form. Each kit shall be secured in a stationary, double-locked system or other secure method approved by the Department.

This notice is intended to serve only as a notice of emergency adoption. This agency intends to adopt the provisions of this emergency rule as a permanent rule, having previously published a notice of proposed rule making, I.D. No. HLT-50-05-00005-P, Issue of December 14, 2005. The emergency rule will expire January 4, 2007.

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

Regulatory Impact Statement

Statutory Authority:

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

Section 3321(1)(b) authorizes the commissioner to make regulations that exempt a pharmacy from the licensing requirements of article 33 for the sale of controlled substances to a practitioner for the immediate needs of the practitioner receiving such substances.

Legislative Objectives:

Article 33 of the Public Health Law, officially known as the New York State Controlled Substances Act, was enacted in 1972 to govern and control the possession, prescribing, manufacturing, dispensing, administering, and distribution of licit controlled substances within New York. Section 3300-a expressly states that one of the statute's purposes is to allow the legitimate use of controlled substances in health care.

Needs and Benefits:

This regulation effectuates the above stated legislative purpose of section 3300-a of the New York State Controlled Substances Act. It will ensure timely access to controlled substances by practitioners and patients for emergency situations in extended care facilities and other health care facilities licensed by the Department as Class 3a, institutional dispenser limited. (See section 3302(18) of the Public Health Law for the definition of "institutional dispenser".) However, for the purpose of this impact statement, Class 3a institutional dispenser, Class 3a facility, and Class 3a healthcare facility shall not mean an adult care facility subject to the provisions of Title 18 NYCRR Parts 487, 488 and 490.

Section 80.47 of Title 10 regulations requires that controlled substances be administered to patients in healthcare facilities licensed by the Department as Class 3a institutional dispensers limited (*i.e.*; nursing homes, convalescent homes, health-related facilities, adult homes, homes for the aged, correctional facilities) only pursuant to a prescription issued

by an authorized practitioner. The regulation also requires that such prescriptions must be dispensed by a registered pharmacy.

Administrators, nursing personnel, and consultant pharmacists of Class 3a facilities have expressed their concern to the Department that the prescription requirements of Section 80.47 are a restriction to timely access to controlled substances by practitioners and patients when immediate administration is medically necessary. On urgent occasions such as a sudden seizure or onset of intractable pain, the severity of the situation may make it impossible for a practitioner to first issue a prescription for the drug in order to promptly treat the condition. Further, Class 3a facilities do not have onsite pharmacies. Even if a practitioner is able to first issue a prescription for a controlled substance to treat a patient in an emergency, that prescription may not immediately be dispensed by an outside pharmacy because the pharmacy may be too distant from the Class 3a facility or the emergency may have occurred during the pharmacy's non-business hours. These situations can, and do, result in needed medications not being administered in a timely fashion to relieve a patient's severe symptoms or suffering.

The proposed amendment to Section 80.47 of the regulations authorizes the administration of a controlled substance from an emergency medication kit to a patient in an emergency situation in a Class 3a healthcare facility. Necessary complements to this amendment are the proposed amendments to Sections 80.11(f), 80.49 and 80.50(e) of Title 10 regulations. The proposed change to Section 80.11(b)(6) is merely grammatical.

The amendment to Section 80.11(f) authorizes a licensed pharmacy to supply controlled substances to a practitioner in a Class 3a facility for stocking in emergency medication kits. The amendments to Section 80.50(e) authorize a Class 3a healthcare facility to possess a limited supply of controlled substances in an emergency medication kit and specify limitations on the quantities of such substances and requirements for their safeguarding. The amendment to Section 80.49 specifies recordkeeping requirements for controlled substances administered from emergency kits. When instituted together, these amendments will provide for timely access to controlled substances by practitioners and patients in the long-term care facility environment while simultaneously requiring adequate measures to ensure the security of such substances.

The federal Drug Enforcement Administration (DEA) also recognizes the need for storing controlled substances in emergency kits for administration to patients during urgent situations in long-term care facilities that are not eligible to hold a DEA registration. Since 1980, the DEA has issued a Statement of Policy containing guidelines for state regulatory agencies to follow when authorizing long-term care facilities to maintain such kits. Such guidelines have been incorporated in the proposed regulatory amendments.

The proposed regulatory amendments will enhance the quality of care of every patient in a long-term care facility licensed by the Department of Health. Such regulation will result in substantial benefit to the public health, which the Department has both a civic and legislative responsibility to ensure.

Costs:

Costs to Regulated Parties

Healthcare facilities licensed as Class 3a institutional dispensers limited already possess required secure cabinets for safeguarding controlled substances. Such secure cabinets can also safeguard emergency kits containing controlled substances. Those facilities choosing to maintain such emergency kits will incur minimal costs to do so. These costs will be reflected in the purchase of the limited supplies of controlled substances and the sealable emergency kits required to secure and store them.

Costs to State and Local Government

There will be no costs to state or local government.

Costs to the Department of Health

There will be no additional costs to the Department.

Local Government Mandates:

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

Paperwork:

Class 3a healthcare facilities are currently required by regulations to keep records of the receipt of all controlled substances prescribed for individual patients. Such facilities are also required to record all controlled substances dispensed and administered to such patients. These recordkeeping requirements would include the requisition and receipt of controlled substances for stocking in emergency medication kits.

Practitioners authorized to prescribe controlled substances are required by regulations to make a notation in a patient record of all controlled

substances prescribed for that patient. The amendment to Section 80.47 requires that the administration of a controlled substance to a patient from an emergency kit in a Class 3a facility be pursuant to the written or oral medical order of a practitioner.

The Department anticipates a minimal increase in paperwork documenting the requisition, distribution, medical order, and administration of controlled substances contained in emergency medication kits. Such increase will be more than offset by the enhancement of healthcare for patients in the long term care environment.

Duplication:

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

Alternatives:

The intent of the proposed regulation is to ensure access to controlled substance medications when urgently needed. The department believes it is in the best interest of the public health to authorize such accessibility to relieve pain or suffering. There are no alternatives that would ensure accessibility to controlled substances by practitioners and patients for emergency situations in long term care facilities and other health care facilities licensed as Class 3a, institutional dispenser limited.

Federal Standards:

The regulatory amendment does not exceed any minimum standards of the federal government. This amendment achieves consistency with existing federal and New York State laws and regulations promulgated to authorize the legitimate use of controlled substances in health care.

Compliance Schedule:

These regulations will become effective immediately upon filing a Notice of Emergency Adoption with the Secretary of State. At that time, in order that the public health derive maximum benefit from this regulatory amendment, all Class 3a license holders will be authorized to possess and administer controlled substances in an emergency medication kit to meet the immediate, legitimate need of a patient.

Regulatory Flexibility Analysis

Effect of Rule on Small Business and Local Government:

This proposed rule will affect practitioners, pharmacists, retail pharmacies, and nursing homes and other healthcare facilities licensed by the Department as Class 3a institutional dispensers limited. Local government will only be affected if it operates one of the above facilities.

According to the New York State Department of Education, Office of the Professions, as of April, 2003, there were 113,666 licensed and registered practitioners authorized to prescribe and order the administration of controlled substances. However, this rule will affect only those practitioners who prescribe or order the administration of controlled substances for patients and residents of long term care facilities or supply such facilities with controlled substances for emergency medication kits.

According to the New York State Board of Pharmacy, as of June 30, 2003, there were a total of 4,521 pharmacies in New York State. Of these, 60 are sole proprietorship, 297 are partnerships, 73 are small chains (fewer than 3 pharmacies per chain) and the rest are large chains or other corporations (some of which may be small businesses) or located in public institutions. According to the New York State Education Department's Office of the Professions, as of April 1, 2003, there were 18,950 licensed and registered pharmacists in New York. However, this rule will affect only those pharmacies and pharmacists that dispense prescriptions for controlled substances to patients and residents of long term care facilities or supply such facilities with controlled substances for emergency medication kits.

Of the 1,282 healthcare facilities licensed by the department as Class 3a institutional dispensers limited, the rule will affect only those facilities that choose to maintain controlled substances in emergency medication kits. However, for the purpose of this impact statement, Class 3a institutional dispenser, Class 3a facility, and Class 3a healthcare facility shall not mean an adult care facility subject to the provisions of Title 18 NYCRR Parts 487, 488 and 490.

Compliance Requirements:

There are no compliance requirements. While the proposed amendment authorizes Class 3a facilities to possess and administer controlled substances from emergency medication kits, the regulation does not require such facilities to do so.

Professional Services:

No additional professional services are necessary.

Compliance Costs:

Other than the cost of the controlled substances and sealable emergency medication kits for those Class 3a facilities choosing to possess such kits, there are no compliance costs associated with the proposed regulation.

Economic and Technological Feasibility:

The proposed rule is both economically and technologically feasible. Class 3a healthcare facilities that choose to possess and administer controlled substances from emergency medication kits will use existing equipment for security and recordkeeping requirements.

The Department anticipates that these facilities will incur minimal expenditures for limited supplies of controlled substances and the sealable emergency kits in which to store them. Such expenditures will be more than offset by the enhancement of medical care for patients in Class 3a healthcare facilities.

Minimize Adverse Impact:

The agency considered the approaches in section 202-b(1) of SAPA and found them inapplicable. The proposed regulation minimizes any adverse impact by not requiring pharmacies to supply controlled substances to Class 3a facilities for emergency medication kits. Pharmacies are authorized to engage in such activity strictly on a voluntary basis.

Small Business and Local Government Participation:

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

During the drafting of this regulation, the Department met with the Pharmaceutical Society of the State of New York (PSSNY), the Chain Pharmacy Association of New York State, the New York Council of Health Systems Pharmacists, and the New York State Chapter of American Society of Consultant Pharmacists.

Rural Area Flexibility Analysis

Types and Estimated Numbers of Rural Areas:

The proposed rule will apply to participating pharmacies and Class 3a healthcare facilities located in all rural areas of the state. Outside of major cities and metropolitan population centers, the majority of counties in New York contain widespread rural areas. These can range in extent from small towns and villages, and their surrounding areas, to locations that are very sparsely populated.

Compliance Requirements:

There are no compliance requirements. The proposed amendment authorizes pharmacies to distribute limited supplies of controlled substances to Class 3a facilities for maintaining in emergency medication kits. The regulation also authorizes those healthcare facilities to possess and administer controlled substances to patients from such kits in an emergency situation. However, these actions are undertaken on a voluntary basis by both pharmacy and healthcare facility. The regulation does not require either party to participate.

Present regulations require pharmacies and Class 3a facilities to maintain specified records of dispensing, receipt, and administration of controlled substances. The proposed regulation requires a minimum of additional record-keeping to ensure limited access to emergency medication kits and safeguarding of the controlled substances contained therein. However, for the purpose of this impact statement, Class 3a institutional dispenser, Class 3a facility, and Class 3a healthcare facility shall not mean an adult care facility subject to the provisions of Title 18 NYCRR Parts 487, 488 and 490.

Professional Services:

Pharmacies already employ the professional services of licensed and registered pharmacists. Class 3a healthcare facilities employ the services of practitioners, nurses, and consultant pharmacists. The proposed regulation would require no additional professional services, either public or private, in rural areas.

Compliance Costs:

Compliance costs to pharmacies opting to distribute limited supplies of controlled substances to Class 3a facilities will be negligible, since these pharmacies already maintain an existing inventory of such controlled substances. Other than the cost of the controlled substances and the sealable medication kits in which to store them, the compliance cost to Class 3a facilities choosing to possess such kits will be minimal.

Economic and Technological Feasibility:

The proposed rule is both economically and technologically feasible. Class 3a healthcare facilities that choose to possess and administer controlled substances from emergency medication kits will use existing equipment for security and recordkeeping requirements.

The Department anticipates that these facilities will incur minimal expenditures for limited supplies of controlled substances and the sealable emergency kits in which to store them. Such expenditures will be more than offset by the enhancement of medical care for patients in Class 3a healthcare facilities.

Minimizing Adverse Impact:

The agency considered the approaches in Section 202-bb(2) of SAPA and found them inapplicable.

In ensuring access to controlled substances for legitimate medical treatment by practitioners and patients in Class 3a healthcare facilities, the proposed amendment does not impose any adverse impact upon rural areas. In fact, because in a rural setting pharmacies supplying prescriptions for controlled substances may be located at increased distances from long term care facilities, it is anticipated that these healthcare facilities would derive maximum benefit for their patients by being authorized to maintain limited supplies of controlled substances in sealed medication kits for use in emergency situations.

Rural Area Participation:

During the drafting of this regulation, the Agency met with and solicited comment from consultant pharmacists to Class 3a facilities, many of which are located in rural areas. It was the overwhelming consensus that pharmacists could better meet and greatly enhance the healthcare of the patients they serve in such facilities by being authorized to supply controlled substances for emergency medication kits. Administrative and nursing personnel in such facilities have also voiced to the Agency their need for emergency access to controlled substances for administration to patients to alleviate suffering in urgent situations. The agency addressed many of these concerns in the proposed regulation.

Job Impact Statement

Nature of Impact:

This proposal will not have a negative impact on jobs and employment opportunities. In benefiting the public health by ensuring access to controlled substances for legitimate healthcare needs, the proposed amendment is not expected to either increase or decrease jobs overall.

Assessment of Public Comment

The agency received no public comment.

