

RULE MAKING ACTIVITIES

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

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

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

Department of Agriculture and Markets

NOTICE OF ADOPTION

Species of Ash Trees, Parts Thereof and Products and Debris Therefrom Which Are at Risk to Infestation by the Emerald Ash Borer

I.D. No. AAM-01-11-00014-A

Filing No. 438

Filing Date: 2011-05-17

Effective Date: 2011-06-01

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

Action taken: Repeal of Part 141; and addition of a new Part 141 to Title 1 NYCRR.

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

Subject: Species of ash trees, parts thereof and products and debris therefrom which are at risk to infestation by the emerald ash borer.

Purpose: To establish the emerald ash borer quarantine to prevent the further spread of this beetle to other areas.

Text of final rule: Part 141 of 1 NYCRR is repealed and a new Part 141 is added thereto, to read as follows:

Part 141

Control of the Emerald Ash Borer

(Statutory Authority: Agriculture and Markets Law sections 18, 164 and 167)

Section 141.1. Definitions

For the purpose of this Part, the following words, names and terms shall be construed respectively, to mean:

(a) *Certificate of inspection.* A valid form certifying the eligibility of products for intrastate movement under the requirements of this Part.

(b) *Compliance agreement.* An approved document, executed by persons or firms, covering the restricted movement, processing, handling or utilization of regulated articles not eligible for certification for intrastate movement.

(c) *Emerald Ash Borer.* The insect known as the Emerald Ash Borer, *Agilus planipennis*, in any stage of development.

(d) *Firewood.* This term applies to any kindling, logs, chunkwood, boards, timbers or other wood cut and split, or not split, into a form and size of twenty eight inches or less appropriate for use as fuel.

(e) *Infestation.* This term refers to the presence of the Emerald Ash Borer in any life stage or as determined by evidence of activity of one or more of the life stages.

(f) *Inspector.* An inspector of the New York State Department of Agriculture and Markets, or cooperator from the New York State Department of Environmental Conservation (DEC) or the United States Department of Agriculture (USDA), when authorized to act in that capacity.

(g) *Limited permit.* A valid form authorizing the restricted movement of regulated articles from a quarantined area to a specified destination for specified processing, handling or utilization.

(h) *Moved; movement.* Shipped, offered for shipment to a common carrier received for transportation or transported by a common carrier, or carried, transported, moved or allowed to be moved into or through any area of the State.

(i) *Nursery stock.* This term applies to and includes all trees, shrubs, plants and vines and parts thereof.

(j) *Quarantined Area.* This term applies to Niagara, Erie, Orleans, Genessee, Wyoming, Allegany, Monroe, Livingston, Steuben, Wayne, Ontario, Yates, Schuyler, Chemung, Greene, Ulster, Chautauqua and Cattaraugus Counties.

(k) *Regulated article.* This term applies to firewood from any species of tree, and any trees and all host material, living, dead, cut or fallen, inclusive of nursery stock, logs, green lumber, stumps, roots, branches and debris of the following genera: White Ash (*Fraxinus Americana*); Green Ash (*Fraxinus pennsylvanica*); Black Ash (*Fraxinus nigra*); and Blue Ash (*Fraxinus quadrangulata*), and any wood material that is comingled and otherwise indistinguishable from the regulated article.

Section 141.2. Quarantined area.

Regulated articles as described in section 141.3 of this Part shall not be shipped, transported or otherwise moved from any point within Niagara, Erie, Orleans, Genessee, Wyoming, Allegany, Monroe, Livingston, Steuben, Wayne, Ontario, Yates, Schuyler, Chemung, Greene, Ulster, Chautauqua and Cattaraugus Counties to any point outside of said counties, except in accordance with this Part.

Section 141.3. Regulated articles.

(a) *Prohibited movement.*

(1) *The intrastate movement of living Emerald Ash Borer in any stage of development, whether moved independent of or in connection with any other article, except as provided in section 141.9 of this Part.*

(2) *The intrastate movement of nursery stock from the quarantined area to any point outside the quarantined area.*

(3) *The intrastate movement of regulated articles other than nursery stock from the quarantined area to any point outside the quarantined area, except as provided in section 141.5 of this Part.*

(b) *Regulated movement.*

(1) *Regulated articles shall not be moved from the quarantined area to any point outside the quarantined area, except under a limited permit*

or unless accompanied by a certificate of inspection indicating freedom from infestation.

(2) Regulated articles may be moved through the quarantined area if the regulated articles originated outside the regulated area and:

(i) the points of origin and destination are indicated on a waybill accompanying the regulated article; and

(ii) the regulated articles, if moved through the quarantined area during the period of May 1 through August 31, are moved in an enclosed vehicle or are completely covered to prevent access by the Emerald Ash Borer; and

(iii) the regulated articles are moved directly through the quarantined area without stopping, except for refueling and traffic conditions, or have been stored, packed, or handled at locations approved by an inspector as not posing a risk of infestation by the Emerald Ash Borer.

Section 141.4. Conditions governing the intrastate movement of regulated articles.

(a) Movement from quarantined area. Unless exempted by administrative instructions of the Commissioner of Agriculture and Markets of the State of New York, regulated articles shall not be moved intrastate from the quarantined area to or through any point outside thereof unless accompanied by a valid certificate or limited permit issued by an inspector, authorizing such movement.

Section 141.5. Conditions governing the issuance of certificates and permits.

(a) Certificates of inspection. Certificates of inspection may be issued for the intrastate movement of regulated articles when they have been inspected and determined to have been:

(1) treated, fumigated, or processed by approved methods; or

(2) grown, produced, manufactured, stored, or handled in such a manner that, in the judgment of the inspector, no infestation would be transmitted thereby, provided that subsequent to certification, the regulated articles shall be loaded, handled, and shipped under such protection and safeguards against reinfestation as are required by the inspector.

(b) Limited permits. Limited permits may be issued for the movement of noncertified regulated articles to specified destinations for specified processing, handling, or utilization. Persons shipping, transporting, or receiving such articles may be required to enter into written compliance agreements to maintain such sanitation safeguards against the establishment and spread of infestation and to comply with such conditions as to the maintenance of identity, handling, processing, or subsequent movement of regulated products and the cleaning of cars, trucks and other vehicles used in the transportation of such articles, as may be required by the inspector. Failure to comply with conditions of the agreement will result in its cancellation.

(c) Cancellation of certificates of inspection or limited permits. Certificates or limited permits issued under these regulations may be withdrawn or canceled by the inspector and further certification refused whenever in his or her judgment the further use of such certificates or permits might result in the dissemination of infestation.

Section 141.6. Inspection and disposition of shipments.

Any car or other conveyance, any package or other container, and any article or thing to be moved, which is moving, or which has been moved intrastate from the quarantined area, which contains, or which the inspector has probable cause to believe may contain, infestations of the Emerald Ash Borer, or articles or things regulated under this quarantine, may be examined by an inspector at any time or place. When articles or things are found to be moving or to have been moved intrastate in violation of these regulations, the inspector may take such action as he deems necessary to eliminate the danger of dissemination of the Emerald Ash Borer. If found to be infested, such articles or things must be free of infestation without cost to the State except that for inspection and supervision.

Section 141.7. Assembly of regulated articles for inspection.

(a) Persons intending to move intrastate any regulated articles shall make application for certification as far in advance as possible, and will be required to prepare and assemble materials at such points and in such manner as the inspector shall designate, so that thorough inspection may be made or approved treatments applied. Articles to be inspected as a basis for certification must be free from matter which makes inspection impracticable.

(b) The New York State Department of Agriculture will not be responsible for any cost incident to inspection, treatment, or certification other than the services of the inspector.

Section 141.8. Marking requirements.

Every container of regulated articles intended for intrastate movement shall be plainly marked with the name and address of the consignor and

the name and address of the consignee, when offered for shipment, and shall have securely attached to the outside thereof a valid certificate (or limited permit) issued in compliance with these regulations: provided, that:

(a) for lot freight shipments, other than by road vehicle, one certificate may be attached to one of the containers and another to the waybill; and for carlot freight or express shipment, either in containers or in bulk, a certificate need be attached to the waybill only and a placard to the outside of the car, showing the number of the certificate accompanying the waybill; and

(b) for movement by road vehicle, the certificate shall accompany the vehicle and be surrendered to consignee upon delivery of shipment.

Section 141.9. Shipments for experimental and scientific purposes.

Regulated articles may be moved intrastate for experimental or scientific purposes, on such conditions and under such safeguards as may be prescribed by the New York State Department of Agriculture and Markets. The container of articles so moved shall bear, securely attached to the outside thereof, an identifying tag issued by the New York State Department of Agriculture and Markets showing compliance with such conditions.

Final rule as compared with last published rule: Nonsubstantive changes were made in sections 141.1(d) and 41.3(b)(2).

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

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

The revisions to the text of the rule are not substantial, consisting of the addition of a length dimension (28 inches) to the definition of "firewood" in section 141.1(d); and the deletion of the ambient air temperature range requirement (40 degrees F or higher) during which regulated articles are required to be covered when transported within the quarantined area during the EAB's flight season (May 1 through August 31). Since these revisions further clarify a definition and an existing requirement in the proposed regulation, it was determined that the changes are not substantial. Accordingly, a revised regulatory impact statement, regulatory flexibility analysis, rural area flexibility and job impact statement are not required.

Assessment of Public Comment

The agency received no public comment.

NOTICE OF ADOPTION

Certification of Small Grain Seeds

I.D. No. AAM-03-11-00012-A

Filing No. 437

Filing Date: 2011-05-17

Effective Date: 2011-06-01

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

Action taken: Amendment of Part 97 of Title 1 NYCRR.

Statutory authority: Agriculture and Markets Law, sections 141 and 142

Subject: Certification of small grain seeds.

Purpose: To amend land requirements, field standards and seed standards for the certification of small grain seeds.

Text or summary was published in the January 19, 2011 issue of the Register, I.D. No. AAM-03-11-00012-P.

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

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

Assessment of Public Comment

The agency received no public comment.

Office of Alcoholism and Substance Abuse Services

EMERGENCY RULE MAKING

Opioid Treatment Services

I.D. No. ASA-22-11-00001-E

Filing No. 428

Filing Date: 2011-05-11

Effective Date: 2011-05-11

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

Action taken: Repeal of Part 828; and addition of new Part 828 to Title 14 NYCRR.