EMERGENCY RULE MAKING

Expansion of the New York State Newborn Screening Panel

I.D. No. HLT-47-06-00007-E

Filing No. 1327

Filing date: Nov. 3, 2006

Effective date: Nov. 3, 2006

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

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

Statutory authority: Public Health Law, section 2500-a

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

Specific reasons underlying the finding of necessity: New York State Public Health Law Section 2500-a authorizes the Commissioner of Health to designate additional diseases or conditions for inclusion in the Newborn Screening Program test panel by regulation. This regulatory amendment adds one condition – galactosylceramidase deficiency, or Krabbe disease, a lipid storage disorder – to the 43 genetic/congenital disorders and one infectious disease that comprise New York State's newborn screening test panel, pursuant to existing 10 NYCRR Section 69-1.2. The Department of Health finds that immediate adoption of this rule is necessary to preserve the public health, safety and general welfare, and that compliance with State Administrative Procedure Act (SAPA) Section 202(1) requirements for this rulemaking would be contrary to the public interest and welfare.

Immediate implementation of the proposed screening for Krabbe disease is both feasible and obligatory at this time. A laboratory test method was recently reported in the medical literature as being capable of detecting Krabbe disease using a dried blood spot specimen (*i.e.*, the typical newborn screening sample). Through pilot testing using residual newborn screening specimens stripped of all identifiers, the Department's Wadsworth Center Newborn Screening Program has determined that a scaled-up version of the recently developed test method could reproducibly generate reliable results for the large number of newborn specimens accepted by the Program. The required instrumentation (*i.e.*, tandem mass spectrometers) is already in operation at the Department's Wadsworth Center laboratory dedicated to newborn screening. A system for follow-up and ensuring access to necessary treatment for identified infants is fully established and adequately staffed. Now that the Program is technically proficient in tandem mass spectrometry testing, experienced in spectrometric data collection and interpretation, and has demonstrated proficiency in triage and referral procedures, failure to include Krabbe disease testing immediately

would mean infants would go untested, undetected, and may thus suffer irreversible nerve damage and an early death.

Affected infants typically succumb to Krabbe disease by two to five years of age after an agonizing clinical course. Newborns with Krabbe disease appear normal for the first few months of life, but manifest extreme irritability, spasticity, and developmental delay before six months of age. Without newborn screening, a child may not be recognized with Krabbe disease until he/she develops clinical signs and symptoms. Early detection through screening is critical to successful treatment of Krabbe disease with transplanted donor stem cells. The urgency of the Department's decision to avoid further delays in screening for Krabbe disease was underscored by recent clinical trial findings, published in the *New England Journal of Medicine* in May 2005, which concluded, "Transplantation of umbilical cord-blood from unrelated donors in newborns with infantile Krabbe's disease favorably altered the natural history of the disease. Transplantation in babies after symptoms had developed did not result in substantive neurologic improvement."

To avoid unnecessary and potential medically detrimental delays in screening newborns for Krabbe disease, the amended regulatory language in 10 NYCRR Section 69-1.2 is hereby adopted by emergency promulgation.

Subject: Expansion of the New York State newborn screening panel.

Purpose: To add Krabbe disease to the New York State newborn screening panel and clarify the requirement for timely specimen transfer.

Text of emergency rule: Section 69-1.2 of Subpart 69-1 is amended as follows:

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

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

- argininemia (ARG);
- argininosuccinic acidemia (ASA);
- biotinidase deficiency;
- branched-chain ketonuria, also known as maple syrup urine disease (MSUD);
- carnitine palmitoyl transferase Ia deficiency (CPT-IA);
- carnitine palmitoyl transferase II deficiency (CPT-II);
- carnitine-acylcarnitine translocase deficiency (CAT);
- carnitine uptake defect (CUD);
- citrullinemia (CIT);
- cobalamin A,B cofactor deficiency (Cbl A,B);
- congenital adrenal hyperplasia (CAH);
- cystic fibrosis (CF);
- dienoyl-CoA reductase deficiency (DE REDUCT);
- galactosemia;
- galactosylceramidase deficiency (*Krabbe disease*);
- glutaric acidemia type I (GA-I);
- hemoglobinopathies, including homozygous sickle cell disease;
- homocystinuria;
- human immunodeficiency virus (HIV) exposure and infection;
- 3-hydroxy-3-methylglutaryl-CoA lyase deficiency (HMG);
- hyperammonemia/ornithinemia/citrullinemia (HHH);
- hypermethioninemia (HMET);
- hypothyroidism;
- isobutyryl-CoA dehydrogenase deficiency (IBG or IBCD);
- isovaleric acidemia (IVA);
- long-chain 3-hydroxyacyl-CoA dehydrogenase deficiency (LCHADD);
- malonic aciduria (MAL);
- medium-chain acyl-CoA dehydrogenase deficiency (MCADD);
- medium-chain ketoacyl-CoA thiolase deficiency (MCKAT);
- medium/short-chain hydroxyacyl-CoA dehydrogenase deficiency (M/SCHAD);
- 2-methylbutyryl-CoA dehydrogenase deficiency (2MBG);
- 3-methylcrotonyl-CoA carboxylase deficiency (3-MCC);
- 3-methylglutaconic aciduria (3MGA);
- 2-methyl 3-hydroxy butyryl-CoA dehydrogenase deficiency (2M3HBA);
- methylmalonic acidemia (Cbl C,D);
- methylmalonyl-CoA mutase deficiency (MUT);
- mitochondrial acetoacetyl-CoA thiolase deficiency (BKT);
- mitochondrial trifunctional protein deficiency (TFP);

multiple acyl-CoA dehydrogenase deficiency (MADD, also known as GA-II);

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

Subdivisions (a) and (g) of Section 69-1.3 are amended as follows:

Section 69-1.3 Responsibilities of the chief executive officer. The chief executive officer shall ensure that a satisfactory specimen is submitted to the testing laboratory for each newborn born in the hospital, or admitted to the hospital within the first twenty-eight (28) days of life from whom no specimen has been previously collected, and that the following procedures are carried out:

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

* * *

(g) All specimens shall be allowed to air dry thoroughly on a flat nonabsorbent surface for a minimum of four (4) hours prior to [transmittal] forwarding to the testing laboratory. All specimens shall be forwarded to the testing laboratory within twenty-four (24) hours of collection [by first class mail] using the testing laboratory's delivery service or [its] an equivalent arrangement designed to ensure delivery of specimens to the testing laboratory no later than forty-eight (48) hours after collection.

This notice is intended to serve only as a notice of emergency adoption. This agency intends to adopt this emergency rule as a permanent rule and will publish a notice of proposed rule making in the *State Register* at some future date. The emergency rule will expire January 31, 2007.

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

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:

This proposal, which would add one condition – galactosylceramidase deficiency, or Krabbe disease – to the list of 43 genetic/congenital disorders and one infectious disease currently in regulation, is in keeping with the Legislature's public health aims of early identification and timely medical intervention for all the State's youngest citizens.

Needs and Benefits:

Data compiled from New York State's Newborn Screening Program ("Program") and other states' programs have shown that timely intervention and treatment for metabolic disorders can drastically improve affected infants' survival chances and quality of life. For Krabbe disease, early detection through screening is critical to successful treatment.

Krabbe disease is a lipid storage disorder caused by a deficiency of the enzyme galactosylceramidase; it occurs with an incidence of approximately one in 100,000 births.

Affected infants typically succumb to Krabbe disease by two to five years of age after an agonizing clinical course. Newborns appear normal for the first few months of life but manifest extreme irritability, spasticity, and developmental delay before six months of age. Regression in psychomotor development results in feeding difficulties and marked hypertonicity, and eventually progresses to loss of voluntary movement. The infants become deaf and blind, and are prone to pneumonia and other infections; death from infection is common. However, Krabbe disease can be treated if detected early. Treatment is primarily by hematopoietic stem cell transplant using donor cord blood samples. Without newborn screening, a child may not be recognized as having Krabbe disease until he/she develops clinical signs and symptoms.

Costs:

Costs to Private Regulated Parties:

Birthing facilities will incur no new costs related to collection and submission of newborn blood specimens to the Program, since the same dried blood spot specimens now collected and forwarded to the Program for other currently available testing would also be tested for Krabbe dis-

ease. Starting in 2005, the Department began to offer free-of-cost delivery services to deter birthing facilities from bundling specimens to save postage costs, and encourage timely shipment of individual newborn specimens; birthing facilities do not incur postage or other delivery costs for the pre-paid delivery service.

The Program estimates that 150 to 200 newborns would screen positive for the new condition annually. Since timing is crucial, i.e., treatment must be started early to be effective, newborns that screen positive – those with low activity of the affected enzyme, galactosylceramidase, as measured in the dried blood spot specimen – will undergo DNA-based molecular analysis, using the same specimen submitted for the initial enzyme test. Infants determined to carry mutations associated with Krabbe disease will require a confirmatory test that measures enzyme activity using a liquid blood specimen. Positive screening results are expected to be confirmed in an estimated 10 to 50 percent of infants who undergo the confirmatory enzyme activity testing. These 15 to 100 infants will be referred for additional diagnostic workup, including: a measurement of protein in spinal fluid; a brain stem evoked auditory response (BAER) test; and magnetic resonance imaging (MRI) to assess white matter in the brain. Results from the entire battery of tests will be reviewed by an advisory committee to the Department, comprised of experts in metabolic disorders and Krabbe disease detection and treatment, and representing facilities with a role in ensuring successful implementation of this proposal. If an infant is determined to be afflicted with Krabbe disease, a pre-established communications system will be activated, and plans for treatment begun immediately. The Department anticipates that more than 95 percent of referred infants will ultimately be found not to be afflicted with Krabbe disease, based on laboratory test and clinical assessment data.

Specialized care centers (i.e., medical centers with facilities for, and staff expert in, diagnosis and treatment of inherited metabolic diseases), local hospitals designated by such centers, and pediatricians in private practice would likely incur minimal costs related to fulfilling their responsibilities for specimen collection to perform additional laboratory testing and referral of screening-positive infants for diagnostic services; such costs would be limited to human resources costs of approximately 0.5 person-hour. Specialized care centers, and to a lesser extent local hospitals and independent providers, will incur additional human resources costs for supplying diagnostic and treatment services, and ongoing medical management to the approximately two to ten infants per year whose disorder is confirmed. Costs of laboratory testing for infants who screen positive for Krabbe disease include an estimated \$200 for confirmatory enzyme analysis; and, for infants whose results are confirmed, another \$50 for measurement of protein in the infant's spinal fluid, as well as the provider's charge for a lumbar puncture.

For infants with a confirmed diagnosis of Krabbe disease, costs would also be incurred for required clinical services and procedures, including: medical and consultative services rendered by a neurologist, a developmental pediatrician and a hematologist with expertise in stem cell transplantation; HLA typing and chemotherapy; MRI testing to monitor the affected infant's brain post-transplant; and genetic counseling for the family. The actual total cost of all requisite services and procedures to evaluate and treat a newborn with Krabbe disease cannot be assessed more exactly due to the large variations in charges for the professional component of specialists' and ancillary providers' services, and the scope of required services, including the length of time required for hospitalization.

The Department expects that costs of medical services and supplies will be reimbursed by all payor mechanisms now covering the care of children identified with conditions in the current newborn screening panel. The Department also expects that medical care providers will claim reimbursement from payors at a rate equal to the usual and customary charge, thereby recouping costs.

Costs for Implementation and Administration of the Rule:

Costs to State Government:

Although funding for the State's Newborn Screening Program requires State expenditures, proactively treating congenital abnormalities ultimately may result in savings by precluding the need for more financially burdensome medical and institutional services.

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

Costs to the Department:

Costs incurred by the Department's Wadsworth Center for performing newborn screening tests, providing short- and long-term follow-up, and supporting continuing research in neonatal and genetic diseases are covered by State budget appropriations recently augmented by dedicated line-item funding for Program expansion. Starting in 2005, the Department assumed the costs of specimen submission by making a pre-paid delivery service available to birthing facilities. The Program's budget includes \$90,000 for specimen delivery services; however, no part of the expenditure for these services is a direct result of this amendment.

The Program expects to sustain minimal to no additional laboratory instrumentation costs related to this proposal, since the necessary technology is already in place. A system for follow-up and assured access to necessary treatment for identified infants is fully established. No additional staff would be required as a result of this proposal.

The Department will incur costs, estimated at from \$3,800 to \$4,000 annually, to provide specimen collection kits, including materials and postage, to pediatricians for collecting liquid blood specimens from an estimated 200 presumptive-positive infants, and forwarding the specimens by overnight courier for confirmatory testing at one or more laboratories approved by the Department.

Costs to Local Government:

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

Local Government Mandates:

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

Paperwork:

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

Duplication:

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

Alternative Approaches:

Potential delays in detection of Krabbe disease until onset of clinical signs and symptoms would result in increased infant morbidity and mortality, and are therefore unacceptable. Given the strong indications that treatment is available to ameliorate adverse clinical outcomes in affected infants, the Department has determined that there are no alternatives to mandating newborn screening for this condition.

Federal Standards:

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

Compliance Schedule:

The director of the Newborn Screening Program has participated in discussions with representatives of the Governor's Office, the Health Commissioner's Office and the Department's Public Affairs Group to optimize coordinated notification of affected parties and implementation of this single additional test into the newborn screening program. Educational materials for parents and health care professionals have been updated with information on the expanded screening panel. The Program is collaborating with various Department offices, including the Office of Medicaid Management and the Office of Managed Care, to ensure adequate reimbursement and coverage inclusiveness for required follow-up services, including confirmatory and diagnostic testing, treatment and monitoring.

The Department is continuing to work with the State Newborn Screening Task Force members, directors of specialty care centers, national experts in Krabbe disease diagnosis and treatment, health care professionals, and payors on ongoing assessment of the scope of needed follow-up services and their availability. On January 13, 2006, the director of the Newborn Screening Program gave an invited presentation to the North-eastern New York Organization of Nurse Executives, regarding the Department's plans for including Krabbe disease in the screening panel and

the expected impact of such plans on hospitals. On January 30, 2006, participants in a conference on Krabbe disease in New York City reviewed this State's Krabbe disease testing algorithm and plans to ensure the health care infrastructure's readiness to implement this proposal. In addition to staff from several Department offices with a role in the algorithm's implementation, representatives from specialty care centers, transplant facilities, advocacy organizations, a confirmatory testing laboratory, and other interested parties also attended the conference.

Strong support for the amendment is expected from patient advocacy organizations representing affected individuals and families, as well as the medical community at large. The Commissioner of Health is expected to notify all New York State-licensed physicians of this newborn screening panel expansion. The letter will also be distributed to hospital chief executive officers (CEOs) and their designees responsible for newborn screening, as well as other affected parties. There appears to be no potential for organized opposition. Consequently, regulated parties should be able to comply with these regulations as of their effective date, upon filing a Notice of Emergency Adoption with the Secretary of State.

Regulatory Flexibility Analysis**Effect on Small Businesses and Local Governments:**

This proposed amendment to add one new condition – a lipid storage disorder known as galactosylceramidase deficiency, or Krabbe disease – to the list of 43 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 Krabbe disease is operated as a small business. Local government, including the New York City Health and Hospitals Corporation, operates 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 actual 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 the same 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. However, birthing facilities and at-home birth attendants (i.e., licensed midwives) would be required to follow up infants screening positive for Krabbe disease, and assume referral responsibility for medical evaluation and additional testing. This 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. Therefore, the Department expects that regulated parties will be able to comply with these regulations as of their effective date, upon filing a Notice of Emergency Adoption with the Secretary of State.

Professional Services:

No need for additional professional services is anticipated. Birthing facilities' existing professional staffs are expected to be able to assume any increase in workload resulting from the Program's newborn screening for Krabbe disease and identification of screening-positive infants. Infants with positive screening tests for Krabbe disease would be referred to a facility employing a physician and other medical professionals with expertise in Krabbe disease.

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 same 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 Krabbe disease, primarily because the testing proposed under this regulation is expected to result in, on average, fewer than one screening-positive infant per week at each of the 11 birthing facilities that are small businesses. Communicating the need and/or arranging referral for medical evaluation of one additional identified infant would require 0.5 person-hour, and these tasks are expected to be able to be accomplished with existing staff.

Affected small business, and government-operated hospitals and independent providers operating as a small business, such as primary and ancillary care providers (*i.e.*, pediatricians, neurologists and hematologists), may incur additional human resources costs for supplying post-evaluation and treatment services, and ongoing medical management services to the approximately two to three screening-positive infants whose disorder is confirmed. Clinical services and procedures required for an affected infant could include: medical and consultative services rendered by a neurologist, a developmental pediatrician, and a hematologist with expertise in stem cell transplantation; a spinal tap for spinal fluid specimen collection; and genetic counseling for the family. It is unlikely that practitioners and facilities that are small businesses would incur costs related to treatment, such as costs for chemotherapy to depress the immune system prior to transplant; the transplantation procedure itself; laboratory testing; magnetic resonance imaging (MRI) to monitor the affected infant's brain post-transplant; and costs related to the infant's occupying a bed in the neonatal intensive care unit. The cost of all required services and procedures to evaluate and treat newborns with Krabbe disease born annually in New York State cannot be estimated due to large variations in charges for the professional component of specialists' and ancillary providers' services, and the scope of required services. The Department provides the following prevailing rates, so that small businesses that may become involved in treatment and ongoing care of affected infants may be better able to estimate costs: \$300 for a comprehensive-level office visit; \$150 for genetic counseling visits; \$2,500 for imaging services; and \$250 for confirmatory laboratory testing.

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

Economic and Technological Feasibility:

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

Minimizing Adverse Impact:

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

Small Business and Local Government Participation:

The feasibility of adding Krabbe disease to the State's newborn screening panel has been discussed with affected parties ever since the Department began testing for a number of new conditions using tandem mass spectrometry technology. Therefore, regulated parties that are small businesses and local governments have been aware of the Department's intention to include Krabbe disease in the panel for some time.

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 a population density 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 a population density characteristic of rural areas.

This proposed amendment to add one new condition – galactosylceramidase deficiency or Krabbe disease, a lipid storage disorder – to the list of 43 genetic/congenital disorders and one infectious disease for which every newborn in the State must be tested, will affect hospitals, alternative

birthing centers, and physician and midwifery practices located in rural areas, provided such facilities care for infants 28 days of age or under, or are required to register the birth of a child. The Department estimates that 54 hospitals and birthing centers operate in rural areas, and another 30 birthing facilities are located in counties with low-population density townships. No facility recognized as having medical expertise in clinical assessment and treatment of Krabbe disease 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, since the same 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 Krabbe disease, 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 a Notice of Emergency Adoption 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 Krabbe disease and identification of screening-positive infants. Infants with a positive screening test for Krabbe disease will be referred to a facility employing a physician and other medical professionals with expertise in Krabbe disease.

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 same 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 0.5 person-hour, and these tasks are expected to be able to be accomplished with existing staff. 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 confirmatory testing data.

Rural providers, including clinical specialists (*i.e.*, medical geneticists) and primary and ancillary care providers (*i.e.*, pediatricians, neurologists and hematologists), may incur additional human resources costs for providing post-evaluation and treatment services, and ongoing medical management to the approximately two to three infants per year whose disorder is confirmed. Clinical services and procedures required for an affected infant could include: medical and consultative services rendered by a neurologist, a developmental pediatrician, and a hematologist with expertise in stem cell transplantation; a spinal tap procedure for spinal fluid specimen collection; laboratory testing; and genetic counseling for the family. It is unlikely that facilities in rural areas would incur costs related to treatment, such as costs for chemotherapy to depress the immune system prior to transplant; the transplantation procedure itself; magnetic resonance imaging (MRI) to monitor the affected infant's brain post-transplant; and costs related to the infant's occupying a bed in the neonatal intensive care unit. The cost of all requisite services and procedures to evaluate and treat infants with Krabbe disease born annually in New York State cannot be estimated due to large variations in charges for the profes-

sional component of specialists' and ancillary providers' services, and the scope of requisite services, including the length of time required for hospitalization. To the extent specialized services would be delivered in a rural area, the Department provides the following prevailing rates, so that rural providers who may become involved in treatment and ongoing care of affected infants may be better able to estimate costs: \$300 for a comprehensive-level office visit; \$150 for genetic counseling visits; \$2,500 for imaging services; and \$250 for confirmatory laboratory testing.

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

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 testing to statewide infant public health and welfare. These amendments will not have an adverse impact on the ability of regulated parties in rural areas to comply with Department requirements for mandatory newborn screening, as full compliance would entail minimal changes to present collection, reporting, follow-up and recordkeeping practices.

Rural Area Participation:

The feasibility of adding Krabbe disease to the newborn screening panel has been discussed with affected parties ever since the Department began testing for a number of new conditions using tandem mass spectrometry technology. Therefore, regulated parties located in rural areas have been aware of the Department's intention to include Krabbe disease in the panel for some time.

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 one condition – a lipid storage disorder known as Krabbe disease – to the scope of newborn screening services already 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.

NOTICE OF ADOPTION

Inpatient Medical Orders

I.D. No. HLT-32-06-00002-A

Filing No. 1328

Filing date: Nov. 3, 2006

Effective date: Nov. 22, 2006

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

Action taken: Amendment of section 94.2 of Title 10 NYCRR.

Statutory authority: Public Health Law, sections 3308, 3701 and 3703

Subject: Inpatient medical orders.

Purpose: To allow the supervising physician and the hospital to determine if countersignature of RPA inpatient medical orders is necessary. Currently such countersignature is mandatory.

Text or summary was published in the notice of proposed rule making, I.D. No. HLT-32-06-00002-P, Issue of August 9, 2006.

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

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

Assessment of Public Comment

The agency received no public comment.

PROPOSED RULE MAKING NO HEARING(S) SCHEDULED

Department of Health Fees for the Operational Period

I.D. No. HLT-47-06-00004-P

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

Proposed action: Repeal of section 87.22 and addition of section 400.22 to Title 10 NYCRR.

Statutory authority: Public Health Law, sections 2868 and 2881; and Public Authorities Law, section 2976-A3

Subject: Increase Department of Health fees for the operational period.

Purpose: To increase Department of Health fees as allowed by the State budget.

Text of proposed rule: Section 87.22 is hereby repealed in its entirety and Reserved.

[Section 87.22 – Charges for the operational period

87.22 Charges for operational period. (Public Health Law, 2868, 2881) The governmental supervising agency charges for the operational period from occupancy date to mortgage discharge shall be an annual charge of two-tenths of one percent of the mortgage loan, payable monthly to the State Department of Health by the mortgagor. Adjustments of charges for the operational period shall be made by adjusting future operational period payments.] Reserved

A new Section 400.22 is added to Part 400 to read as follows:

400.22 Charges in connection with certain health care facility financings. (Public Health Law, Sections 2868, 2881, Public Authorities Law, Section 2976-a(3)) In connection with the issuance of bonds, notes, or other obligations issued by public benefit corporations (which for purposes of this section shall include the Dormitory Authority of the State of New York and industrial development agencies (IDAs) created pursuant to title one of article eighteen – A of the general municipal law or any other provision of law) for the financing of hospital projects approved by the Commissioner for which reimbursement is provided pursuant to Article 28 of the Public Health Law, the commissioner shall charge for the operational period of such financing which shall be from occupancy date to mortgage discharge, an annual charge of three-tenths of one percent of the mortgage loan, for inspection, regulation, supervision and audit payable monthly to the State Department of Health by the mortgagor. Adjustments of charges for the operational period shall be made by adjusting future operational period payments. For purposes of this section, the term "hospital" shall have the same meaning as is set forth in subdivision one of section twenty-eight hundred one of the public health law.

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

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

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

Regulatory Impact Statement

Statutory Authority:

Public Health Law (PHL) sections 2868 and 2881 authorize the Commissioner of Health to establish and charge eligible nursing home and hospital borrowers under PHL Articles 28-A and 28-B such fees and charges for inspection, regulation, supervision and audit as the Commissioner may determine to be just and reasonable in order to recover departmental costs in performing these functions. New section 2976-a(3) of the Public Authorities Law allows the Commissioner of Health to charge such fees from eligible nursing home and hospital borrowers if they are financed by Industrial Development Agencies (IDA).

Legislative Objectives:

The legislative objective is to provide additional funding to ensure the continued monitoring of nursing home and hospital mortgage loans and to cover equally all such financings.

Needs and Benefits:

Many hospitals and other health facilities throughout the State have become obsolete and are no longer adequate to meet the needs of modern medicine. As a result of rapid technological changes, such facilities require substantial structural or functional changes. Others have become unsuited for continued use by virtue of their location and the physical characteristics of their existing plants. Such inadequate and outmoded facilities deny the people of the State the benefits of health care of the highest quality, efficiency, and modernization promptly provided at a reasonable cost. Their replacement and modernization is essential to protect and prolong the lives of the state's population and cannot readily be accomplished by the ordinary unaided operation of private enterprise. It is the purpose of this fee increase to continue the supervision and regulation of these facili-

ties regardless of whether they are financed under Article 28-A or 28-B of the Public Health Law or by IDA.

Costs to State Government:

There will be no additional costs to state government.

Costs of Local Government:

There will be no additional costs to local government.

Costs to Private Regulated Parties:

The operational fees charged by the Department of Health will increase by one-tenth of one percentage point for Article 28-A and 28-B financed facilities, and the proposal will establish an operational fee of .3% for IDA financed facilities. The annual increase in costs for such financings will be approximately \$4 million.

Costs to the Department of Health:

There will be no additional costs to the Department of Health.

Local Government Mandates:

This regulation does not pose any program, service, duty, or other responsibility on any county, city, town, village, school, fire district, or other special district.

Paperwork:

There is no additional paperwork for providers.

Duplication:

These regulations do not duplicate existing state or federal regulations.

Alternatives:

The increased fees are the result of revenue increasing initiatives allowed by State law. Therefore, there are no alternatives for the increased revenues available other than through this regulation change.

Federal Standards:

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

Compliance Schedule:

The proposed regulation establishes a required fee increase for certain facility financing that will be billed by the Department of Health when the regulation has been officially promulgated.

Contact Person:

Mr. William R. Johnson
 NYS Department of Health
 Office of Regulatory Reform
 Empire State Plaza
 Room 2415, Corning Tower
 Albany, New York 12237
 (518) 473-7488
 (518) 486-4834 FAX
 REGSQNA@health.state.ny.us

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

Regulatory Flexibility Analysis

Effect on Small Business:

For the purpose of this analysis, small businesses are considered to be not-for-profit general hospitals, diagnostic and treatment centers, and nursing homes with 100 or fewer full time employees. Based upon recent financial and statistical data from the Institutional Cost Report, there are 8 not-for-profit general hospitals, 31 long-term care facilities and 191 diagnostic and treatment centers that were identified as employing 100 or fewer employees. The minimum bond issue for a Dormitory Authority financing is in excess of \$5 million. Although the IDA threshold is considerably lower, the cost associated with long-term capital financing through bond issuance is generally prohibitive for small financings.

Compliance Requirements:

There are no mandatory compliance requirements as a result of these amendments. Facilities with the applicable financing will be billed the .3% fee.

Professional Services:

No new additional professional services are required in order for providers to comply with these amendments.

Compliance Costs:

There are no initial capital costs as a result of complying with these amendments. The annual increase in fees for the applicable financings will be approximately \$4 million.