Statutory authority: Mental Hygiene Law, sections 19.07, 19.09, 19.21, 19.40, 32.01, 32.05, 32.07 and 32.09

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

Specific reasons underlying the finding of necessity: 1. The regulation has not been changed substantially in 24 years and the treatment of opioid addiction has changed substantially over that period of time and recognizes and allows for advances in toxicology testing and pharmacology.

2. Federal regulations were promulgated 9 years ago and this regulation brings NYS more reflective of the Federal regulations.

Subject: Opioid Treatment Services.

Purpose: Bring the current practice of opioid treatment services within NYS and to bring the regulation into alignment with Federal regulations.

Substance of emergency rule: The proposed regulations would revise Section 828 of the Mental Hygiene law (Requirements for the operation of chemotherapy substance abuse programs) to allow for changes in addiction treatment services as the last changes to the regulation occurred under DSAS as Part 1040 in 1984 as 1040.21. It was then renumbered as Part 828 and moved to OASAS in 2000, with no significant changes. The methadone regulation has existed for 24 years without change even though the Federal rules of opioid treatment have changed due to advancements and evidence based practice.

Changes for Opioid Treatment Programs

- Conform OASAS regulations to federal regulations (42 CFR Part 8) regarding certification of opioid treatment programs (OTP).
- Adds regulations related to buprenorphine (methadone alternative) treatment, removing an obstacle to physicians to administer buprenorphine in OTPs where clients may receive supportive services.
- Provides for opioid medical maintenance (OMM), pursuant to federal waiver, for certain qualified opioid patients and providers.
- Provides guidelines for certified providers to provide services at additional locations.
- Requires medical directors to become certified in an area of addiction medicine.
- Requires testing for Hepatitis and makes testing for STDs optional.
- Increases flexibility in toxicology testing.
- No longer requires OASAS approval for methadone dosage increases above 200 milligrams.
- Recognizes that treatment for opioid addiction may be provided in a residential or in-patient setting and makes provisions for regulation of such services.
- Greater consistency between federal and state regulations will benefit both providers and clients.
- Adds language that states only clients with a primary diagnosis of opioid addiction may be admitted to an OTP.
- Annual physical still required however at clinics discretion patient may be able to go to their private MD.
- New language added for transfer patients.
- More flexibility for counselor to patient staffing ratios.
- Greater flexibility in providing patients with take home medication and removes agency approval on a one-time basis for up to 30 days take home dose.
- Adds recall to reduce diversion.
- Defines role of security guards at the OTP.
- Defines aftercare.

- States specialized services that are not defined by regulation must be approved by OASAS prior to implementation.
- States providers must establish a community relations policy and committee.
- Providers must establish a quality improvement policy.
- Requires 50% of the counseling staff to be CASAC or CASAC-T within four years.

This regulation was originally published in the NYS Register in December 2008. Many providers commented and OASAS responded. Here are the additional changes to the regulation.

- Adds language for approved medication which provides programs the ability to use methadone, buprenorphine or any other agent approved for opioid treatment by federal authorities.
- Provides for opioid medical maintenance (OMM), pursuant to federal waiver, for certain qualified opioid patients and providers.
- Adds language for health care coordinator which is consistent with other regulations in the Part.
- Changed language for nurse/patient ratio back to prior language as no change was intended.
- Continuing care treatment is limited to four months, where after a client who requires more counseling should be referred to another modality.
- Increases flexibility in toxicology testing.
- Multidisciplinary team language changed to be consistent with our regulations in the Part.
- Mandatory use of Locatdr form lifted.
- Allows for prescribing professionals to perform medical services except for initial dose and medical maintenance.
- Clarified definitions for taper and detox.
- Clarified language for transfer patients.
- Recognizes that treatment for opioid addiction may be provided in a residential or in-patient setting and makes provisions for regulation of such services.
- Changed the language and now allows an individual who voluntarily completed treatment to return to treatment without confirming current opioid dependence of two years and instead can accept them with one year.

A primary goal of the proposed amendments is to improve treatment cost effectiveness in all opioid treatment programs. The proposed amendments accomplish this in several ways. OTPs flexibility in toxicology testing is expanded to permit the option of oral fluid testing which is less onerous to staff, more dignified for the patient, and allows several patients to be tested simultaneously. Increased toxicology testing will improve patient outcomes through early identification and appropriate counseling. Because fewer patients present with sexually transmitted disease (STD) testing for STD is no longer required, but can be completed as necessary for those patients who request testing or exhibit signs and symptoms. However, to protect the public, testing for Hepatitis is mandated but federal funding or local DOH funds are available for Hepatitis testing and vaccines to offset costs.

More efficient and cost-effective administration is also a goal of the proposed rule. OASAS does not expect to incur increased costs related to administering the new rule. OASAS will modify the review instrument currently used to evaluate OTPs and will provide additional technical assistance to OTPs, but this is not expected to increase agency costs because staff time currently needed to process individual and general regulatory waivers to current regulations will be decreased and can be allocated more efficiently.

Municipalities may recognize savings because the proposed regulation changes the number of years it may take a client to achieve a monthly reduced medication pick-up schedule for take home medications from four years to three years. Medicaid costs for visits and billing will be reduced because the patient goes to an OMM only once per month rather than weekly.

The proposed amendments will result in a reduction in paperwork for both OASAS and its certified providers. For example, the proposed regulations will reduce the number of individual patient exemptions and general waivers from current regulation, saving providers and the agency costly administrative time. An estimated monthly average of 10 requests for waivers would be eliminated. The proposed regulation allows more flexibility in take home medication and clinic schedule changes, areas of the highest number of individual patient exemptions.

The proposed regulation removes a requirement for OASAS approval for methadone dosage increases above 200 milligrams based on review of several available studies. In January 2007, 103 of 115 certified clinics requested a waiver from OASAS regarding prior OASAS approval for methadone dosage increases; granting the waiver resulted in 114 fewer individual patient exemptions regarding dosage increases during 2007. The proposed draft regulations would eliminate the need for providers to submit this waiver renewal upon recertification.

Federal regulations set the minimum standards and preserve states' authority to regulate OTPs and determine appropriate additional regulations. New York state has many unique concerns because the state has more OTP clinics and patients (115 and 39,314 respectively) than any of the other 44 states and territories providing opioid treatment. In New York City, multiple clinics serving thousands of patients may exist within blocks of each other leading to community resistance and public opposition to community based treatment programs. As a result, New York state regulations tend to be more stringent than federal standards.

OASAS solicited comments on the proposed regulations and possible alternatives from a cross-section of New York's upstate and downstate treatment provider community, as well as urban and rural programs. OASAS utilized a statewide coalition group, the Committee of Methadone Program Administrators (COMPA), to distribute the proposed regulation to all of its members and to collect comments. All comments received were reviewed and incorporated wherever appropriate. The proposed regulations were also shared with the National Alliance of Methadone Advocates (NAMA), New York States Council of Local Mental Hygiene Directors, New York State's Advisory Council, and Alcoholism and Substance Abuse Providers of New York State (ASAP).

This notice is intended to serve only as an emergency adoption, to be valid for 90 days or less. This rule expires August 8, 2011.

Text of rule and any required statements and analyses may be obtained from: Deborah Egel, 1450 Western Ave., Albany, NY 12203, (518) 485-2312, email: DeborahEgel@oasas.state.ny.us

Summary of Regulatory Impact Statement

The proposed Opioid Treatment for Addiction regulation was originally submitted for public review and comment within the field and then publicly in the NYS Department of State Register in December 2008. Prior to these proposed changes the last amendment to the regulation occurred under DSAS as Part 1040 in 1984 as 1040.21. It was then renumbered as Part 828 and moved to OASAS in 2000, with no significant changes. The methadone regulation has existed for 26 years without change even though the Code of Federal Regulations, title 42, Part 8 of opioid treatment have changed due to advancements and evidence based practice. Therefore the impact of the proposal will more closely align state regulations with federal rules that were promulgated in 2001, that changed due to advancements and evidence based practice.

Opioid addiction is a chronic illness which can be treated effectively with medications that are administered under conditions consistent with their pharmacological efficacy, and when treatment includes necessary supportive services such as psychosocial counseling, treatment for co-occurring disorders, medical services and, when appropriate, vocational rehabilitation. Medication assisted treatment is an evidence based practice for opioid dependency treatment. The proposed regulation sets forth standards to guide opioid dependency treatment.

Proposed changes recognize opioid addiction as a chronic illness that can be treated with certain medications (medication assisted treatment) in conjunction with supportive services (counseling, treatment for co-occurring disorders, and vocational rehabilitation).

1. Statutory Authority:

Mental Hygiene Law (MHL) § 19.07(e) authorizes the Commissioner of the Office of Alcoholism and Substance Abuse Services (OASAS) to ensure that persons who abuse or are dependent on alcohol and/or substances and their families receive effective and high quality care and treatment. MHL § 19.09(b) authorizes the Commissioner to adopt regulations to implement any matter under his or her jurisdiction.

MHL § 19.16 requires the commissioner to establish and maintain, either directly or through contract, a central registry for purposes of preventing multiple enrollment in methadone programs.

MHL § 19.40 authorizes the Commissioner to issue operating certificates for the provision of chemical dependence services.

MHL § 19.15(a) bestows upon the Commissioner the responsibility for promoting, establishing, coordinating, and conducting programs for the prevention, diagnosis, treatment, aftercare, rehabilitation, and control in the field of chemical abuse or dependence.

MHL § 19.21 (b) requires the Commissioner to establish and enforce certification, inspection, licensing and treatment standards for alcoholism, substance abuse, and chemical dependence facilities.

MHL § 19.21(d) requires the Commissioner to promulgate regulations to evaluate chemical dependence treatment effectiveness and to establish a procedure for reviewing and evaluating the performance of providers of services in a consistent and objective manner.

MHL § 32.01 authorizes the Commissioner to adopt any regulation reasonably necessary to implement and effectively exercise the powers and perform the duties conferred by MHL article 32.

MHL § 32.05 requires providers to obtain an operating certificate issued by the Commissioner in order to operate chemical dependence services including but not limited to methadone.

MHL § 32.09(b) gives the Commissioner the power to withhold an operating certificate for a Methadone provider until statutory requirements are satisfied.

2. Legislative Objectives:

Article 32 of the Mental Hygiene Law (§ 32.01) enables the Commissioner to regulate and assure consistent high quality of services within the state for persons suffering from chemical abuse or dependence, their families and significant others, and those at risk of becoming chemical abusers. 14 NYCRR Part 828 establishes requirements for chemotherapy substance abuse treatment (methadone). Revising policy and procedures with regard to opioid treatment, will establish a standard for all facilities, which is in the best interest of the patient, and will assist opioid treatment programs to provide better health care services and recovery from opioid dependency.