Minimizing Adverse Impact:

The proposed amendments will have minimal economic impact. The operational fee charged by the Department will increase only by one-tenth of one percentage point for Article 28-A and 28-B projects and by .3% for IDA projects. The Department considered the approaches in Section 202-b(1) of SAPA and found them inapplicable.

Economic and Technological Feasibility Assessment:

There will be no effect on the economic or technological feasibility of small businesses. Billing of the new fees will be the responsibility of Department of Health staff.

Opportunity for Small Business and Local Government Participation:

Small business and local governments will have an opportunity to participate through publication of a general notice of proposed rule making.

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 44 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	Sequoia	Washington
Franklin	Putnam	Wayne
Fulton	Rensselaer	Wyoming
Genesee	St. Lawrence	Yates
Greene	Saratoga	

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:

There will be no additional reporting, record keeping, or other compliance requirements with the proposed rule. Facilities with the applicable financing will be billed the .3% fee.

Professional Services:

There will be no additional professional services that will be needed in a rural area to comply with the proposed rule.

Compliance Costs:

Not-for-profit facilities financing capital projects through the use of Dormitory Authority or Industrial Development Agency bonds will be required to submit payment calculated at three-tenths of one percent of the mortgage loan to the Department of Health. The annual increase in fees for the applicable financings will be approximately \$4 million.

Minimizing Adverse Impact:

The minimum bond issue for a Dormitory Authority financing is in excess of \$5 million. Although the IDA threshold is considerably lower, the cost associated with long-term capital financing through bond issuance is prohibitive for small financings. Considering rural areas generally have small facilities providing care, the adverse impact will be minimized due to limits on the availability of issuing bonds for small facilities. The Department considered the approaches in Section 202-b(1) of SAPA and found them inapplicable. Also, the operational fee charged by the Department will increase only by one-tenth of one percentage point for Article 28-A and 28-B projects and by .3% for IDA projects.

Opportunity for Rural Area Participation:

Rural areas will have the opportunity to participate through publication of a general notice of proposed rulemaking.

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 or employment opportunities. The proposed rule simply establishes an increased Department of Health operational fee for certain financed facilities.

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

**SPARCS Definition of Ambulatory Surgical Procedures
 I.D. No. HLT-47-06-00005-P**

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

Proposed action: This is a consensus rule making to amend section 400.18 of Title 10 NYCRR.

Statutory authority: Public Health Law, section 2803(2)

Subject: SPARCS definition of ambulatory surgical procedures.

Purpose: To improve reporting to SPARCS of surgical procedures performed in freestanding and hospital-based ambulatory surgery centers.

Text of proposed rule: Paragraph (1) of subdivision (a) of Section 400.18 is amended to read as follows:

(1) New York State Statewide Planning and Research Cooperative System (SPARCS) shall mean a statewide centralized health care system which incorporates data submitted to the department by hospitals pursuant to universal data set specifications and subdivision (b) of this section, the patient review instrument data submitted by residential health care facilities pursuant to section 86-2.30 of this Title, ambulatory surgery data submitted by hospital-based and freestanding centers pursuant to subdivision (d) of this section [and section 755.10 of this Title], and emergency services data submitted by hospitals pursuant to subdivision (h) of this section.

Paragraph (14) of subdivision (a) of Section 400.18 is amended to read as follows:

(14) Ambulatory Surgery Data Abstract Project (ASDAP) shall mean the data format used by hospital based and free-standing ambulatory surgery centers to report to the Department of Health pursuant to subdivision (d) of this section [and section 755.10 of this Title].

Subdivision (d) of Section 400.18 is amended to read as follows:

(d) [Data from hospital-based ambulatory surgery services] *Ambulatory surgery data.*

[(1) All hospitals certified by the department to provide hospital-based ambulatory surgery services shall submit to the department for each patient surgical visit the following information and such additional elements as are approved by the commissioner upon finding that they are recommended by the National Uniform Billing Committee and the National Committee on Vital and Health Statistics or are necessary for permitted uses of SPARCS data:

- (i) SPARCS hospital identification number;
- (ii) an identity-shielded patient record number;
- (iii) the patient's birth date, sex and ZIP code;
- (iv) the date of the visit;
- (v) the hour of admission and discharge for the visit;
- (vi) operating room time used;
- (vii) principal diagnosis code;
- (viii) principal procedure code;
- (ix) other procedure code;
- (x) primary reimbursement code;
- (xi) county of the patient's residence;
- (xii) the disposition of the patient on discharge from the service;
- (xiii) physician's or dentist's license number; and
- (xiv) method of anesthesia used.]

(1) *All facilities licensed under article 28 of the Public Health Law that provide ambulatory surgery services shall submit in an electronic format for each patient surgical visit that requires a stay of less than 24 hours any procedure listed in the American Medical Association Current Procedural Terminology (CPT) as prescribed by the commissioner to be maintained on an annual basis, including but not limited to all procedures in the Surgery Section of CPT.*

(2) Facilities shall submit or cause to be submitted such correct or corrected data in computer-readable format according to specifications provided by the commissioner. Any hospital-owned magnetic media will be returned to the hospital subsequent to receipt by the department.

(3) Facilities certified by the department to provide hospital-based ambulatory surgery services shall submit such data within 30 days of the end of each calendar quarter.

(4) Facilities which do not submit data or corrected data within 30 days of receipt of the department's error report concerning such data will not be reimbursed under section 86-1.41 of this Title until compliance with this section is certified in writing by the commissioner or his or her designee.

(5) Requests for deniable individual or aggregate data or data reports based on data submitted pursuant to this section shall be processed pursuant to subdivision (e) of this section.

(6) *Nothing in this section shall be construed to authorize the performance of procedures for which appropriate approval has not been obtained under part 709 and part 710 of this Title.*

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

Consensus Rule Making Determination

Statutory Authority:

The statutory authority for the promulgation of these regulations is contained in section 2803(2) of the Public Health Law which authorizes the State Hospital Review and Planning Council to adopt and amend rules and regulations, subject to the approval of the Commissioner.

Basis:

Because the parties that will be affected by the proposed rule have indicated that they support a broadened definition of ambulatory surgery for SPARCS reporting purposes, the Department does not expect to receive any comments in opposition to the proposed revision following its publication in the State Register. In developing the proposed rule, the Department consulted the New York State Association of Ambulatory Surgery Centers (NYSAAASC), which represents the majority of freestanding ambulatory surgery centers (ASCs) in New York State, and which supports the proposed revision. In addition, both the Greater New York Hospital Association (GNYHA) and the Healthcare Association of New York State (HANYNS), whose members operate hospital-based ASCs, have had the opportunity to review the draft rule and have urged that it be approved.

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 a substantial adverse impact on jobs and employment opportunities. The hospital-based and freestanding ambulatory surgery centers affected by the proposed rule will need to continue to employ their current medical records and administrative personnel who typically compile and submit the required data to the Department of Health. Although the Department expects that most regulated parties will be able to comply with the new rule with existing staff, to the extent that it increases the reporting of ambulatory surgical procedures to DOH, the proposed rule will expand employment opportunities for medical records and administrative staff in ambulatory surgery centers.

PROPOSED RULE MAKING NO HEARING(S) SCHEDULED

Continuing Care Retirement Communities

I.D. No. HLT-47-06-00006-P

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

Proposed action: This is a consensus rule making to amend section 901.9 of Title 10 NYCRR.

Statutory authority: Public Health Law, section 4602(2)(g)

Subject: Notification and submission requirements for continuing care retirement communities.

Purpose: To define the approvals required for any change in the current approved number of residential or health care units comprising the continuing care retirement community.

Text of proposed rule: A new subdivision (f) is added to Section 901.9 to read as follows:

(f) *Any physical restructuring of the community which results in an addition or loss in the number of independent living units, adult care facility units or residential health care facility beds previously approved under the community's Certificate of Authority shall require only the prior approval of the Commissioner, with the advice and consent of the Superintendent, and, if required, the advice and consent of the Attorney General; provided, however, that any change in the number of previously approved adult care facility units or residential health care facility beds must receive all required Department approvals prior to approval of the Commissioner. Establishment of a residential health care facility component and/or an adult care facility component, not previously approved under the community's Certificate of Authority, shall require the prior approval of the Continuing Care Retirement Community Council.*

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

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

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

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

Consensus Rule Making Determination

Statutory Authority:

Article 46 of the Public Health Law ("PHL") provides statutory authority for the establishment and operation of continuing care retirement communities ("CCRCs") in New York State. This proposal is authorized pursuant to PHL Sections 4602(2)(g) and 4603(8). Section 4602(2)(g) authorizes the Continuing Care Retirement Community Council ("Council") to adopt rules and regulations and amendments thereto to effectuate the provisions of Article 46. PHL Section 4603(8) authorizes the Commissioner to promulgate rules and regulations and amendments thereto that have been adopted by the Council to effectuate the provisions of Article 46.

Basis:

The proposed rule establishes a review and approval process for a CCRC that requests certain changes in the community's configuration after its application for a Certificate of Authority has been approved by the Council. Presently, requests for such reconfigurations are reviewed and approved by relevant state agency staff and then presented to the Council for another formal review. This extended review and approval process has been problematic for communities working within financing deadlines. Consequently, the Council has determined that its approval is not necessary in those instances when a community is proposing a change in the number of independent living units, adult care facility units or residential health care facility beds previously approved under its Certificate of Authority. Such reconfiguration requests will continue to be reviewed by appropriate state agency staff. Approval of such requests will be vested in the Commissioner, with the advice and consent of the Superintendent and, if required, the advice and consent of the Attorney General. Any request for a change in the number of previously approved adult care facility units or residential health care facility beds must also receive all required Department approvals prior to the Commissioner's approval. Proposals to establish an adult care facility component or residential health care facility component, not previously approved under the community's Certificate of Authority, will require the prior approval of the Council.

This rule is being proposed as a consensus rule since it is unlikely that there will be any objections to it. The proposed rule will provide a more streamlined approval process for requests made by CCRCs for certain community reconfigurations. The CCRCs which submit such requests have had no objections to the proposed rule since they will benefit from the expedited review and approval process and the Council has itself recommended the change.

Job Impact Statement

A Job Impact Statement is not required pursuant to section 201-a(2)(a) of the State Administrative Procedure Act, since it is apparent from the nature and purpose of the rule that it will not have a substantial adverse impact on jobs and employment opportunities. The effect of the proposed rule will be to establish a more efficient approval process when a continuing care retirement community requests approval to reconfigure the number of independent living units, adult care facility units or residential health care facility beds previously approved under its Certificate of Authority.

Office of Mental Health

EMERGENCY RULE MAKING

Personalized Recovery-Oriented Services

I.D. No. OHM-47-06-00002-E

Filing No. 1325

Filing date: Nov. 2, 2006

Effective date: Nov. 2, 2006

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

Action taken: Repeal of Part 512 and addition of new Part 512 to Title 14 NYCRR.

Statutory authority: Mental Hygiene Law, sections 7.09(b), 31.04(a), 41.05, 43.02(a), (b) and (c); Social Services Law, sections 364(3) and 364-a(1)

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

Specific reasons underlying the finding of necessity: In order to continue to provide essential services to individuals now served by Personalized Recovery-Oriented Services Programs (PROS) and to prevent a loss of services to potential recipients as new PROS programs are approved, it is necessary to adopt this regulation on an emergency basis.

Subject: Program and fiscal requirements for personalized recovery-oriented services.

Purpose: To establish revised standards for personalized recover-oriented services.

Substance of emergency rule: (14 NYCRR Part 512)

This rule will repeal the current Part 512 which established a new licensed program category for Personalized Recovery-Oriented Services (PROS) programs. It will adopt a new Part 512 which has significant clarifications and expanded guidance. The revisions are noted in this summary.

OVERVIEW OF CURRENT STANDARDS

The purpose of PROS programs is to assist individuals to recover from the disabling effects of mental illness through the coordinated delivery of a customized array of rehabilitation, treatment and support services. Such services are available both in traditional program settings and in off-site locations where such individuals live, learn, work or socialize. Providers are expected to create a therapeutic environment which fosters awareness, hopefulness and motivation for recovery, and which supports a harm reduction philosophy.

Depending upon program configuration and licensure category, PROS programs are required to include the following four components:

1) Community Rehabilitation and Support (CRS): designed to engage and assist individuals in managing their illness and in restoring those skills and supports necessary to live in the community.

2) Intensive Rehabilitation (IR): designed to intensively assist individuals in attaining specific life roles such as those related to competitive employment, independent housing and school. The IR component may also be used to provide targeted interventions to reduce the risk of hospitalization or relapse, loss of housing or involvement with the criminal justice system, and to help individuals manage their symptoms.

3) Ongoing Rehabilitation and Support (ORS): designed to assist individuals in managing symptoms and overcoming functional impairments as they integrate into a competitive workplace. ORS interventions focus on supporting individuals in maintaining competitive integrated employment. Such services are provided off-site.

4) Clinical Treatment: designed to help stabilize, ameliorate and control an individual's symptoms of mental illness. Clinical Treatment interventions are expected to be highly integrated into the support and rehabilitation focus of the PROS program. The frequency and intensity of Clinical Treatment services must be commensurate with the needs of the target population.

There are 3 license categories for PROS programs: Comprehensive PROS with clinical treatment (provides all 4 components), Comprehensive PROS without clinical treatment (provides CRS, IR and ORS components), and limited license PROS (provides IR and ORS components only).

All PROS providers, regardless of licensure category, are required to offer individualized recovery planning services and pre-admission screening services. Furthermore, depending on the licensure category, providers are required to offer a specified array of services that are delineated in Part 512. Any additional services may be offered if they are clinically appropriate and approved in advance by OMH. Persons eligible for admission to a PROS program must: be 18 years of age or older; have a designated mental illness diagnosis; have a functional disability due to the severity and duration of mental illness; and have been recommended for admission by a licensed practitioner of the healing arts. Such recommendation may be made by a member of the PROS staff, or through a referral from another provider.

A PROS provider is required to continuously employ an adequate number and appropriate mix of clinical staff consistent with the objectives of the program and the number of individuals served. Providers must maintain an adequate and appropriate number of professional staff relative to the size of the clinical staff. In Comprehensive PROS programs, at least one of the members of the provider's professional staff must be a licensed practitioner of the healing arts, and must be employed on a full-time basis. IR services must be provided by, or under the direct supervision of, professional staff. The regulation provides that if a PROS provider has recipient employees, such employees must adhere to the same requirements as other PROS staff, and must receive specified training regarding confidentiality requirements.

An Individualized Recovery Planning process must be carried out by, or under the direct supervision of, a member of the professional staff, and must be in collaboration with the individual and any persons the individual has identified for participation. The regulation sets out the contents and the time frames for development of the Individualized Recovery Plan (IRP).

The regulation provides standards and requirements that must be met in order for providers to receive Medicaid reimbursement. The reimbursement is a monthly case payment based on the services provided to a PROS participant or collateral in each of the PROS components and the total amount of program participation for the individual during the month. The rate of payment will be a monthly fee determined by the Commissioner and approved by the Division of the Budget. Fee schedules, based on defined Upstate and Downstate geographic area, are included in the regulation.

Part 512 also addresses requirements relating to the content of the case record, co-enrollment in PROS and other mental health programs, quality improvement, organization and administration, governing body, recipient rights, and physical space and premises.

REVISIONS REGARDING REIMBURSEMENT METHODOLOGY

To ensure that the PROS reimbursement standards more clearly support the programmatic intent of the PROS model, and more clearly articulate the billing expectations, the Office of Mental Health (OMH), in collaboration with the Department of Health, has revised the PROS reimbursement methodology. While the concept of a monthly tiered case payment is unchanged, the building blocks of the methodology are now based on program "units."

PROS units are determined by a combination of program participation (measured in time) and service frequency (measured in number), and are accumulated during the course of each day that the individual participates in the PROS program. The units are then aggregated to a monthly total to determine the level of the PROS monthly base rate that can be billed each month. These program units support the billing concept of a "modified threshold visit."

- Program participation is defined as the length of allowable time that recipients or collaterals participate in the PROS program, both on-site and off-site.

- Scheduled meal periods or planned recreational activities that are not specifically designated as medically necessary are excluded from the calculation of program participation.

- Time spent in the provision of services with collaterals, other than a period of the program day that is simultaneously being credited to the recipient, may be included in the calculation of program participation.

- An individual must have at least 15 minutes of continuous program participation within a program day to accumulate any units.

- Program participation is measured and accumulated in 15 minute increments. Increments of less than 15 minutes must be rounded down to the nearest quarter hour to determine the program participation for the day.

- Service frequency is defined as the number of medically necessary services delivered to a recipient, or his or her collateral, during the course of a program day.

- A minimum of one service must be delivered during the course of a program day to accumulate any units.

- Services provided in a group format must be at least 30 minutes in duration.

- Services provided in an individual modality must be at least 15 minutes in duration.

- Medically necessary PROS services include:

- Crisis intervention services;

- Pre-admission screening services;

- Services provided in accordance with the screening and admission note; and

- Services provided in accordance with the IRP.

- PROS units are calculated in accordance with the following rules:

- PROS units are accumulated in .25 increments.

- The maximum number of PROS units per individual per day is five.

- The formula for accumulating PROS units during a program day is as follows:

- If one medically necessary PROS service is delivered, the number of PROS units is equal to the duration of program participation, rounded down to the nearest quarter hour, or two units, whichever is less.

- If two medically necessary PROS services are delivered, the number of PROS units is equal to the duration of program participation, rounded down to the nearest quarter hour, or four units, whichever is less.

- If three or more medically necessary PROS services are delivered, the number of PROS units is equal to the duration of program participation, rounded down to the nearest quarter hour, or five units, whichever is less.

- A minimum of two PROS units must be accrued for an individual during a calendar month in order to bill the monthly base rate.

- Under the revised methodology, providers will continue to bill on a monthly case payment basis.

- To determine the monthly base rate, the daily PROS units accumulated during the calendar month are aggregated and translated into one of the five payment levels. While the current rate codes and billing process will continue to be utilized, new PROS rates are effective for the 2006-07 State fiscal year. The 2005-06 rate adjustment for OMH licensed clinics has been applied to the PROS Clinical Treatment rate.

REVISIONS REGARDING DOCUMENTATION

The PROS documentation standards have been revised in order to clarify the recordkeeping requirements for documenting medical necessity, as well as to support the revised reimbursement methodology.

Within a PROS program, evidence of medical necessity is supported through a combination of screening and assessments, the IRP, and periodic progress notes. In an effort to strengthen the evidence of medical necessity within the IRP, consistent with the principles of person-centered planning, the related requirements have been modified to clarify the programmatic intent. To that end, there is a more explicit requirement for an identified connection between an individual's recovery goals, the barriers to the achievement of those goals that are due to the individual's mental illness, and the recommended course of action. Furthermore, there is a more precise requirement related to justifying the need for services that are more expensive or intensive than those in the CRS component (*i.e.*, IR, ORS or Clinical Treatment services). Finally, there are specific and detailed requirements for the documentation of service delivery used as the basis for the monthly bill.

REVISIONS REGARDING GROUP SIZE

In many instances, PROS services will be provided in a group format. While the PROS program model did not contemplate groups of excessive size, the existing regulations did not explicitly address this issue. To ensure that group services are delivered in a clinically optimal manner, the PROS standards are being revised to limit the size of groups. Each CRS or Clinical Treatment group will generally be limited to 12 participants (recipients and/or collaterals) and each IR group will generally be limited to 8 participants (recipients and/or collaterals) with specified exceptions. From a program operations perspective, the size of the groups (consistent with the above limitations) cannot be exceeded on a "regular and routine" basis. This standard will be monitored and addressed through OMH's certification process.

From a fiscal perspective, reimbursement on behalf of participating group members will be subject to certain limits (assuming that all services are medically necessary).

REVISIONS REGARDING STAFFING

As the result of feedback from a variety of stakeholders, two components of the existing PROS staffing requirements are being revised. One of

the modifications relates to the use of psychiatric nurse practitioners in lieu of a portion of the psychiatrist coverage; the second revision relates to the transition of newly licensed providers to full compliance with the professional staffing requirements.

REVISIONS REGARDING REGISTRATION SYSTEM

Following the original promulgation of the PROS regulations, OMH developed and implemented a PROS registration system. The intent of this system is to establish a process whereby PROS providers and other service providers can be informed, at the earliest possible date, of potential co-enrollment situations that are not otherwise authorized. Therefore, the use of the registration system is intended to prevent duplicative Medicaid billing, and thus reduce the need for post-payment adjustments. The PROS regulations have been revised to accommodate the concept of registration.

REVISIONS REGARDING TRANSITION

With the Commissioner's permission, providers operating pursuant to a PROS operating certificate on or before November 1, 2006, may, subject to certain conditions, continue to operate pursuant to the requirements of Part 512 in effect prior to that date.

This notice is intended to serve only as a notice of emergency adoption. This agency intends to adopt this emergency rule as a permanent rule and will publish a notice of proposed rule making in the *State Register* at some future date. The emergency rule will expire January 30, 2007.

Text of emergency rule and any required statements and analyses may be obtained from: Dan Odell, Bureau of Policy, Legislation and Regulation, Office of Mental Health, 44 Holland Ave., Albany, NY 12229, (518) 473-6945, e-mail: dodell@omh.state.ny.us

Regulatory Impact Statement

1. Statutory authority: Subdivision (b) of Section 7.09 of the Mental Hygiene Law grants the Commissioner of the Office of Mental Health (OMH) the authority and responsibility to adopt regulations that are necessary and proper to implement matters under his or her jurisdiction.

Subdivision (a) of Section 31.04 of the Mental Hygiene Law empowers the Commissioner to issue regulations setting standards for licensed programs for the rendition of services for persons with mental illness.

Section 41.05 of the Mental Hygiene Law provides that a local governmental unit shall direct and administer a local comprehensive planning process for its geographic area in which all providers of service shall participate and cooperate through the development of integrated systems of care and treatment for people with mental illness.

Subdivision (a) of Section 43.02 of the Mental Hygiene Law provides that payments under the medical assistance program for services approved by the Office of Mental Health shall be at rates certified by the Commissioner of Mental Health and approved by the Director of the Budget. Subdivision (b) of Section 43.02 of the Mental Hygiene Law gives the Commissioner authority to request from operators of facilities licensed by the OMH such financial, statistical and program information as the Commissioner may determine to be necessary. Subdivision (c) of Section 43.02 of the Mental Hygiene Law gives the Commissioner of Mental Health authority to adopt rules and regulations relating to methodologies used in establishment of schedules of rates for services.

Sections 364(3) and 364-a(1) of the Social Services Law give OMH responsibility for establishing and maintaining standards for medical care and services in facilities under its jurisdiction, in accordance with cooperative arrangements with the Department of Health.

2. Legislative objectives: Articles 7, 31 and 43 of the Mental Hygiene Law reflect the Commissioner's authority to establish regulations regarding mental health programs and establish rates of payments for services under the Medical Assistance program. Sections 364 and 364-a of the Social Services Law reflect the role of the Office of Mental Health regarding Medicaid reimbursed programs.

3. Needs and benefits: The Personalized Recovery-Oriented Services (PROS) initiative creates a framework to assist individuals and providers in improving both the quality of care and outcomes for people with serious mental illness in New York State.

In 2005, OMH, with input from local government, consumers, family members and provider organizations, developed a new Medicaid license: PROS. This license takes advantage of the flexibility offered through the Rehabilitation Option of the Federal Medicaid Program. The license gives local government and providers the ability to integrate multiple programs into a comprehensive rehabilitation service. Providers may combine clubhouses, intensive psychiatric rehabilitation treatment (IPRT) programs and other rehabilitation program categories, reducing fragmentation and increasing continuity of care and accountability for achieving recovery goals. Also, there is the option to incorporate Continuing Day Treatment (CDT) programs and clinical treatment into a PROS license. These two

program categories are currently licensed separately under mental health regulations.

The PROS license gives service providers the ability to support consumers as they progress with their recovery. The purpose of PROS programs is to assist individuals in recovering from the disabling effects of mental illness through the coordinated delivery of a customized array of rehabilitation, treatment and support services. Such services are expected to be available both in traditional program settings and in off-site locations where such individuals live, learn, work or socialize. Providers must create a therapeutic environment which fosters awareness, hopefulness and motivation for recovery, and which supports a harm reduction philosophy.

The PROS program structure combines under one license basic rehabilitation services; time limited, goal focused intensive rehabilitation, which a consumer can access at various points in the recovery process; ongoing mental health supports to individuals who have secured employment; and an optional clinical treatment component, which allows treatment services to be fully integrated into rehabilitation planning and service provision. All these components are coordinated toward a person's recovery using an Individualized Recovery Plan (IRP).

The PROS license is used to advance the adoption on the front lines of care of several scientifically proven practices which have produced superior outcomes for individuals with severe and persistent psychiatric conditions. These include wellness self-management (also referred to as illness management and recovery), family psycho-education, ongoing rehabilitation and support related to the evidence based practice of supported employment, integrated treatment for co-occurring mental illness and substance abuse, and evidence-based medication practices. By using the comprehensive nature of the PROS license and the IRP, these practices will be able to be provided in combination, offering the potential to amplify recovery outcomes.

Providers collect outcome data in the areas of psychiatric hospitalization, emergency room use, contact with the criminal justice system, consumer satisfaction, employment, education and housing stability. These data are used to help determine program effectiveness and each provider will be asked to develop an ongoing quality improvement process using their outcome data.

The design of PROS addresses many of the care delivery system problems. Access to the range of services needed to facilitate recovery will be increased due to the comprehensive nature of the license. The use of an IRP promotes consumer and provider collaboration toward recovery and fosters integration of rehabilitation, support and treatment, thereby reducing fragmentation. The flexibility of the license stimulates creative development of recovery-oriented services. Consumers are allowed to choose services from more than one PROS provider, so consumer choice is preserved. The design encourages a provider to work with a consumer throughout the recovery process, enhancing accountability for outcomes. By collecting outcome data and using it to help improve individual outcomes and program effectiveness, a data-based continuous quality improvement process is introduced. The various aspects of the PROS license, when viewed as a whole, support and encourage a recovery-focused culture and service delivery system.

To ensure that the PROS reimbursement standards more clearly support the programmatic intent of the PROS model, and more clearly articulate the billing expectations, OMH, in collaboration with the Department of Health, has revised the PROS reimbursement methodology. While the current concept of a monthly tiered case payment is unchanged, the building blocks of the methodology are now based on program "units."

PROS units are determined by a combination of program participation (measured in time) and service frequency (measured in number), and are accumulated during the course of each day that the individual participates in the PROS program. The units are then aggregated to a monthly total to determine the level of the PROS monthly base rate that can be billed each month. These program units support the billing concept of a "modified threshold visit." The revised methodology, using units, provides for a more accurate and effective approach to billing.