3. Needs and Benefits:

The proposed amendments advance the goals of guaranteeing patients the best treatment in a manner that is cost effective and accountable. The proposed amendments are needed because of developments inside and outside the agency including: (1) issues identified during an on-going broad-based dialogue with OASAS certified providers and affiliated stakeholders to define a "gold standard" for treatment and/or identify "best practices" for quality patient-centered care; (2) the need to conform regulations to updated federal standards related to opioid treatment (42 CFR Part 8), and; (3) evolution of social attitudes toward greater acceptance of persons recovering from chemical dependence

Part 828 conforms state and federal regulations affecting approximately 36% (40,000) of addiction patients in New York State. Opioid Treatment Program (OTP) physicians may administer buprenorphine (methadone alternative) in an OTP where clients will receive additional beneficial services such as counseling, toxicology, and medical support. Opioid Medical Maintenance (OMM; pursuant to a federal waiver to select providers approved by OASAS) permits monthly dispensing in a physician's office for certain patients who do not need long-term counseling.

This regulation was originally published in the NYS Register in December 2008. Many providers responded and offered comments. Here are the resulting changes to the regulation.

- Adds regulations related to buprenorphine (methadone alternative) treatment, removing an obstacle to physicians to administer buprenorphine in OTPs where clients may receive supportive services.
- Provides for opioid medical maintenance (OMM), pursuant to federal waiver, for certain qualified opioid patients and providers.
- Adds language for health care coordinator which is consistent with other regulations in the Part.
- Changed language for nurse/patient ratio back to prior language as no change was intended.
- Continuing care treatment is limited to four months, where after a client who requires more counseling should be referred to another modality.
- Increases flexibility in toxicology testing.
- Multidisciplinary team language changed to be consistent with our regulations in the Part.
- Mandatory use of Locatdr lifted.
- Allows for prescribing professionals to perform medical services except for initial dose and medical maintenance.
- Clarified definitions for taper and detoxification.
- Clarified language for transfer patients.
- Recognizes that treatment for opioid addiction may be provided in a residential or in-patient setting and makes provisions for regulation of such services.
- Changed the language and now allows an individual who voluntarily completed treatment to return to treatment without confirming current opioid dependence of two years and instead can accept them with one year.

In addition, all technical issues such as lettering, grammar and punctuation were fixed where necessary.

4. Costs:

Additional costs, if any, are up-front, minimal, and offset by improved treatment outcomes, increased staff efficiency, and clearer compliance directives.

a. Costs to regulated parties:

Patients and service providers are regulated parties. Patients will not incur additional costs. Providers may incur minimal up-front costs associated with laboratory testing, training and/or hiring qualified health professionals, but costs will be offset by improved outcomes, increased staff efficiency, and clearer compliance directives.

The proposed toxicology regulations are more cost effective: optional oral fluid testing is less onerous to staff, more dignified for the patient, and can address several patients simultaneously. Providers will know when patients relapse to deliver appropriate services for improved outcomes. The proposed regulation no longer mandates sexually transmitted disease (STD) testing but recommends testing to be completed as necessary for

patients who request testing or exhibit signs and symptoms. However, to protect the public, testing for Hepatitis is mandated because Hepatitis C has become epidemic; federal and DOH funds offset costs of testing and vaccines.

OASAS proposes requiring medical directors hired after the promulgation of the new rule to be certified in Addiction Medicine. All medical directors must obtain a board certification in one of three types of addiction medicine subspecialties and become buprenorphine certified within four months of employment (completion of an 8-hour course). Physicians may be hired on a probationary basis with four years to obtain certification.

The regulation requires fifty percent of staff to be Qualified Health Professionals (QHPs). Patients in OTPs with multiple medical, psychiatric and psychosocial barriers require specially trained staff. Most OASAS outpatient programs already meet or exceed this requirement because Credentialed Alcohol and Substance Abuse Counselors (CASAC) trainees are counted towards the 50 percent requirement. The proposed amendments for OTPs include a two year implementation to reach the 50% level plus flexibility in medication administration, toxicology and staffing configurations.

Providers will not incur any additional costs for materials. Requirements for OTP quality assurance are already mandated under Federal standards.

b. Costs to the agency, state and local governments:

OASAS does not anticipate increased administrative costs. OASAS will modify the review instrument currently used to evaluate OTPs and provide technical assistance to OTPs. Staff time needed to process individual and general regulatory waivers to current regulations will be decreased and such time can be allocated more efficiently.

Counties, cities, towns or local districts will incur no additional costs. Municipalities may realize savings because the regulation reduces (four years to three years) the time for an OTP client to achieve a monthly medication pick-up schedule; Medicaid costs will be reduced because the patient goes to an OMM monthly rather than weekly.

5. Local Government Mandates:

There are no new mandates or administrative requirements placed on local governments.

6. Paperwork / Reporting:

Paperwork will be reduced by reducing the requests for patient exemptions and regulatory waivers (average of 10 per month). The requirement that OASAS approve methadone dosage increases above 200 milligrams is removed. Studies show that adequate dosage varies among patients depending on metabolism and interaction with concurrent medications, yet inadequate methadone dosing is common (NIH, 1998; Marion, 2005). Dosing flexibility can be safe and improves treatment retention (Tenore, 2004; Maddux, et al, 1997). In January 2007, 103 of 115 OASAS clinics requested a waiver for dosage increases; granting the waiver resulted in 114 fewer individual patient exemptions. The proposed regulation eliminates the necessity of submitting this waiver renewal upon recertification.

7. Duplications:

There are no duplications of other state or federal requirements.

8. Alternatives:

The only other alternative is to keep the existing regulation in place. This would be detrimental to both the opioid treatment providers and patients being served. In an effort to elicit comments on the proposed regulations and possible alternatives, these amendments were shared with New York's treatment provider community, representing a cross-section of upstate and downstate, as well as urban and rural programs. OASAS used a statewide coalition group, the Committee of Methadone Program Administrators (COMPA), to facilitate distribution of this proposed regulation to all of its members and have collected comments. The regulations has been published, more comments were received, reviewed and more changes were made. Additionally, these regulations were also shared with the National Alliance of Methadone Advocates (NAMA), New York State's Council of Local Mental Hygiene Directors, New York State's Advisory Council, and Alcoholism and Substance Abuse Providers of NYS (ASAP).

9. Federal Standards:

Federal regulations set minimum standards for OTPs. New York's take-home regulations are more stringent than federal standards; New York has more OTP clinics and patients (115 and 39,314 respectively) than any of the other states and territories providing opioid treatment. Multiple New York City clinics serve thousands of patients within blocks of each other and often face community resistance.

Methadone diversion and related mortality is a concern because of the number of clinics and a substantial black market (Bell & Zador, 2000, Breslin & Malone, 2006, & Lewis, 1997). Regulations addressing diversion limit patients' receipt of take-home medication (minimum two years of treatment and additional criteria to receive a 30 day take-home supply). The proposed regulation seeks to reduce diversion yet balance patients'

ease of access by increasing testing frequency and adding routine "call backs" for patients with take home doses (Varenbut, et.al, 2007). Studies show benefits to take home options: improves treatment retention, attracts new patients, rewards patients' abstinence or treatment compliance, and improves patient quality of life (Ritter, et al, 2005). Most methadone-related deaths linked to diversion involved patients in pain management centers, not OTPs (Center for Substance Abuse Treatment, 2004; Cicero, 2005).

10. Compliance Schedule:

Providers may comply with the proposed changes upon adoption. Full implementation of this Part will be completed within one year of adoption with the exception of phased-in staffing requirements.

References

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The Center of Substance Abuse Treatment (CSAT) of the Substance Abuse and Mental Health Services Administration (SAMHSA) within the US Department of Health and Human Services (HHS).

Regulatory Flexibility Analysis

Effect of the Rule: The proposed Part 828 will impact certified and/or funded providers. It is expected that the development of opioid treatment programs will require providers to amend some of their policies and procedures in their treatment modality. These new services will result in better patient treatment outcomes. Local health care providers may see an increase in patients seeking medication assisted treatment for opioid dependency due to less restrictive procedures for medication assisted treatment. As a result of patients receiving these services, local governments may see a decrease in services associated with active illicit drug use such as arrests and emergency room visits. Also, local governments and districts will not be affected because any nominal increase in cost will be offset by better patient outcomes.

Compliance Requirements: It is expected that there will be some changes in compliance requirements. However, providers are equipped to make the changes which will enhance patient care. Also, providers are already required by federal statutes to provide certain services such as utilization review, so it is not expected that this regulation, which provides additional guidance on good utilization review practices, will have additional costs.

Professional Services: While it is expected that programs may require additional professional services the impact is nominal because over half of the current opioid treatment providers already meet the criteria set forth in the regulation for qualified health professionals and the regulation allows for phased implementation over four years.

Compliance Costs: Some programs may need additional formally trained staff to meet the proposed requirements; however, new CASAC credentialing rules, acceptance of CASAC trainees and phased implemen-

tation will decrease any barriers for compliance. Laboratory fees may increase; however, existing reimbursement fees should be sufficient to meet these requirements.

Economic and Technological Feasibility: Compliance with the record-keeping and reporting requirements of the proposed Part 828 is not expected to have an economic impact or require any changes to technology for small businesses and government.

Minimizing Adverse Impact: Part 828 has been carefully reviewed to ensure minimum adverse impact to providers. Alcoholism and Substance Abuse Providers of NYS, Inc., Greater New York Hospital Association, Healthcare of New York, The Federal Center for Substance Abuse Treatment, The Federal Drug Enforcement Agency, the OASAS Methadone Transformation Team, the Council of Local Mental Hygiene Directors and the Advisory Council on Alcoholism and Substance Abuse Services and approximately 50 opioid treatment programs were given the opportunity to comment on this proposal. Any impact this rule may have on small businesses and the administration of state or local governments and agencies will either be a positive impact or the nominal costs and compliance are small and will be absorbed into the already existing economic structure. The positive impact for our patients and our health care system, out weigh any potential minimal costs.