Under the revised methodology, providers will continue to bill on a monthly case payment basis. To determine the monthly base rate, the daily PROS units accumulated during the calendar month are aggregated and translated into one of the five payment levels. While the current rate codes and billing process will continue to be utilized, new PROS rates are effective for the 2006-07 State fiscal year. The 2005-06 rate adjustment for OMH licensed clinics has been applied to the PROS Clinical Treatment rate.

The PROS documentation standards have been revised in order to clarify the recordkeeping requirements for documenting medical necessity,

as well as to support the revised reimbursement methodology. Within a PROS program, evidence of medical necessity is supported through a combination of screening and assessments, the IRP, and periodic progress notes. In an effort to strengthen the evidence of medical necessity within the IRP, consistent with the principle of person-centered planning, the related requirements have been modified to clarify the programmatic intent. To that end, there will be a more explicit requirement for an identified connection between an individual's recovery goals, the barriers to the achievement of those goals that are due to the individual's mental illness, and the recommended course of action. Furthermore, there will be a more precise requirement related to justifying the need for services that are more expensive or intensive. Finally, there are specific and detailed requirements for documentation of service delivery used as the basis for the monthly bill.

In many instances, PROS services offered will be provided in a group format. While the PROS program model did not contemplate groups of excessive size, the previous regulation did not explicitly address this issue. To ensure that group services are delivered in a clinically optimal manner, the PROS standards have been revised to limit the size of certain groups. From a program operations perspective, the size of the groups cannot be exceeded on a "regular and routine" basis. This standard will be monitored and addressed through OMH's certification process. From a fiscal perspective, reimbursement on behalf of participating group members will be subject to certain limits (assuming that all services are medically necessary).

As the result of feedback from a variety of stakeholders, two components of the existing PROS staffing requirements have been revised. One of the modifications relates to the use of psychiatric nurse practitioners in lieu of a portion of the psychiatrist coverage; the second revision relates to the transition of newly licensed providers to full compliance with the professional staffing requirements.

Following the original promulgation of the PROS regulations, OMH developed and implemented a PROS registration system. The intent of this system is to establish a process whereby PROS providers and other service providers can be informed, at the earliest possible date, of potential co-enrollment situations that are not otherwise authorized. The use of the registration system is intended to prevent duplicative Medicaid billing, and thus reduce the need for post-payment adjustments. The PROS regulations have been revised to accommodate the concept of registration. The revised PROS regulation will support the growth of the PROS program as it develops to its full potential. Note: The Commissioner may permit providers operating pursuant to a PROS operating certificate on or before November 1, 2006, to continue to operate pursuant to the requirements of Part 512 in effect prior to November 1, 2006. Such permission shall be granted only if such providers shall have submitted and the Commissioner shall have approved a transition plan setting forth a timetable for complying with the requirements of this Part.

4. Costs:

a. Any additional costs to existing efficiently and economically run programs that are converting to PROS will be fully funded through the PROS Medicaid fee and/or start-up funding provided by the Office of Mental Health.

b. Sufficient funding has been included in the current enacted budget to enable economically and efficiently run programs to convert to PROS. Approximately 350 providers have programs that are eligible for conversion to PROS. Existing resources associated with these programs include approximately \$251 million in gross program funding, of which \$139 million is State funding, \$14 million is local funding and \$97 million is Federal funding. After conversion to PROS, gross program funding is estimated to be \$283 million of which State resources are \$129 million, local resources are \$14 million and Federal resources are \$140 million. The implementation of PROS is estimated to result in no increase in local funding.

5. Local government mandates: The regulation will not mandate any additional imposition of duties or responsibilities upon county, city, town, village, school or fire districts. The regulation will provide for optimal county involvement in the process of evaluating the quality and appropriateness of PROS programs. Counties may choose to participate in this process with the Office of Mental Health, but it is not required.

6. Paperwork: This rulemaking will require programs that participate to complete the paperwork which is necessary to receive medical assistance payments and will not result in a substantial change in paperwork requirements.

7. Duplication: The regulatory amendment does not duplicate existing State or federal requirements.

8. Alternatives: The only alternative considered was to continue to use the current program and licensing standards without revision. This alternative was rejected because of the need for further clarification of the current standards and additional regulatory guidance to ensure compliance with programmatic intent and federal requirements for Medicaid reimbursement.

9. Federal standards: The regulatory amendment does not exceed any minimum standards of the federal government for the same or similar subject areas.

10. Compliance schedule: The regulatory amendment will be effective November 2, 2006.

Regulatory Flexibility Analysis

A Regulatory Flexibility Analysis is not submitted with this notice because this new rule will not impose an adverse economic impact on small businesses or local governments. This rule, which repeals Part 512, the current regulation authorizing the Personalized Recovery-Oriented Services (PROS) program, and adds a new Part 512, will revise certain PROS program standards including those relating to the process of obtaining reimbursement, reimbursement rates, establishing group size, staffing and registration.

The providers who will be subject to this rule will be organizations that now hold or in the future apply to establish a PROS program. The majority of these provider organizations are not-for-profit corporations and county governments who currently operate outpatient programs funded and licensed by the Office of Mental Health and/or provide mental health services under contract with local governments and/or OMH and are supported by state and/or local funding.

The existing programs and services that have transitioned or will transition into PROS include Intensive Psychiatric Rehabilitation Treatment and Continuing Day Treatment, currently licensed by the Office of Mental Health (OMH). They also include services previously or currently funded by OMH, but not licensed, such as Psychosocial Clubs, On-Site Rehabilitation, Ongoing Integrated Employment, Enclave in Industry, Affirmative Business, Client Worker and Supported Education.

The licensed programs are currently required to be established through a process that is subject to Part 551 of 14NYCRR and must comply, on an ongoing basis, with the appropriate program and fiscal regulations as contained in Title 14, including standards for receiving Medicaid reimbursement. The unlicensed programs are established and provide services under contracts with OMH and/or the local governmental unit (the county or the City of New York, depending on location) and are subject to contractual program and fiscal requirements. The requirements are, in part, specific to the funding streams involved, which include: Local Assistance Regular, Community Support Services, Reinvestment, Ongoing Integrated Employment, Psychiatric Rehabilitation, Flexible Funding and Medicaid. While many of the fiscal contractual requirements are the same, there are certain fiscal requirements specific to certain funding streams. Most funding passes from the State to local governments and then to providers and is subject to both State and local government contract requirements.

The PROS program, as revised, will continue to promote comprehensive and coordinated services, foster continuity, and result in more effective program organization and service delivery. It will reduce program-related paper work involved with transfers; for example, an Intensive Psychiatric Rehabilitation Treatment Program must currently discharge an individual when that person achieves the stated goal even if the person needs ongoing support to maintain that goal. That individual's ongoing needs may then require transfer to another program in order to obtain necessary clinical services. The PROS program provides for integration of programs and services, and it will serve to reduce the paperwork required in such a situation, as what were formerly separate programs and services will now be service components under a single PROS license.

The revised PROS regulation continues to provide for a case payment approach to reimbursement which simplifies the Medicaid billing process. The multiple program and service components that formerly had to comply with separate contract requirements for each program funding stream and/or Medicaid fee-for-service with a more complex billing process will, under the revised PROS regulation, come together into a single program and be funded by a comprehensive per client case payment, billed on a monthly basis. For a number of service providers, billing Medicaid, as opposed to contract funding, may be a new experience. In recognition of this, OMH has and will continue to provide start-up funding for Medicaid billing development costs for providers transitioning to a PROS license in Phase I of implementation. Such start-up funds will be provided in accordance with need and availability of appropriations. Model recordkeeping forms will also be developed by OMH and made available to all providers,

for use at their discretion. The case payment rate has been enhanced under the revised regulation to a level sufficient to fund the costs of providing the PROS services, including the costs of documenting compliance and billing for services.

Rural Area Flexibility Analysis

A Rural Area Flexibility Analysis is not submitted with this notice because the amended rule will not impose any adverse economic impact on rural areas. Rural and non-rural programs will benefit from the integration of now separate programs and services and the revisions will not have a unique or negative impact on Personalized Recovery-Oriented Services (PROS) programs in rural areas.

Job Impact Statement

A Job Impact Statement is not submitted with this notice because it will have no negative impact on jobs and employment opportunities. It is expected that employment opportunities for individuals receiving services from a new Personalized Recovery-Oriented Services (PROS) provider will increase when compared to the current fragmented service system and that the revised PROS regulation will not significantly differ from the current regulation in terms of impact on jobs and employment opportunities.

Office of Mental Retardation and Developmental Disabilities

NOTICE OF EXPIRATION

The following notice has expired and cannot be reconsidered unless the Office of Mental Retardation and Developmental Disabilities publishes a new notice of proposed rule making in the NYS Register.

Article 16 Clinic Service Authorization Levels

I.D. No.	Proposed	Expiration Date
MRD-44-05-00021-P	November 2, 2005	November 2, 2006

Department of Motor Vehicles

EMERGENCY RULE MAKING

Drinking Driver Program and Conditional License Eligibility and Re-Licensure Requirements

I.D. No. MTV-47-06-00001-E
Filing No. 1323
Filing date: Nov. 1, 2006
Effective date: Nov. 1, 2006

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

Action taken: Amendment of Parts 134 and 136 of Title 15 NYCRR.
Statutory authority: Vehicle and Traffic Law, sections 215(a), 510(6)(a), 1192(10)(a) and (d), 1193(2)(c)(1), 1196(4) and 1196(7)(a)

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

Specific reasons underlying the finding of necessity: Precludes multiple DWI offenders from obtaining a conditional license and from being prematurely re-licensed under certain circumstances.

Subject: Drinking Driver Program and conditional license eligibility and re-licensure requirements.

Purpose: To set forth Drinking Driver Program and conditional license eligibility criteria for multiple DWI offenders and establishes re-licensure requirements for such offenders.

Text of emergency rule: Section 134.2 is amended to read as follows:

134.2 Persons eligible for program. Any person who is convicted of a violation of any subdivision of section 1192 of the Vehicle and Traffic Law, or is found to have been operating a motor vehicle after having consumed alcohol in violation of section 1192-a of this article, or of an alcohol or drug related traffic offense in another state, shall be eligible for enrollment in an alcohol and drug rehabilitation program unless: such person has participated in a program established pursuant to article 31 of the Vehicle and Traffic Law within the five years immediately preceding the date of commission of the alcohol or drug-related offense or such person has been convicted of a violation of any subdivision of section 1192 of such law [other than a violation committed prior to November 1, 1988] during the five years immediately preceding commission of an alcohol or drug-related offense; with respect to persons convicted of a violation of section 1192 of the Vehicle and Traffic Law, is prohibited from enrolling in a program by the judge who imposes sentence upon the conviction; or the commissioner is prohibited from issuing such new license to a person because of two convictions of a violation of section 1192 of the Vehicle and Traffic Law where physical injury, as defined in section 10.00 of the Penal Law, has resulted in both instances. *Notwithstanding the provisions of this section, a person shall be eligible for enrollment in the alcohol and drug rehabilitation program if such person is sentenced pursuant to the plea bargaining provisions set forth in Vehicle and Traffic Law section 1192(10)(a)(ii) and 1192(10)(d).*

Paragraph (8) of subdivision (a) of section 134.7 is amended to read as follows:

(8) The person has been penalized under section 1193(1)(d)(1) of the Vehicle and Traffic Law for any violation of subdivision 2, 2-a, 3, [or] 4, or 4-a of [such] section 1192 of such law.

Subdivision (a) of section 134.7 is amended by adding a new paragraph (13) to read as follows:

(13) *The person, during the five years preceding the commission of the alcohol or drug-related offense or a finding of a violation of section 1192-a of the Vehicle and Traffic Law, participated in the alcohol and drug rehabilitation program or has been convicted of a violation of any subdivision of section 1192 of such law.*

Subdivision (b) of section 134.10 is amended to read as follows:

(b) Results of satisfactory completion of a rehabilitation program. Upon satisfactory completion of a program, any unexpired suspension or revocation which was issued as a result of the conviction for which the person was eligible for enrollment in the program may be terminated by the commissioner unless the termination is prohibited under section 1193 of the Vehicle and Traffic Law or this Subchapter *or if the termination is based upon enrollment in the program pursuant to the plea bargaining provisions of Vehicle and Traffic Law section 1192(10)(a)(ii) and 1192(10)(d), if such person would not otherwise be eligible for enrollment in the program pursuant to section 1196(4) of such law.*

Section 134.11 is amended to read as follows:

134.11 Issuance of unconditional driver's license. Satisfactory completion of a rehabilitation program or expiration of the term of suspension, whichever occurs first, will initiate the necessary action to provide for the termination of the suspension or revocation which was the basis for entry into the rehabilitation program. Upon a determination of satisfactory completion of the rehabilitation program or the term of suspension, and unless otherwise determined by the commissioner, *as provided for in subdivision (b) of section 134.10 of this Part*, a notice of termination of the suspension or revocation and an unconditional license will be issued. However, no such license will be issued until all civil penalties due the department are paid or if there are any outstanding suspensions, revocations, or bars against such license until such suspensions, revocations, or bars are satisfactorily disposed of by the applicant. Any conditional license which is still valid will be terminated concurrently with the return of the unconditional driver's license and must be returned to the department. A conditional license shall not be renewed more than one year after the issuance of the conditional license if a revocation is issued for a chemical test refusal and the holder of the conditional license has not paid the civil penalty required by section 1194 of the Vehicle and Traffic Law.

Subdivision (a) of Section 136.6 is amended to read as follows:

(a) There shall be assigned to each safety factor a negative unit as follows:

Safety Factor	Assigned Negative Units	
	Over one year to three years of application	Within one year of application
(1) for each reportable accident of record with a finding by the referee of gross negligence in the operation of a motor vehicle in a manner showing a reckless disregard for the life and property of others.	-5	-8
(2) for each reportable accident of record with conviction involvement or with a finding by the referee of a violation of the Vehicle and Traffic Law	-3	-4
(3) for the first and second speeding conviction of record*	-3	-4
(4) for the third and subsequent speeding conviction*	-5	-8
(5) for reckless driving	-5	-8
(6) for each conviction of record for leaving the scene of a personal injury accident of record	-8	-11
(7) for each alcohol related offense of record as follows:		
(i) conviction for violation of sub-division (1) of section 1192 of the Vehicle and Traffic Law:		
1st offense	-5	-8
2nd offense	-8	-11
3rd offense	-11	-14
(ii) conviction for violation of subdivision (2), (2-a), (3), [or] (4), or (4-a) of section 1192 of the Vehicle and Traffic Law:		
1st offense	-11	-14
2nd or subsequent offense	-6	-11
(iii) chemical test refusal		
(8) for each conviction of homicide, criminally negligent homicide, or assault arising out of the operation of a motor vehicle	-11	-14
(9)(i) for each incident of driving during a period of alcohol-related license suspension or revocation	-10	-12
(ii) for each other incident of driving during a period of license suspension or revocation	-8	-10
(10) for each conviction or finding by the Commissioner's referee of a violation of section 392 of the Vehicle and Traffic Law	-3	-4
(11) for each other conviction of record for a moving violation	-2	-3

*For each speeding violation of 25 miles per hour or more over the posted speed limit, add one point.

Paragraph (2) of subdivision (d) of Section 136.6 is amended to read as follows:

(2) Where a first conviction of any subdivision [(2)] of section 1192 of the Vehicle and Traffic Law and a finding of a chemical test refusal arise out of the same incident, only one of these two safety factors having equal weight is considered in a review of the total record because these safety factors are not independent of each other.

Section 136.9 is amended to read as follows:

136.9 Effect of completion of the alcohol and drug rehabilitation program. The successful completion of the article 21 alcohol and drug rehabilitation program, where no intervening safety factors occurred between the date such person entered the program and the date the application for a license is made and with no subsequent incidents of operating a motor vehicle while under the influence of alcoholic beverages or drugs, shall be considered evidence of rehabilitative effort satisfactory for the purposes of this Part. *Provided, however, if enrollment in the program based upon the plea bargaining provisions of Vehicle and Traffic Law section 1192(10)(a)(ii) and 1192(10)(d), and if such person would not otherwise have been eligible for enrollment in the program pursuant to section 1196(4) of such law, then completion of the program, may not, in the commissioner's discretion, be deemed evidence of rehabilitative effort.*

This notice is intended to serve only as a notice of emergency adoption. This agency intends to adopt this emergency rule as a permanent rule and will publish a notice of proposed rule making in the *State Register* at some future date. The emergency rule will expire January 29, 2007.

Text of emergency rule and any required statements and analyses may be obtained from: Michele L. Welch, Counsel's Office, Department of

Motor Vehicles, Empire State Plaza, Swan St. Bldg., Rm. 526, Albany, NY 12228, (518) 474-0871, e-mail: mwelc@dmv.state.ny.us

Regulatory Impact Statement

1. Statutory authority: Section 215(a) of the Vehicle and Traffic Law authorizes the Commissioner to enact regulations to control the exercise of the powers of the Department of Motor Vehicles. Section 510(6)(a) of such law provides that where a license revocation is mandatory, no new license shall be issued except in the discretion of the Commissioner. Section 1193(2)(c)(1) of such law provides that where a license is revoked pursuant to an alcohol-related conviction, no new license shall be issued after the expiration of the minimum revocation period, except in the discretion of the Commissioner. Section 1192(10)(a) and (d) of such law relate to plea bargaining provisions in driving while intoxicated prosecutions and the requirement to attend the Drinking Driver Program. Section 1196(4) of such law relates to eligibility to enroll in the Drinking Driver Program. Section 1196(5) of such law provides that completion of the Drinking Driver Program may, in the discretion of the Commissioner, serve to terminate the suspension or revocation arising out of the alcohol-related conviction. Section 1196(7)(a) of such law relates to conditional license eligibility for those persons convicted of alcohol-related offenses.

2. Legislative objectives: This proposal is consistent with legislative objectives that grant the Commissioner of Motor Vehicles broad discretion in establishing criteria for the restoration of driver's licenses and the relicensing of individuals whose licenses have been suspended or revoked for alcohol-related offenses. It is also in accord with legislative objectives that afford the Commissioner discretion in determining eligibility for a conditional license, a limited use license issued to persons convicted of alcohol-related offenses. Currently, a person convicted of alcohol-related offenses may enroll in the Drinking Driver Program (DDP), as set forth in section 1196 of the Vehicle and Traffic Law, if such person has not, within the preceding five years, been convicted of an alcohol related offense or participated in the DDP. Under Chapter 732 of the Laws of 2006, section 1192(10) of such law is amended to provide that under certain plea bargaining provisions involving alcohol-related offenses, the court must require the defendant to enroll in the DDP even if such person is not otherwise eligible. Under current law, when a person successfully completes DDP, the suspension or revocation arising out of the alcohol conviction is terminated. Under this proposal, DDP completion would not serve to terminate the suspension or revocation for individuals who are not otherwise DDP eligible. This accords with the Legislature's intent, and DMV's current policy, that multiple alcohol offenders must show proof of rehabilitation in order to have their licenses restored.

3. Needs and benefits: These regulations are necessary to put the public on notice that multiple alcohol-related offenders who are not otherwise eligible for the DDP, pursuant to Vehicle and Traffic Law section 1196(4), shall not have their licenses restored upon completion of DDP, if enrollment for DDP is mandated by a court pursuant to the plea bargaining provision in Vehicle and Traffic Law section 1192(10). Currently, a person convicted of alcohol-related offenses may enroll in the Drinking Driver Program (DDP), as set forth in section 1196 of the Vehicle and Traffic Law, if such person has not, within the preceding five years, been convicted of an alcohol related offense or participated in the DDP. Under Chapter 732 of the Laws of 2006, section 1192(10) of such law is amended to provide that under certain plea bargaining provisions involving alcohol-related offenses, the court must require the defendant to enroll in the DDP even if such person is not otherwise eligible under section 1196(4). Under current law, when a person successfully completes DDP, the suspension or revocation arising out of the alcohol conviction is terminated. Under this proposal, DDP completion would not serve to terminate the suspension or revocation for individuals who are not otherwise DDP eligible. In addition, under this proposal, and consistent with current law, a person not eligible for the DDP would not be eligible for a conditional license.

This regulation is important because it provides, in accordance with current DMV policies and reapplication procedures, as set forth in Parts 134 and 136, that a recidivist DWI offender who is not eligible for the DDP must show proof of rehabilitation from an approved treatment provider prior to re-licensure. It would be contrary to public safety if a multiple DWI offender who completed DDP twice within five years is permitted to be re-licensed without having been evaluated by a treatment provider with expertise in alcohol counseling. In addition, under Part 136, applicants for re-licensure are denied a license if they have 25 or more negative units accumulated within a specified time period. Negative units are assigned for various violations of the Vehicle and Traffic Law. This amendment adds the two new alcohol offenses, Vehicle and Traffic Law 1192(2-a) and (4-a), to the offenses that trigger negative units. Thus, these amendments are

necessary to protect the public from drivers who pose a significant high-way risk.

4. Costs: There are no costs to the public, local government or to this agency. The Department already has staff and procedures in place to process multiple offenders applying for re-licensure.

Source: DMV's Driver Improvement Bureau.

5. Local government mandates: This proposal does not impose any mandates upon local governments.

6. Paperwork: This proposal does not impose any additional paperwork requirements on the Department.

7. Duplication: This proposal does not duplicate, overlap or conflict with any relevant rule or legal requirement of the State and federal governments.

8. Alternatives: No significant alternatives were considered. A no action alternative was not considered.

9. Federal standards: The proposal does not exceed any minimum standards of the federal government for the same or similar subject areas.

10. Compliance: Immediate with adoption of this rule.

Regulatory Flexibility Analysis

A Regulatory Flexibility Analysis is not attached because this rule will not have a disproportionate impact on small businesses or local governments, nor will it impose any adverse economic impact or reporting, recordkeeping or other compliance requirements on small businesses or local governments.

Rural Area Flexibility Analysis

A Rural Area Flexibility Analysis is not submitted with this proposal because it will have no adverse or disproportionate impact on the rural areas of the State.

Job Impact Statement

A Job Impact Statement is not submitted with this statement because it will not have an adverse impact on job creation or development in New York State.

Niagara Frontier Transportation Authority

NOTICE OF ADOPTION

Procurement Guidelines

I.D. No. NFT-35-06-00005-A

Filing No. 1324

Filing date: Nov. 2, 2006

Effective date: Nov. 22, 2006

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

Action taken: Amendment of section 1159.4 of Title 21 NYCRR.

Statutory authority: Public Authorities Law, sections 1299-e(5) and 1299-t

Subject: The NFTA's procurement guidelines.

Purpose: To amend the NFTA's procurement guidelines to clarify internal review requirements.

Text or summary was published in the notice of proposed rule making, I.D. No. NFT-35-06-00005-P, Issue of August 30, 2006.

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

Text of rule and any required statements and analyses may be obtained from: Ruth A. Keating, Niagara Frontier Transportation Authority, 181 Ellicott St., Buffalo, NY 14203, (716) 855-7398, e-mail: Ruth_Keating@nfta.com

Assessment of Public Comment

The agency received no public comment.

Public Service Commission

NOTICE OF WITHDRAWAL

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

The following rule makings have been withdrawn from consideration:

I.D. No.	Publication Date of Proposal
PSC-33-06-00018-P	August 16, 2006
PSC-33-06-00019-P	August 16, 2006
PSC-33-06-00020-P	August 16, 2006
PSC-33-06-00021-P	August 16, 2006

NOTICE OF ADOPTION

Uniform Business Practices and Related Matters

I.D. No. PSC-36-05-00018-A

Filing date: Nov. 7, 2006

Effective date: Nov. 7, 2006

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

Action taken: The commission, on Oct. 18, 2006, denied a proposal by Accent Energy instead directed certain utilities to submit a plan discussing what they can do to make it easier for customers to gain access to their utility account numbers.

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

Subject: Revisions to uniform business practices and related matters.

Purpose: To revise sections 4 (Customer Information) and 5 (Changes in Service Providers) of the uniform business practices, or any other section(s) which may be necessary to authorize and ESCO to receive history information or enroll a customer following access to the customer's utility account number from a source other than the customer.

Substance of final rule: The Commission denied a proposal by Accent Energy and instead directed the utilities (Consolidated Edison Company of New York Inc., Orange and Rockland Utilities, Inc., Central Hudson Gas & Electric, New York State Electric & Gas Corporation, Rochester Gas & Electric Corporation, National Grid, National Fuel Gas Corporation, KeySpan Energy of New York, and KeySpan Energy of Long Island) to submit a plan discussing what the companies can do to make it easier for customers to gain access to their utility account numbers, subject to the terms and conditions set forth in the order.

Final rule compared with proposed rule: No changes.

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

Assessment of Public Comment

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

(98-M-1343SA13)

NOTICE OF ADOPTION

Recovery of Costs by the New York Municipal Power Agency

I.D. No. PSC-29-06-00009-A

Filing date: Nov. 6, 2006

Effective date: Nov. 6, 2006

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

Action taken: The commission, on Oct. 18, 2006, adopted an order approving the petition of the New York Municipal Power Agency, on behalf of its member Municipal Electric Systems, to recover the costs of a new Energy Efficiency Program.

Statutory authority: Public Service Law, sections 4 and 66(12)

Subject: Recovery of costs of an Energy Efficiency Program.

Purpose: To approve the recovery of a charge of one mill per kWh to pay for an enhanced Energy Efficiency Program.

Substance of final rule: The Public Service Commission adopted an order approving the petition of the New York Municipal Power Agency on behalf of its member Municipal Electric Systems, to recover the costs of a new energy efficiency program through its purchased power adjustment clause with modifications, subject to the terms and conditions set forth in the order.

Final rule compared with proposed rule: No changes.

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

Assessment of Public Comment

An assessment of public comment is not submitted with this notice because the rule is within the definition contained in section 102(2)(a)(ii) of the State Administrative Procedure Act.
(06-E-0744SA1)

NOTICE OF ADOPTION

Transfer of Water Supply Assets by Ocean Bay Park Water Corporation and the Suffolk County Water Authority

I.D. No. PSC-33-06-00030-A

Filing date: Nov. 6, 2006

Effective date: Nov. 6, 2006

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

Action taken: The commission, on Oct. 18, 2006, adopted an order approving the transfer of real property and the water plant assets of Ocean Bay Park Water Corporation to the Suffolk County Water Authority.

Statutory authority: Public Service Law, sections 2, 5, 89-b and 89-h

Subject: Transfer of water supply assets.

Purpose: To transfer the water supply assets of Ocean Bay Park Water Corporation to the Suffolk County Water Authority.

Substance of final rule: The Commission adopted an order approving the transfer of real property and water plant assets of Ocean Bay Park Water Corporation to the Suffolk County Water Authority, subject to the terms and conditions set forth in the order.

Final rule compared with proposed rule: No changes.

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

Assessment of Public Comment

An assessment of public comment is not submitted with this notice because the rule is within the definition contained in section 102(2)(a)(ii) of the State Administrative Procedure Act.
(06-W-0830SA1)

PROPOSED RULE MAKING NO HEARING(S) SCHEDULED

Transfer of Ownership Interests by WPS Empire State, Inc., et al.