Small Business and Local Government Participation: The proposed regulations were shared with New York's treatment provider community including, Alcoholism and Substance Abuse Providers of NYS, Inc., Greater New York Hospital Association, Healthcare of New York, The Federal Center for Substance Abuse Treatment, The Federal Drug Enforcement Agency, the OASAS Methadone Transformation Team, the Council of Local Mental Hygiene Directors and the Advisory Council on Alcoholism and Substance Abuse Services.

Rural Area Flexibility Analysis

A rural flexibility analysis is not provided since these proposed regulations would have no adverse impact on public or private entities in rural areas. The majority of opioid treatment providers are located in NYC. There are a few others upstate, but they are in cities, of various sizes. There are only three providers located in Ulster, Broome and Montgomery which may be considered a rural area however they are in towns where the density is greater than 150 people per square mile. The compliance, recordkeeping and paperwork requirements are the minimum needed to insure compliance with state and federal requirements and quality patient care.

Job Impact Statement

The implementation of Part 828 will have an impact on jobs in that it will require 50% of the staff at an OTP to be a qualified health professional which is in alignment with other NYS treatment regulations (eg. Part 822). The hiring of formally trained staff will improve patient outcomes. At the present time OASAS has determined that most programs already meet or exceed this requirement. In addition, the regulation allows for CASAC trainees to be counted towards the 50% of QHP on staff and there is a phased implementation over the course of four (4) years. Finally, the change in CASAC testing requirements should increase the number of CASAC's in NYS. So while the current staff may need to enter formal education programs in order to maintain their employment this will help create new professional staff in New York State. This regulation will not adversely impact jobs outside of the agency.

Assessment of Public Comment

Effective Monday February 8, 2010 OASAS adopted the new NYS OASAS Part 828 Opioid Treatment Program regulations. Since the emergency adoption of the new Part 828 regulations, OASAS has received numerous inquiries from OTPs requesting clarification of the new emergency Part 828. The purpose of this Frequently Asked Questions document is to share with all OTPs the questions asked and answers provided to OTPs. The answers are intended to provide clarification to the new Part 828 regulations to assist OTPs in the implementation of the new regulations.

Please note that OASAS will be pursuing regulatory changes identified in this document during a formal full rule making process which will include a formal public comment period. This full rule making will be part of the OASAS revisions to our Part 822 Outpatient regulations which will result in the Opioid Treatment Program regulations being merged with the other outpatient regulations into one comprehensive regulation.

Definitions (828.4)

1. Q. 828.4(m) the definition for Opioid Detoxification states not to exceed 4 weeks. Can an OTP provide long-term detoxification treatment?

A. OTPs with a long-term detoxification treatment protocol should submit a waiver request with supporting documentation to the waiver committee.

Additional location (828.5)

2. Q. How do I apply for an additional location?

A. Applications for an additional location for Part 828 OTPs are not being processed at this time.

Screening for admission & Admission procedures (828.7 & 828.8)

3. Q. 828.7(h) applicants with a chronic immune deficiency condition shall be screened and admitted on a priority basis. How do we make that determination if past records are not received within 72 hours?

A. All applicants to OTPs must be screened for admission through face-to-face contact and admitted within 72 hours, if regulatory admission criteria are met and the OTP is below certified capacity. Admissions are based on the OTPs own medical and clinical evaluation. No records from any entity are required to admit an applicant to treatment, i.e., the non-receipt of a record cannot prevent an admission. If at certified capacity, the OTP must maintain and use a waiting list of otherwise acceptable applicants.

Applicants who are pregnant or with a chronic immune deficiency are deemed priority applicants. OTPs place priority applicants at the head of any waiting list and give such applicants the opportunity to be admitted before anyone on the list. The priority is determined as best as possible by patient's history and physical evaluation.

4. Q. In Section 828.8(a) Admission Procedures it states each person admitted to an OTP shall be evaluated within 24 hours but no longer than 72 hours when necessary. What type of evaluation is this referring to?

A. The intention of 828.8(a) is a patient must be screened for admission through face-to-face contact and admitted and medicated within 24 hours but no longer than 72 hours when necessary. This is not referring to the comprehensive physical exam which must be conducted within the first week.

5. Q. The new regulations indicate that a physical evaluation must be performed by a physician 828.7(d). A subsequent section 828.8(e)(4) states that a prescribing professional must complete a physical examination - does this mean all admissions must see a physician prior to admission?

A. Yes. It is the expectation that the physician sees all patients face-to-face as part of the admission. Admitting the patient to maintenance or detoxification treatment must be done by a physician. This cannot be deferred under any circumstance. In an emergency, a physician can be provided with the results of a physical evaluation by a qualified health care provider, by phone or fax, and the physician can admit the patient over the phone based upon that assessment. The patient record must be signed by the program physician within 72 hours.

Evaluation and comprehensive physical examination are not referring to the same requirement. 828.7(d) refers to a physical evaluation prior to admission. The evaluation is necessary to make the determination of addiction by a physician. Evaluation is defined as the verification of addiction prior to admission. The physician must diagnose addiction or dependence, document that diagnosis, and admit each patient to maintenance. 828.8(e)(4) refers to a comprehensive physical examination. The comprehensive physical examination includes other medical conditions which may be conducted by a prescribing professional. Examination is defined as the full physical examination, post admission, including results of serology and other test results. The examination should cover all major organs and the patient's overall health status.

6. Q. In section 828.8(d) it states "a physician must substantiate the determination of a history of opioid dependence and current physical dependence". Does this have to be done by a physician?

A. Yes. Determination is the decision to admit a patient to opioid treatment which must be done by a physician.

7. Q. In 828.8(e)(2) Admission Procedures it states staff must obtain medical, addiction, and mental health information in the development of the comprehensive treatment plan within two weeks of admission. 828.9(d) states that a comprehensive individualized patient centered treatment plan is due within 30 days of admission. When is the psychosocial and comprehensive treatment plan due?

A. The term "complete, narrative psychosocial history" found in the old regulations has been replaced with "obtain medical, addiction and mental health information". As written, the regulations require OTPs to obtain the medical, addiction and mental health information that will be used in the development of the treatment plan within two weeks of admission and the completed comprehensive treatment plan is due within 30 days.

8. Q. Under section 828.8(e)(5) required laboratory tests it states (vi) Hepatitis A, B or C. Is it really "or" instead of "and"? Can an OTP test only for Hepatitis C?

A. The regulations purposely states "or" to allow a prescribing professional to use good clinical judgment. For example, if a patient gives a history of Hepatitis B or vaccination with Twinrix, then really only Hepatitis C is indicated.

9. Q. 828.8(e)(6) tests for sexually-transmitted diseases should be completed as necessary. Does this mean that a test for syphilis is no longer required?

A. Yes.

10. Q. The reference for the annual exam now says: 828.8(f) A prescribing professional must annually repeat the physical examination required at admission. A patient can choose to have a non-OTP licensed practitioner complete the annual physical examination to determine health condition with all required results, including ordered tests, recorded in the patient's chart. Does this mean that annual lab work and/or a ppd are still required?

A. Yes "all required results" includes annual lab work and/or a ppd. A patient must receive an annual physical either at the OTP or if the patient chooses from a non-OTP licensed practitioner who includes all medically indicated lab work.

11. Q. What date does an OTP use to complete required documentation, such as annual physicals and quarterly treatment plans, when an OTP accepts a transfer patient from another OTP -- is it the "admission" date of the sending OTP or the "transfer" date of the receiving OTP [Parts 828.8(k)(4) and 828.9(f)].

A. The "admission" date of the sending OTP is the official date to use for all required documentation when a patient is transferred from one OTP to another, whether within New York State, from another state, or within a provider's own system of multiple sites. For example, if Program A admits a patient on January 1st and transfers that patient to Program B on May 1st, the patient's annual physical is due every January 1st, while the patient's quarterly treatment plan is due April, June, September, and December. Unfortunately, the date confusion is usually caused by either terminology or administrative systems. Clarity occurs when treatment continuity is kept foremost in mind. To extend the above example, Program B need not complete an "admission" physical on May 1st -- as many OTPs do in practice -- as no actual admission occurred in the continuous treatment of the patient.

OTPs should determine whether a transfer is temporary or permanent prior to receiving the patient from the sending OTP.

12. Q. 828.8(l)(6) regarding billing for patients in temporary treatment. Medicaid billing is on a weekly basis and is a flat rate for the week. Frequently patients are being guest medicated temporarily in another program for only part of the week, and in the home program for the rest of the week. Since Medicaid cannot be billed for a partial week, which OTP can bill the sending or receiving OTP?

A. The regulation as written is incorrect. The regulation should state: "6) the sending OTP cannot bill Medicaid for non-threshold visits nor collect fees from self-pay patients during the temporary treatment period."

Pursuant to Medicaid law and a long established Medicaid policy in our State, an OTP program can only bill for services provided to an admitted patient. The billing consists of a weekly methadone fee which is reimbursement for all the services a patient is supposed to get from the program during the week. If OTP A temporarily transfers a patient to OTP B for a few days, OTP A can bill Medicaid if the patient made a threshold visit to OTP A that week. OTP B can not bill Medicaid because the patient is not admitted to OTP B.

Individual treatment (828.9) and Recordkeeping (828.10)

13. Q. It states in 828.9(c) that all patients must have an individual session at least once a month. Is this correct? We have a counseling policy but time frames are determined by patient need and circumstances not set by time in treatment.

A. The regulation states that individualized treatment includes one individual counseling session each month. OTPs with a counseling policy that differs from this regulation may submit a waiver request with supporting documentation to the waiver committee.

14. Q. 828.9(f): Does the "summary of the patient's progress in each of the specified treatment plan goals" need to be part of the treatment plan or could this be covered in a progress note?

A. No. The summary must be documented in the treatment plan review which is separate from the comprehensive treatment plan and not a progress note.

15. Q. What do you do with a patient who is not responding to treatment [828.9(i)]?

A. The phrase "not responding to treatment" generally refers to documentation of chronic patterns of positive toxicologies for illicit substances, numerous unexplained absences, continued non compliance with the OTP rules and regulations and /or repeated relapses after significant time in treatment. However, the results of a single or isolated incident in this regard should not be considered as "not responding" to treatment. OTPs should intervene with a patient who is not responding to treatment including but not limited to discussion of the patient's treatment at a case conference, revision of the patient's treatment plan and documentation of any decisions in the patient record. If the treatment plan is revised, then going forward treatment plans are reviewed based on the date the plan was revised.