I.D. No. PSC-47-06-00013-P

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

Proposed action: The Public Service Commission is considering a petition from WPS Empire State, Inc., WPS Niagara Generation LLC and USRG Niagara Biomass LLC requesting approval of the transfer of ownership interests in an approximately 53 MW electric generating facility located in Niagara Falls, NY.

Statutory authority: Public Service Law, section 70

Subject: Transfer of ownership interests in an approximately 53 MW electric generating facility located in Niagara Falls, NY.

Purpose: To approve the transfer of ownership interests in an approximately 53 MW electric generating facility located in Niagara Falls, NY.

Substance of proposed rule: The Public Service Commission is considering a petition from WPS Empire State, Inc., WPS Niagara Generation LLC and USRG Niagara Biomass LLC requesting approval of the transfer of ownership interests in an approximately 53 MW electric generating facility located in Niagara Falls, 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: Central Operations, Public Service Commission, Bldg. 3, Empire State Plaza, Albany, NY 12223-1350, (518) 474-2500

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

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

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

Statements and analyses are not submitted with this notice because the proposed rule is within the definition contained in section 102(2)(a)(ii) of the State Administrative Procedure Act.
(06-E-1301SA1)

PROPOSED RULE MAKING NO HEARING(S) SCHEDULED

Indebtedness to be Incurred by USRG Niagara Biomass LLC

I.D. No. PSC-47-06-00014-P

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

Proposed action: The Public Service Commission is considering a petition from USRG Niagara Biomass LLC requesting approval to incur indebtedness through debt obligations of no more than \$50 million.

Statutory authority: Public Service Law, section 69

Subject: Indebtedness to be incurred by USRG Niagara Biomass LLC.

Purpose: To approve the indebtedness to be incurred by USRG Niagara Biomass LLC.

Substance of proposed rule: The Public Service Commission is considering a petition from USRG Niagara Biomass LLC requesting approval to incur indebtedness through debt obligations of no more than \$50 million. 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: Central Operations, Public Service Commission, Bldg. 3, Empire State Plaza, Albany, NY 12223-1350, (518) 474-2500

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

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

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

Statements and analyses are not submitted with this notice because the proposed rule is within the definition contained in section 102(2)(a)(ii) of the State Administrative Procedure Act.
(06-E-1307SA1)

PROPOSED RULE MAKING NO HEARING(S) SCHEDULED

Submetering of Electricity by American Metering and Planning Services, Inc.

I.D. No. PSC-47-06-00015-P

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

Proposed action: The Public Service Commission is considering whether to grant, deny or modify, in whole or part, the petition filed by American Metering and Planning Services, Inc., to submeter electricity at 110 Livingston St., Brooklyn, NY.

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

Subject: Petition for the submetering of electricity.

Purpose: To consider the request of American Metering and Planning Services, Inc., to submeter electricity at 110 Livingston St., Brooklyn, NY.

Substance of proposed rule: The Public Service Commission is considering whether to grant, deny or modify, in whole or part, the petition filed by American Metering and Planning Services, Inc., to submeter electricity at 110 Livingston Street, Brooklyn, New York.

Text of proposed rule and any required statements and analyses may be obtained by filing a Document Request Form (F-96) located on our website <http://www.dps.state.ny.us/f96dir.htm>. For questions, contact: Central Operations, Public Service Commission, Bldg. 3, Empire State Plaza, Albany, NY 12223-1350, (518) 474-2500

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

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

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

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

(06-E-1315SA1)

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

Market Supply Charge by Orange and Rockland Utilities, Inc.

I.D. No. PSC-47-06-00016-P

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

Proposed action: The Public Service Commission is considering whether to approve or reject, in whole or in part, a proposal filed by Orange and Rockland Utilities, Inc. to make various changes in the rates, charges, rules and regulations contained in its schedule for electric service, P.S.C No. 2 to become effective Feb. 1, 2007.

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

Subject: Market supply charge (MSC).

Purpose: To modify its MSC to separate actual market prices from costs and adjustments, including hedging gains/losses, currently contained in the MSC, in compliance with the commissioner's order issued Aug. 2, 2006 in Case 06-M-0003.

Substance of proposed rule: The Commission is considering Orange and Rockland Utilities, Inc. (O&R) request to revise its electric tariff, P.S.C. No. 2, in compliance with Commission Order Denying Complaint in Part and Directing Tariff Filing, issued August 2, 2006 in Case 06-M-0003. The Order directed O&R to implement a modified Market Supply Charge (MSC) based on day ahead hourly market prices of the New York Independent System Operator. The modified MSC will be set monthly and consist of a load shape weighted average of the hourly supply charges for energy, ancillary service/NYPA Transmission Adjustment Charge, and capacity. The proposal also revises the MSC to separate it into two distinct components (i.e., Market Price of Electric Supply and MSC Adjustment) on customers' bills and the total of these two components, including applicable government surcharges, will be billed to all applicable customers in each billing month. The Commission may approve, reject or modify, in whole or in part, O&R's request.

Text of proposed rule and any required statements and analyses may be obtained by filing a Document Request Form (F-96) located on our website <http://www.dps.state.ny.us/f96dir.htm>. For questions, contact: Central Operations, Public Service Commission, Bldg. 3, Empire State Plaza, Albany, NY 12223-1350, (518) 474-2500

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

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

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

Statements and analyses are not submitted with this notice because the proposed rule is within the definition contained in section 102(2)(a)(ii) of the State Administrative Procedure Act.
(06-M-0003SA2)

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

Transfer of Franchises or Stock by Aqua New York, Inc.

I.D. No. PSC-47-06-00017-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 a supplement to joint petition filed on Oct. 31, 2006, by Aqua New York, Inc. and New York Water Service Corporation (NYWS) modifying its proposal contained in its joint petition filed on June 9, 2006.

Statutory authority: Public Service Law, sections 4(1), 5(1)(f), 89-c(1) and 89-h

Subject: Transfer of franchises or stock and water rates and charges.

Purpose: To approve the supplemental joint petition filed on Oct. 31, 2006.

Substance of proposed rule: On October 31, 2006, a Supplement to Joint Petition was filed by Aqua New York, Inc. and New York Water Service Corporation (NYWS) requesting approval to transfer NYWS to Aqua New York, Inc., extend the existing NYWS rate plan one year to April 30, 2009, and include a System Improvement Charge subject to certain conditions. In addition, the joint petitioners request that property tax expense in excess of the target from May 1, 2008 through April 30, 2009 be deferred at 100% and recovered or refunded through the Property Tax Reconciliation Clause; and, that NYWS be allowed to defer the difference between the actual annual Pension and OPEBs expense through April 30, 2009, and the amount of Pension (\$835,964) and OPEBs (\$346,869) expense currently included in rates. The Supplement also withdraws the proposed NYWS Acquisition Incentive Account filed on June 9, 2006.

The Commission may approve or reject, in whole or in part, or modify the supplemental joint 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: Central Operations, Public Service Commission, Bldg. 3, Empire State Plaza, Albany, NY 12223-1350, (518) 474-2500

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

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

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

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

(06-W-0700SA2)

**Department of Taxation and
Finance**

NOTICE OF ADOPTION

Fuel Use Tax on Motor Fuel and Diesel Motor Fuel

I.D. No. TAF-34-06-00006-A

Filing No. 1333

Filing date: Nov. 7, 2006

Effective date: Nov. 7, 2006

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

Action taken: Amendment of section 492.1(b)(1) of Title 20 NYCRR.

Statutory authority: Tax Law, sections 171, subd. First; 301-h(c); 509(7); 523(b); and 528(a)

Subject: Fuel use tax on motor fuel and diesel motor fuel and the art. 13-A carrier tax jointly administered therewith.

Purpose: To set the sales tax component and the composite rate per gallon of the fuel use tax on motor fuel and diesel motor fuel for the calendar quarter beginning Oct. 1, 2006, and ending Dec. 31, 2006, and reflect the aggregate rate per gallon on such fuels for such calendar quarter for purposes of the joint administration of the fuel use tax and the art. 13-A carrier tax.

Text or summary was published in the notice of proposed rule making, I.D. No. TAF-34-06-00006-P, Issue of August 23, 2006.

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

Text of rule and any required statements and analyses may be obtained from: John W. Bartlett, Tax Regulations Specialist 4, Department of Taxation and Finance, Bldg. 9, State Campus, Albany, NY 12227, (518) 457-2254, e-mail: tax_regulations@tax.state.ny.us

Assessment of Public Comment

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

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

Fuel Use Tax on Motor Fuel and Diesel Motor Fuel

I.D. No. TAF-47-06-00011-P

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

Proposed action: Amendment of section 492.1(b)(1) of Title 20 NYCRR.

Statutory authority: Tax Law, sections 171, subd. First; 301-h(c); 509(7); 523(b); and 528(a)

Subject: Fuel use tax on motor fuel and diesel motor fuel and the art. 13-A carrier tax jointly administered therewith.

Purpose: To set the sales tax component and the composite rate per gallon of the fuel use tax on motor fuel and diesel motor fuel for the calendar quarter beginning Jan. 1, 2007, and ending March 31, 2007, and reflect the aggregate rate per gallon on such fuels for such calendar quarter for purposes of the joint administration of the fuel use tax and the art. 13-A carrier tax.

Text of proposed rule: Section 1. Paragraph (1) of subdivision (b) of section 492.1 of such regulations is amended by adding a new subparagraph (xlv) to read as follows:

	Motor Fuel	
Sales Tax Component	Composite Rate	Aggregate Rate
(xliv) October-December 2006	22.0	37.9
(xlv) January-March 2007	22.0	38.6
14.0		
	Diesel Motor Fuel	
Sales Tax Component	Composite Rate	Aggregate Rate
14.0	22.0	36.15
14.0	22.0	36.85

Text of proposed rule and any required statements and analyses may be obtained from: John W. Bartlett, Tax Regulations Specialist 4, Department of Taxation and Finance, Bldg. 9, State Campus, Albany, NY 12227, (518) 457-2254, e-mail: tax_regulations@tax.state.ny.us

Data, views or arguments may be submitted to: Marilyn Kaltenborn, Director, Technical Services Division, Department of Taxation and Finance, Bldg. 9, State Campus, Albany, NY 12227, (518) 457-1153, e-mail: tax_regulations@tax.state.ny.us

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

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

Amount of Sales and Use Tax to be Collected

I.D. No. TAF-47-06-00012-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 Part 530 and section 532.1 of Title 20 NYCRR.

Statutory authority: Tax Law, sections 171, subd. First; 1142(1) and (8); and 1250 (not subdivided)

Subject: Amount of sales and use tax to be collected.

Purpose: To update and simplify Part 530 of the Sales and Use Taxes Regulations by eliminating obsolete and unnecessary sales and use tax rates that are set by and pursuant to the Tax Law; and eliminating other provisions of Part 530 that would merely be redundant without such tax rate information.

Text of proposed rule: Section 1. The heading of Part 530 of the regulations is amended to read as follows:

[TAX RATES] **AMOUNT TO BE COLLECTED**

Section 2. The statutory authority cited in the heading of Part 530 of the regulations is amended to read as follows:

(Statutory authority: Tax Law, sections 171, [1105, 1110,] 1111, 1132, 1142, [1210, 1211, 1212, 1212-A,] 1250)

Section 3. Sections 530.1–530.3 of the regulations are REPEALED and sections 530.4 and 530.5 are renumbered to be sections 530.1 and 530.2.

Section 4. The heading of section 530.1, as renumbered, is amended to read as follows:

Section 530.1 Collection of tax. (*Tax Law, section 1132(b)*)

Section 5. The cross-reference following subparagraph (iii) of paragraph (4) of subdivision (b) of section 532.1 of the regulations is amended to read as follows:

“Cross-reference:” For posting of signs at retail service stations, see section [530.38] 530.2 of this Title.

Text of proposed rule and any required statements and analyses may be obtained from: John W. Bartlett, Tax Regulations Specialist 4, Department of Taxation and Finance, Bldg. 9, State Campus, Albany, NY 12227, (518) 457-2254, e-mail: tax_regulations@tax.state.ny.us

Data, views or arguments may be submitted to: Marilyn Kaltenborn, Director, Technical Services Division, Department of Taxation and Finance, Bldg. 9, State Campus, Albany, NY 12227, (518) 457-1153, e-mail: tax_regulations@tax.state.ny.us

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

Consensus Rule Making Determination

The Department of Taxation and Finance has determined that no person is likely to object to the adoption of this rule as written because the amendments merely make technical, conforming, and editorial changes that are not controversial in nature. The rule makes no changes in administrative policies regarding existing statutes and has no impact on taxpayers.

The primary purpose of this proposal is to update and simplify Part 530 of the Sales and Use Taxes Regulations by eliminating obsolete and unnecessary sales and compensating use tax rates that are set by and pursuant to the Tax Law, and by eliminating other provisions of Part 530 that would be redundant without such tax rate information. Such provisions merely describe the various tax rates and their corresponding imposition sections in Articles 28 and 29 of the Tax Law. Other changes made by the rule are simply conforming and editorial in nature.

Job Impact Statement

A Job Impact Statement is not being submitted with this rule because it is evident from the subject matter of the rule that it would have no impact on jobs and employment opportunities. The rule merely updates and simplifies Part 530 of the Sales and Use Taxes Regulations by eliminating obsolete and unnecessary sales and compensating use tax rates that are set by and pursuant to the Tax Law, and by eliminating other provisions of Part 530 that would be redundant without such tax rate information. The rule also makes other changes that are simply conforming and editorial in nature.