16. Q. It states in 828.9(i) Each OTP shall conduct multidisciplinary team meetings at least monthly. Patients who are non-responsive to treatment shall have their treatment plans revised. If the treatment plan is not

modified then the OTP must notate the reason. If the treatment plan is revised in compliance with 828.9 then going forward treatment plans are reviewed based on the date plan revised not admission date?

A. Yes.

17. Q. What documentation is required for counseling services?

A. A patient's record should contain documentation of all counseling services, immediate notations and summaries (828.10(b)(6)). The content and/or outcome of all visits must be fully documented in the individual patient's treatment record (828.23(f)). In addition, a summary of the content and outcome of all counseling services shall be entered in the patient's record at least monthly. Remarkable or notable occurrences shall be recorded in immediate notations. (828.9(g)). The summary which is entered at least monthly is in addition to the documentation of counseling visits. OTPs must be in compliance with both requirements at this time. OASAS will review these requirements after the proposed regulation is submitted to the NYS Department of State and published in the New York State Register for public comment.

18. Q. Do the regulations require the physician's signature on the treatment plan?

A. No. As per 828.9(d), (f) the treatment plan must be reviewed and signed and dated by at least three members of the multi-disciplinary team but not specifically the signature of the physician. Multi-disciplinary team is defined in Part 800.2(a)(12). The physician's signature could be on the treatment plan but is only required at admission and annual review. If the physician does not sign the treatment plan, the physician is not relieved of the responsibility for the patient's treatment.

19. Q. It states in 828.10(f) Each OTP must retain all patient records at least 6 years after discharge or contact, or three years after patient reaches the age of 18, whichever time period is longer. Why the 3 year option?

A. The three year option is for a patient who is discharged as a minor. The provision is to preserve legal rights of minors, in the event they had suffered some actionable legal harm. A patient's record must be kept for at least 6 years.

Medication administration (828.11)

20. Q. Section 828.11 Medication administration (h) A patient's approved medication shall not be withheld to enforce patient compliance with clinic rules or procedures, including but not limited to, rules on submitting to toxicology tests. Does this also pertain to take out medication or just daily dose? If a patient has a pickup schedule based on employment and fails to provide proof of employment by a certain, agreed upon date, can the program refuse to provide take out medication and be in compliance with this regulation.

A. This section is referring to patient's observed daily dose at the window, which can only be delayed, reduced or not administered for an emergent medical reason. This was added to the new regulations because in the past programs have abused withholding a patient's medication for many non-medical reasons.

An OTP may change a patient's take home schedule based on non-compliance with clinic policies for take-home (failure to provide proof of employment by an agreed upon date) and that OTP will be in compliance with this regulation. It is expected that an OTP will give a patient a warning prior to the change being made.

Take-home medication (828.12)

21. Q. In 828.12.b.2.v Take-home medication: it states employment or other productive activity. We have a large number of patients who are at or above retirement age or are on disability (SSI, SSD). They would not meet this criterion for take-home bottles. Do we have to complete an exemption request form for each individual who is otherwise stable but not engaged in a productive activity or not allow them take-home medication?

A. No. The regulation states "after a clinical review and consideration of the criteria below..." In considering the listed criteria, employment history, age, health and other conditions should be factored into the consideration. Therefore, a patient who is at or above retirement age would be allowed take-home medication as the patient is retired from employment, unable to work due to disability/illness, etc.

22. Q. Previously we needed OASAS approval for take-homes in excess of 14 bottles. Based on the new regulation 828.12 (e) with the one time, up to 30 take-home doses, this is no longer necessary, correct?

A. Yes, that is correct. OASAS approval would only be necessary for a one time take-home bottle release of 31 doses or more.

23. Q. Under the new regulations Part 828.12 3(e), if a patient requests and receives 30 take-home bottles for a job training and 4 months later requires an additional 30 bottles, is that allowed under these regulations?

A. Yes. A prescribing professional can order up to 30 take-home doses for a patient at any one time. There is no limit on how many times a year an order for additional take-home medication may be made for an isolated circumstance. However, the order can not be made continuously to make a permanent schedule change.

24. Q. 828.12(f) allows clinics to dispense methadone to someone other

than the patient. Will a clinic be allowed to bill Medicaid for this type of activity? Is it allowable under our current billing structure and would it be allowable under APGs?

A. Prior to the new regulations, OTPs were allowed with OASAS prior approval to dispense to a "designated other". The new regulation allows for OTPs to dispense to a visiting nurse or nursing home personnel without prior approval and to family members or other persons with prior approval. Medicaid rules still apply and a patient, not the designated other, has to make a threshold visit in order for the OTP to bill Medicaid. Some of these situations are very short term; for example a patient has knee surgery and can not come in to the clinic for a period of time. Other times it is a long term arrangement where a patient may have a chronic debilitating illness. Under APGs the patient would need to come to the clinic face-to-face in order to bill for medication administration.

25. In 828.12(f) what is required to release medication to a designated third party other than the patient?

A. During a patient's time in treatment at an OTP, there may be times when a patient is unable to go to the OTP to be medicated and receive take-home medication due to a medical condition, incarceration, residential treatment, transportation issue, etc. Prior OASAS approval is required to release a patient's medication to a designated third party (also known as a designated other) who is not a visiting nurse or nursing home personnel, such as a non-minor family member, spouse, significant other, or home attendant. The request will only need to be made to OASAS once as long as the request does not specify a specific time frame for the arrangement. A new request to OASAS would need to be made if the designated third party changes. Patients who are physically compromised or unable to go to their OTP should identify and provide consent for a designated other to pick-up their medication. The designated other should meet with clinic staff who should explain clinic policies and procedures and ensure the designated other is responsible and can safely handle the medication. A request should then be made to OASAS (and CSAT) to approve the designated other. OTPs should use a "chain of custody" record whenever a designated other picks up medication for a patient. A "chain of custody" is a document containing the signatures of all people who have handled the medication. The completed "chain of custody" record should be placed in the patient's medical record.

Prior OASAS approval is not required for a release of medication to a designated third party that is a visiting nurse or nursing home personnel. This decision will be made on the reasonable clinical judgment of the prescribing professional as documented in the chart. As stated above, the patient's consent should be obtained and documented in the chart. The need to re-evaluate a non-OASAS approved designated other must be re-evaluated monthly and documented in the chart.

Prior OASAS (and CSAT) approval is not required if the patient is brought to the clinic by a third party, for example if a patient is incarcerated in jail and escorted by a police officer to the OTP or if a patient is residing in a nursing home or residential facility and escorted to the OTP by facility staff. A chain of custody form however, should be used in those situations.

26. Q. Can we keep a patient on a once-per-week visit schedule even if they are eligible for a less frequent one in order to remain financially viable?

A. No. In general, a patient's schedule should not be determined with income, coverage or payment as a criteria. A patient's schedule should be the most appropriate schedule for his/her overall progress in treatment, based on prudent clinical judgment and regulatory criteria. The number of visits required based on length of time in treatment is a minimum. A patient's schedule may exceed what is allowable by regulation as appropriately determined by the physician.

Toxicology (828.13)

27. Q. In the new regulations 828.13(d) regarding frequency of toxicologies, "...at least bi-weekly thereafter". How is bi-weekly defined?

A. Bi-weekly is defined every two weeks.

28. 828.13(d)(1) states an OTP shall conduct monthly tests only for those patients who complete at least three months of bi-weekly tests that show no positive illicit results and who are on a 30 day take-home schedule. Should the word "and" be "or"?

A. Both. The regulation should read "An OTP shall conduct monthly tests only for those patients who complete at least three months of bi-weekly tests that show no positive illicit results and/or who are on a 30 day take-home schedule."

29. Q. Can patients who are currently on a monthly toxicology testing schedule remain on a monthly testing schedule if they are not on a 30 day take-home schedule?

A. Yes as long as the patient's toxicology test results do not show more than one positive illicit result within three month period [828.13(d)(2)].

30. Q. Our OTP computer system is designed to schedule patients "every 28 days" or "every 14 days" rather than "once a month" or "twice a month." Therefore we do not have any patients on a 30 day take

home schedule. Does this mean that we cannot have any patients on a monthly toxicology testing schedule?

A. No. The intention of the regulation is that patient should be on a once per month schedule in order to be have toxicology testing monthly.

31. Q. I am also confused by the wording in 828.13(d)(2). Does it mean that a single positive toxicology requires resuming bi-weekly testing or one positive result does not but more than one positive result does?

A. Per 828.13(b) no significant treatment decision shall be based solely on a single test result. Toxicology testing is considered a "significant treatment decision". Therefore one single positive illicit toxicology result does not require resuming bi-weekly testing.

Staffing (828.14)

32. Q. A nursing supervisory position is no longer a mandated position?

A. The nursing requirements in the new regulations are the same as in old regulations: 2 FT nurses for up to 300 patients at least one of whom is a registered nurse. The registered nurse shall be responsible for the general supervision of the nursing staff.

33. Q. 828.14(i) states at least 50% of all counselors on staff must be QHP...for period commencing effective date of this Part and ending one year thereafter at least 35% of aggregate clinical staff...from one year to two years 40% of clinical staff QHP and after two year period 50% of clinical staff QHP. Does this mean 50% of clinical staff does not just include counselors? Who is considered clinical staff?

A. The regulation should state clinical staff (not counselors) throughout section. Clinical staff member is defined in Part 800.2(4). "Clinical staff member" means an individual employed by the governing authority that is regularly supervised, receives regularly scheduled in-service training, and provides clinical services as required by this Part.

34. Q. Is the % QHP across division if multiple PRUs or per PRU?

A. 50% of clinical staff must be QHP at each individual OTP PRU.

35. 828.14(j) Staffing states at least fifty percent of all counselors on staff must be Qualified Health Professionals (QHPs) or CASAC trainees. Does a Licensed Mental Health Counselor (LMHC) count as a QHP?

A. Yes a LMHC may count as a QHP if an OTP receives OASAS approval through a waiver request. "LMHC" is not listed under Part 800.2(a)(15), however, an OTP may request a waiver from the Waiver Committee to include LMHC and a LMHC who also meets the additional training /experience requirements of Part 800.2(a)(15) will be automatically approved to be considered a non-CASAC QHP upon submission of the waiver.

36. 828.14(j) Does the designated Healthcare Coordinator have to be direct staff of a program? Could an OTP designate someone employed by another program/agency such as ARCS with which there is a service agreement?

A. Per regulation each program needs to have an OTP staff person as the designated Healthcare Coordinator. The designee does not have to be a new hire. The designee can not be contracted with an outside person/agency.

37. Q. Re 828.14(k): Each OTP can employ security guards to provide security for the OTP, its occupants and operations. Security guards are not clinical staff and shall not have any clinical responsibilities or be involved in clinical services or clinical activities..." Does this mean that only personnel who would otherwise qualify for a medical or counseling position will be allowed to hand out the labels and bottles for routine urine collection?

A. No. This regulation pertains only to the role of security guards.

38. Q. Regarding staffing, if none of our counselors at present are CASAC-Ts or QHP, are we expected to let go of current employees in order to comply with the new regulations?

A. OTPs must be in compliance with the regulations in the stated timeframes. However, instead of replacing excellent staff, staff could be encouraged to pursue a CASAC-T. While there are several ways to obtain a CASAC Trainee, those having a 4 year degree (Masters) in a Human Services field will be able to acquire the CASAC-T easily within the stated timeframe by meeting one of the following:

- 4,000 hours of work experience (Masters Degree substitutes for 4,000 hours or work experience)

and

- 85 hours of education/training, obtained within 10 years from submission of the application, relating to the knowledge of alcoholism and substance abuse

Or

- 350 hours of education/training, obtained within 10 years from submission of the application, in the following areas, as follows:

85 hours relating to the knowledge of alcoholism and substance abuse
150 hours related to alcoholism and substance abuse counseling
70 hours related to assessment; clinical evaluation; client record keeping and discharge planning

45 hours related to professional and ethical responsibilities

Additionally, effective immediately, OASAS has elected to grant a

waiver to persons whose CASAC, CPP, or CPS credential has expired for two or more years which will permit them to apply now to reinstate their credential using the fee structure that will be adopted when the new Part 853 Credentialing Regulations are promulgated. This new fee structure will significantly reduce the cost of reinstatement from the current maximum of \$650 (for applicants more than 5 years expired) to a maximum of \$350 (\$150 renewal fee and \$200 in late fees).

For further information on the CASAC Trainee, please call the OASAS Credentialing Unit at 800-482-9564 (option 2).

Continuing care (828.19)

39. Q. When does the clock start for how long a patient may remain in continuing care?

A. A patient may remain in continuing care for no more than 4 months from 2/8/10 which is the date the new emergency Part 828 regulations became effective.

40. Q. Can an OTP prescribe buprenorphine to a patient who has completed a methadone taper in continuing care?

A. No, continuing care treatment is a protocol for a patient who has completed an opioid maintenance taper whether the approved medication was methadone or buprenorphine, therefore the patient should not be receiving any approved medication at the OTP including a prescription for buprenorphine while in continuing care.

Community relations (828.21)

41. Q. 828.21(b) the office shall require such policy to include forming a community committee which meets regularly to discuss actions to improve community relations. The old regulations stated may require. Shouldn't the committee be based on need?

A. The regulation requires a community relations policy to include forming a community committee.

Standards pertaining to Medicaid reimbursement (828.23)

42. Q. 828.23(a) If a provider can only bill Medicaid for patients that make a threshold visit can fee paying patients be billed in same situation? There is concern about having 2 different standards.

A. Yes. Fee paying patients should be billed for weekly threshold visits only. There should not be a separate standard.

43. Q. 828.24(c) if the Medicaid weekly fee is only for admitted patients, can providers bill patients separately for pre-admission services?

A. No. Part 828 OTPs receive a weekly threshold visit only and it is to be used AFTER the patient has been admitted to the Part 828. The weekly Medicaid rate is an all-inclusive rate. Services can not be charged separately.

In response to questions regarding prescribing professional as defined in 828.4(r), please read the summary below.

Prescribing Authority for Nurse Practitioners (NP) and Physician Assistants (PA) for Methadone

Methadone for opioid addiction is regulated through licensed facilities including CSAT, DEA, Department of Health, OASAS and the State Education Department.

CSAT

Admitting the patient to maintenance or detoxification treatment must be done by a physician. This cannot be deferred under any circumstance. The expectation is that the physician sees every patient face to face as part of the admission. In an emergency, a physician can be provided with the results of a physical examination by a qualified health care provider, by phone or fax and the physician admits the patient over the phone based upon that assessment and determines initial dose to be administered to patient. The patient record must be signed by the program physician within 72 hours. (see 42 CFR 8.12(e) and (f)(2)).

Practitioners, or agents of practitioners who are licensed under State law and registered under Federal law, may administer or dispense opioid agonist treatment medications. In New York, physician assistants under the supervision of a physician, and nurse practitioners working with a collaborative agreement, are authorized to modify patient medication levels and take-home schedules (see 42 CFR 8.12(h)(4)(1)).

Non-physician health care professionals are permitted to conduct various activities under the regulations. For example, under 42 CFR 8.12(f), an authorized health care professional under the supervision of the program physician may conduct the required initial physical examination. On the other hand, only a medical director or program physician shall determine a patient's eligibility for take-home medications under (see 42 CFR 8.12 (i)(2)).

Under the regulations, the medical director and program physicians are responsible for program-wide medication dosing and administration policies. In addition, significant deviations from approved product labeling must be documented by a program physician and medical director (see 42 CFR 8.12 (h)(4)).

Drug Enforcement Agency

Each practitioner may administer or dispense directly (but not prescribe) methadone to a narcotic dependant person for the purpose of maintenance or detoxification treatment if the practitioner meets both of the following conditions (see 21 CFR § 1306.07):

(1) "The practitioner is separately registered with DEA as a narcotic treatment program".

(2) "The practitioner is in compliance with DEA regulations regarding treatment qualifications, security, records, and unsupervised use of the drugs pursuant to the Act".

New York State Public Health Law

Controlled substances may be prescribed for, or administered or dispensed to an addict or habitual user:

Methadone, or such other controlled substance designated by the commissioner as appropriate for such use, may be administered to an addict by a practitioner or by his designated agent acting under the direction and supervision of a practitioner, as part of a substance abuse or chemical dependence program approved pursuant to article twenty-three or thirty-two of the mental hygiene law (see Title 5 § 3351(1)(5)).

New York State OASAS

"A Prescribing Professional is any medical professional appropriately licensed under New York State law and registered under federal law to prescribe approved medications". (MH Chapter 21 Part § 828.4(r)).

Physician's Assistants

Section 3703(3) of the Public Health Law authorizes a registered physician's assistant to prescribe controlled substances - including Schedule II who is registered with the DEA beginning December 13, 2007. The law requires such prescribing to be:

- "In good faith and in the physician's assistant's lawful scope of practice";
- "Authorized by the physician's assistant's supervising physician";
- "For patients under the care of the supervising physician".

Methadone, a schedule II medication, can be prescribed by a PA when treating for pain management.

Nurse Practitioners

A licensed Nurse Practitioner who is registered with the DEA is authorized to prescribe controlled substances - including Schedule II as evidenced in a letter that was jointly signed by NPANYS and NYSNA dated Nov. 2005 to then NYS Department of Health Commissioner Novello which stated that NPs are authorized by NYS law to prescribe schedule II-IV medications. Methadone, a schedule II medication, can be prescribed by an NP when treating for pain management.

Synthesizing the law, as it pertains to Methadone, the analysis is as follows:

If an NP or PA is licensed and has received a DEA number they may write orders in an OTP to modify patient medication levels, PA's are required to be under the supervision of a physician. NP's and PA's may not admit a patient to an OTP nor can they prescribe methadone for addiction.

Buprenorphine

Buprenorphine is the only Schedule III medication for which law explicitly mandates that only physicians can prescribe it (Drug Addiction Treatment Act. (2000). Pub. L. No. 106-310, Div. B, Title XXXV, Section 3502(a)). (October 17, 2000) an authorized physician may prescribe, administer or dispense an approved controlled substance, and a licensed registered pharmacist may dispense an approved controlled substance, to a patient participating in an authorized controlled substance maintenance program approved pursuant to Article 32 of the Mental Hygiene Law for the treatment of narcotic addiction.

In addition an authorized physician prescribing an approved controlled substance for the treatment of narcotic addiction, in addition to preparing and signing an official New York State prescription in accordance with Section 3332 of the Public Health Law and Section 80.69 of this Part, shall also write his/her unique DEA identification number on the prescription.

Department of Correctional Services

NOTICE OF ADOPTION

Transfer of Foreign Nationals

I.D. No. COR-10-11-00003-A

Filing No. 432

Filing Date: 2011-05-16

Effective Date: 2011-06-01

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

Action taken: Amendment of sections 130.1(b), 130.2(c), (d), (e), (f)(2), (g), (i) and (j) of Title 7 NYCRR.

Statutory authority: Correction Law, sections 5(4) and 71.1(b)1-b

Subject: Transfer of Foreign Nationals.

Purpose: To provide clarity regarding eligibility requirements, revise terminology, and to update an employee job title.

Text or summary was published in the March 9, 2011 issue of the Register, I.D. No. COR-10-11-00003-P.

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

Text of rule and any required statements and analyses may be obtained from: Maureen E. Boll, Deputy Commissioner and Counsel, NYS Dept. of Corrections and Community Supervision, Harriman State Campus - Building 2 - 1220 Washington Avenue, Albany, NY 12226-2050, (518) 457-4951, email: Regs@docs.state.ny.us

Assessment of Public Comment

The agency received no public comment.

Education Department

EMERGENCY RULE MAKING

Technical Amendment of Section 100.2(ee)(2)

I.D. No. EDU-09-11-00007-E

Filing No. 436

Filing Date: 2011-05-17

Effective Date: 2011-05-17

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

Action taken: Amendment of section 100.2(ee)(2) of Title 8 NYCRR.

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

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

Specific reasons underlying the finding of necessity: The amendments concerning diploma credit for languages other than English (LOTE) and State assessments in Social Studies, that were adopted at the December 2010 Regents meeting (EDU-40-10-00022-P), inadvertently omitted language in section 100.2(ee)(2) that was added in a prior, separate amendment concerning Academic Intervention Services, that was permanently adopted at the October 2010 Regents meeting (EDU-31-10-00004-P). The proposed amendment is necessary to clarify and resolve this inconsistency by including the omitted language.

The proposed amendment was adopted as an emergency action at the February 7-8, 2011 Regents meeting. A Notice of Emergency Adoption and Proposed Rule Making was published in the State Register on March 2, 2011.

The proposed amendment has now been adopted as a permanent rule at the May 16-17, 2011 Regents meeting. Pursuant to the State Administrative Procedure Act, the earliest the permanent rule may become effective is after its publication in the State Register on June 1, 2011. Since the February 2011 emergency adoption will expire on May 16, 2011, 90 days after its filing with the Department of State on February 15, 2011, there would be a lapse in the rule's effectiveness. Another emergency adoption is necessary for the preservation of the general welfare to ensure that the emergency rule adopted at the February 2011 Regents meeting remains continuously in effect until the effective date of its adoption as a permanent rule.

Subject: Technical amendment of section 100.2(ee)(2).

Purpose: To add language that was inadvertently omitted in a previous rule making.

Text of emergency rule: Paragraph (2) of subdivision (ee) of section 100.2 of the Regulations of the Commissioner of Education is amended, effective May 17, 2011, as follows:

(2) Requirements for providing academic intervention services in grade [four] *three* to grade eight. Schools shall provide academic intervention services when students:

(i) score below:

(a) the State designated performance level on one or more of the State elementary assessments in English language arts, mathematics or science, *provided that for the 2010-2011 school year only, the following shall apply:*

(1) *those students scoring at or below a scale score of 650 shall receive academic intervention instructional services; and*

(2) *those students scoring above a scale score of 650 but below level 3/proficient shall not be required to receive academic intervention instructional and/or student support services unless the school district, in its discretion, deems it necessary. Each school district shall develop and maintain on file a uniform process by which the district determines whether to offer AIS during the 2010-2011 school year to students who scored above a scale score of 650 but below level 3/proficient on a grade 3-8 English language arts or mathematics State assessment in 2009-2010, and shall no later than the commencement of the first day of instruction either post to its Website or distribute to parents in writing a description of such process;*

and/or

(b) the State designated performance level on a State elementary assessment in social studies administered prior to the 2010-2011 school year; provided that beginning in the 2010-2011 school year, at which time a State elementary assessment in social studies shall no longer be administered, a school shall provide academic intervention services when students are determined to be at risk of not achieving State learning standards in social studies pursuant to clause (iii) of this paragraph;

(ii) . . .

(iii) . . .

This notice is intended to serve only as a notice of emergency adoption. This agency intends to adopt the provisions of this emergency rule as a permanent rule, having previously submitted to the Department of State a notice of proposed rule making, I.D. No. EDU-09-11-00007-EP, Issue of March 2, 2011. The emergency rule will expire July 15, 2011.

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

Regulatory Impact Statement

1. STATUTORY AUTHORITY:

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

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

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

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

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

Education Law section 3204(3) provides for the courses of study in the public schools.

2. LEGISLATIVE OBJECTIVES:

The proposed amendment is consistent with the authority conferred by the above statutes and is necessary to implement policy enacted by the Board of Regents.

3. NEEDS AND BENEFITS:

The amendments concerning diploma credit for languages other than English (LOTE) and State assessments in Social Studies, that were adopted at the December 2010 Regents meeting (EDU-40-10-00022-A), inadvertently omitted language in section 100.2(ee)(2) that was added in a prior, separate amendment concerning Academic Intervention Services, that was permanently adopted at the October 2010 Regents meeting (EDU-31-10-00004-A). The proposed amendment is necessary to clarify and resolve this inconsistency by including the omitted language.

COSTS:

(a) Costs to State government: None.

(b) Costs to local government: The proposed amendment establishes modified requirements for the provision of AIS during the 2010-2011 school year to provide flexibility to school districts and to hold districts harmless from the expected fiscal impact of an increase in the number of students required to receive AIS as a result of a change in cut scores for the grades 3-8 assessments in English language arts and mathematics which determine student proficiency. School districts may incur some costs associated with distributing to parents of students a written description of the district's process for determining whether AIS will be offered to students who scored above a scale score of 650 but below level 3/proficient on a grade 3-8 English language arts or mathematics State assessment in 2009-2010. However, the proposed amendment allows school districts to post the description on its Website in lieu of distributing to parents, and it is anticipated that any associated costs would be minimal and can be absorbed using existing district staff and resources. More importantly, any such costs would be more than offset by the reduction in costs to schools districts resulting from implementation of the modified AIS requirements in the 2010-2011 school year.

(c) Costs to private regulated parties: None.

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

5. LOCAL GOVERNMENT MANDATES:

The proposed amendment establishes modified requirements for the provision of AIS during the 2010-2011 school year to provide flexibility to school districts and to hold districts harmless from the expected fiscal impact of an increase in the number of students required to receive AIS as a result of a change in cut scores for the grades 3-8 assessments in English language arts and mathematics which determine student proficiency. As part of the modified requirements, the proposed amendment requires each school district to develop and maintain on file a uniform process by which the district determines whether to offer AIS during the 2010-2011 school year to students who scored above a scale score of 650 but below level 3/proficient on a grade 3-8 English language arts or mathematics State assessment in 2009-2010, and to either post to its Website or distribute to parents in writing a description of such process no later than the commencement of the first day of instruction.

6. PAPERWORK:

The proposed amendment requires each school district to develop and maintain on file a uniform process by which the district determines whether to offer AIS during the 2010-2011 school year to students who scored above a scale score of 650 but below level 3/proficient on a grade 3-8 English language arts or mathematics State assessment in 2009-2010, and to either post to its Website or distribute to parents in writing a description of such process no later than the commencement of the first day of instruction.

7. DUPLICATION:

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

8. ALTERNATIVES:

There were no significant alternatives and none were considered.

9. FEDERAL STANDARDS:

There are no related federal standards.

10. COMPLIANCE SCHEDULE:

It is anticipated regulated parties will be able to achieve compliance with the proposed rule by its effective date.

Regulatory Flexibility Analysis

1. EFFECT OF RULE:

The amendment applies to each school district within the State.

2. COMPLIANCE REQUIREMENTS:

The amendments concerning diploma credit for languages other than English (LOTE) and State assessments in Social Studies, that were adopted at the December 2010 Regents meeting (EDU-40-10-00022-A), inadvertently omitted language in section 100.2(ee)(2) that was added in a prior, separate amendment concerning Academic Intervention Services, that was permanently adopted at the October 2010 Regents meeting (EDU-31-10-00004-A). The proposed amendment is necessary to clarify and resolve this inconsistency by including the omitted language.

The amendment establishes modified requirements for the provision of academic intervention services (AIS) during the 2010-2011 school year to provide flexibility to school districts and to hold districts harmless from the expected fiscal impact of an increase in the number of students required to receive AIS as a result of a change in cut scores for the grades 3-8 assessments in English language arts and mathematics which determine student proficiency. As part of the modified requirements, the proposed amendment requires each school district to develop and maintain on file a uniform process by which the district determines whether to offer AIS during the 2010-2011 school year to students who scored above a scale score of 650 but below level 3/proficient on a grade 3-8 English language arts or mathematics State assessment in 2009-2010, and to either post to its Website or distribute to parents in writing a description of such process no later than the commencement of the first day of instruction.

Specifically, the amendment provides that for the 2010-2011 school year only:

(1) Students scoring at or below a scale score of 650 must receive academic intervention instructional services.

(2) Students scoring above a scale score of 650 but below level 3/proficient will not be required to receive academic intervention instructional and/or student support services unless the school district deems it necessary.

(3) Each school district shall develop and maintain on file a uniform process by which the district determines whether to offer AIS during the 2010-11 school year to students who scored above a scale score of 650 but below level 3/proficient on a grade 3-8 English language arts or mathematics State assessment in 2009-10, and shall post to its Website or distribute to parents in writing a description of such process no later than the commencement of the first day of instruction.

(4) In recognition of the effects on school districts of a change in cut scores for such school year, a waiver is given for the 2010-2011 school year from the requirement that school districts review and revise their description of AIS based on student performance results.

3. PROFESSIONAL SERVICES:

The amendment imposes no additional professional service requirements on school districts.

4. COMPLIANCE COSTS:

The amendment establishes modified requirements for the provision of AIS during the 2010-2011 school year to provide flexibility to school districts and to hold districts harmless from the expected fiscal impact of an increase in the number of students required to receive AIS as a result of a change in cut scores for the grades 3-8 assessments in English language arts and mathematics which determine student proficiency. School districts may incur some costs associated with distributing to parents of students a written description of the district's process for determining whether AIS will be offered to students who scored above a scale score of 650 but below level 3/proficient on a grade 3-8 English language arts or mathematics State assessment in 2009-2010. However, the proposed amendment allows school districts to post the description on its Website in lieu of distributing to parents, and it is anticipated that any associated costs would be minimal and can be absorbed using existing district staff and resources. More importantly, any such costs would be more than offset by the reduction in costs to schools districts resulting from implementation of the modified AIS requirements in the 2010-2011 school year.

5. ECONOMIC AND TECHNOLOGICAL FEASIBILITY:

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

6. MINIMIZING ADVERSE IMPACT:

The purpose of the amendment is to provide flexibility to school districts in providing academic intervention services (AIS) during the 2010-2011 school year in order to hold districts harmless from the expected fiscal impact of an increase in the number of students required to receive AIS as a result of a change in cut scores for the grades 3-8 assessments in English language arts and mathematics. School districts will continue to have the option to offer services to those children who they feel are in need of the additional support.

7. SMALL BUSINESS AND LOCAL GOVERNMENT PARTICIPATION:

Comments on the amendment were solicited from school districts through the offices of the district superintendents of each supervisory district in the State, and from the chief school officers of the five big city school districts.

Rural Area Flexibility Analysis

1. TYPES AND ESTIMATED NUMBER OF RURAL AREAS:

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

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

The amendments concerning diploma credit for languages other than English (LOTE) and State assessments in Social Studies, that were adopted at the December 2010 Regents meeting (EDU-40-10-00022-A), inadvertently omitted language in section 100.2(ee)(2) that was added in a prior, separate amendment concerning Academic Intervention Services, that was permanently adopted at the October 2010 Regents meeting (EDU-31-10-00004-A). The proposed amendment is necessary to clarify and resolve this inconsistency by including the omitted language.

The amendment establishes modified requirements for the provision of academic intervention services (AIS) during the 2010-2011 school year to provide flexibility to school districts and to hold districts harmless from the expected fiscal impact of an increase in the number of students required to receive AIS as a result of a change in cut scores for the grades 3-8 assessments in English language arts and mathematics which determine student proficiency. As part of the modified requirements, the proposed amendment requires each school district to develop and maintain on file a uniform process by which the district determines whether to offer AIS during the 2010-2011 school year to students who scored above a scale score of 650 but below level 3/proficient on a grade 3-8 English language arts or mathematics State assessment in 2009-2010, and to either post to its Website or distribute to parents in writing a description of such process no later than the commencement of the first day of instruction.

Specifically, the amendment provides that for the 2010-2011 school year only:

(1) Students scoring at or below a scale score of 650 must receive academic intervention instructional services.

(2) Students scoring above a scale score of 650 but below level 3/proficient will not be required to receive academic intervention instructional and/or student support services unless the school district deems it necessary.

(3) Each school district shall develop and maintain on file a uniform process by which the district determines whether to offer AIS during the 2010-11 school year to students who scored above a scale score of 650 but below level 3/proficient on a grade 3-8 English language arts or mathematics State assessment in 2009-10, and shall post to its Website or distribute to parents in writing a description of such process no later than the commencement of the first day of instruction.

(4) In recognition of the effects on school districts of a change in cut scores for such school year, a waiver is given for the 2010-2011

school year from the requirement that school districts review and revise their description of AIS based on student performance results.

The amendment imposes no additional professional services requirements on school districts in rural areas.

3. COMPLIANCE COSTS:

The amendment establishes modified requirements for the provision of AIS during the 2010-2011 school year to provide flexibility to school districts and to hold districts harmless from the expected fiscal impact of an increase in the number of students required to receive AIS as a result of a change in cut scores for the grades 3-8 assessments in English language arts and mathematics which determine student proficiency. School districts may incur some costs associated with distributing to parents of students a written description of the district's process for determining whether AIS will be offered to students who scored above a scale score of 650 but below level 3/proficient on a grade 3-8 English language arts or mathematics State assessment in 2009-2010. However, the proposed amendment allows school districts to post the description on its Website in lieu of distributing to parents, and it is anticipated that any associated costs would be minimal and can be absorbed using existing district staff and resources. More importantly, any such costs would be more than offset by the reduction in costs to schools districts resulting from implementation of the modified AIS requirements in the 2010-2011 school year.

4. MINIMIZING ADVERSE IMPACT:

The amendment provides flexibility to school districts in providing academic intervention services (AIS) during the 2010-2011 school year in order to hold districts harmless from the expected fiscal impact of an increase in the number of students required to receive AIS as a result of a change in cut scores for the grades 3-8 assessments in English language arts and mathematics. School districts will continue to have the option to offer services to those children who they feel are in need of the additional support.

5. RURAL AREA PARTICIPATION:

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

Job Impact Statement

The amendment establishes modified requirements for the provision of academic intervention services (AIS) during the 2010-2011 school year to provide flexibility to school districts and to hold districts harmless from the expected fiscal impact of an increase in the number of students required to receive AIS as a result of a change in cut scores for the grades 3-8 assessments in English language arts and mathematics which determine student proficiency.

The amendment will not have an adverse impact on jobs or employment opportunities. Because it is evident from the nature of the amendment that it will have a positive impact, or no impact, on jobs or employment opportunities, no further steps were needed to ascertain those facts and none were taken. Accordingly, a job impact statement is not required and one has not been prepared.

**NOTICE OF EMERGENCY
ADOPTION
AND REVISED RULE MAKING
NO HEARING(S) SCHEDULED**

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

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

Filing No. 434

Filing Date: 2011-05-17

Effective Date: 2011-05-17

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

Action Taken: Amendment of sections 80-1.1, 80-3.3(b)(2)(i), 80-3.7; and addition of section 80-5.22 to Title 8 NYCRR.

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

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

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

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

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

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

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

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

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

A Notice of Revised Rule Making will be published in the State Register on June 1, 2011. It is anticipated that the proposed amendment will be presented to the Board of Regents for adoption as a permanent rule at its July 2011 meeting, which is the first scheduled meeting after the expiration of the 30-day public comment period mandated by the State Administrative Procedures Act for revised rule makings. Emergency action is needed to ensure that the revised rule remains continuously in effect until it can be adopted as a permanent rule on August 10, 2011.

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

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

Text of emergency/revised rule: 1. Paragraphs (45) through (47) of subdivision (b) of Section 80-1.1 of the Regulations of the Commissioner of Education should be renumbered (46) through (48) of Section 80-1.1 of the Regulations of the Commissioner of Education, effective May 17, 2011.

2. A new paragraph (45) of subdivision (b) is added to Section 80-1.1 of the Regulations of the Commissioner of Education, effective May 17, 2011, to read as follows:

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

3. Subparagraph (i) of paragraph (2) of subdivision (b) of section 80-3.3 of the Regulations of the Commissioner of Education is amended, effective May 17, 2011, to read as follows:

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

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

4. Section 80-3.7 of the Regulations of the Commissioner of Education is amended, effective May 17, 2011, to read as follows:

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

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

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

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

(i)

(ii) Special list in middle childhood education (5-9) and adolescence education (7-12).

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

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

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

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

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

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

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

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

(b) . . .

(c) . . .

5. Section 80-5.22 of the Regulations of the Commissioner is added, effective May 17, 2011 as follows:

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

(a) *General requirements.*

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

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

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

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

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

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

This notice is intended to serve as both a notice of emergency adoption and a notice of revised rule making. The notice of proposed rule making was published in the *State Register* on March 2, 2011, I.D. No. EDU-09-11-00005-. The emergency rule will expire July 15, 2011.

Emergency rule compared with proposed rule: Substantial revisions were made in sections 80-3.3(a)(2), 80-3.7 and 80-5.22.

Text of rule and any required statements and analyses may be obtained from: Christine Moore, New York State Education Department, 89 Washington Avenue, Albany, New York 12234, (518) 408-1189, email: cmoore@mail.nysed.gov

Data, views or arguments may be submitted to: Peg Rivers, New York State Education Department, 89 Washington Avenue, Albany, New York 12234, (518) 408-1189, email: privers@mail.nysed.gov

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

Revised Regulatory Impact Statement

Since publication of a Notice of Proposed Rule Making in the *State Register* on March 2, 2011, the following substantial revisions were made to the proposed rule:

Section 80-3.3(a)(2)(i) of the Regulations of the Commissioner of Education is amended to delete the reference to grades 5-9.

Section 80-3.7 of the Regulations of the Commissioner of Education is amended to provide that candidates with a graduate degree in science, technology, engineering or mathematics who apply for an initial teaching certificate under 80-3.7(a)(3)(ii)(3) may continue to meet the education requirements for classroom teaching certificates through individual evaluation after February 1, 2012. This section is further amended to delete any reference to grades 5-9.

Section 80-5.22 of the Regulations of the Commissioner of Education is amended to include in the employment and support commitment for the Transitional G certificate a requirement that the school district submit a plan for mentoring and appropriate instructional support as determined by school leadership and at least 70 hours of professional development targeted toward appropriate pedagogical skills, over the two years of employment as part of its employment commitment.

The above revisions to the proposed rule require revisions to the Needs and Benefits, Local Government Mandates and Paperwork sections of the previously published Regulatory Impact Statement.

3. NEEDS AND BENEFITS:

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

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

The transitional G certificate will be valid for two years from its effective date and will not be renewable. It will be limited to employment with an employing entity.

5. LOCAL GOVERNMENT MANDATES:

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

6. PAPERWORK:

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

Revised Regulatory Flexibility Analysis

Since publication of a Notice of Proposed Rule Making in the *State Register* on March 2, 2011, the proposed rule was revised as set forth in the Revised Regulatory Impact Statement herewith.

The above revisions to the proposed rule require that the Small Businesses and Local Governments compliance requirements sections of the previously published Regulatory Flexibility Analysis be revised to read as follows:

(a) Small businesses:

The purpose of the proposed amendment is to establish an expedited pathway for individuals with advanced degrees in science, technology, engineering and mathematics and at least two years of postsecondary teaching experience to become certified in science or mathematics in

grades 7-12 to address the demonstrated shortage areas in these subjects and grade levels. The amendment does not impose any reporting, record-keeping, or compliance requirements and will not have an economic impact on small businesses. Because it is evident from the nature of the rule that it does not affect small businesses, no further steps were needed to ascertain that fact and none were taken.

(b) Local governments.

2. Compliance requirements:

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

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

Revised Rural Area Flexibility Analysis

Since publication of a Notice of Proposed Rule Making in the State Register on March 2, 2011, the proposed rule was revised as set forth in the Revised Regulatory Impact Statement filed herewith.

The above revisions to the proposed rule require that the Reporting, recordkeeping and other compliance requirements and professional services section of the previously published Rural Area Flexibility Analysis be revised to read as follows:

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

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

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

Revised Job Impact Statement

Since publication of the Notice of Proposed Rule Making in the State Register on March 2, 2011, the proposed rule was revised as set forth in the Revised Regulatory Impact Statement filed herewith.

The proposed rule, as so revised, relates to an expedited certification pathway for individuals with advanced degrees in Science, Technology, Engineering and Mathematics (STEM) and related teaching experience at the post-secondary level to obtain a teaching certificate in Earth Science, Biology, Chemistry, Physics, Mathematics or in a Closely Related Field in grades 7-12. The revised rule will not have a substantial adverse impact on job or employment opportunities. Because it is evident from the nature of the revised rule that it will have no impact on jobs or employment opportunities, no further measures were taken. Accordingly, a job impact statement is not required and one has not been prepared.

Assessment of Public Comment

Since publication of a Notice of Proposed Rule Making in the State Register on March 2, 2011, the State Education Department received the following comments:

1. COMMENT: Two comments expressed concern that the Transitional G Certificate would not require any college or university teacher preparation.

One comment noted that under this option, it is conceivable that a person with a master's degree in mathematics, two years of teaching young adults in a college setting, no awareness of NYS Learning Standards, IEP or 504 plans, and strategies for English language learners could be the Teacher of Record for sixth graders. This may be a candidate who has never had an opportunity to explore classroom management, how to vary instructional approaches for student characteristics, or middle school/high school assessment approaches.

Another comment suggested that shifting this responsibility to in-service or BOCES will have a detrimental effect of taking those in higher education who study pedagogy out of the process. It will also mean that new teachers will not have the ability to meet other teachers from different districts to discuss what works.

DEPARTMENT RESPONSE: Originally the draft regulation was proposed at the Regents December 2010 meeting with a requirement of two years of post secondary teaching experience, a graduate degree in a STEM area, and six semester hours of coursework in pedagogy for Initial certification.

The Higher Education Committee of the Board of Regents discussed this proposal at its December 2010 meeting and expressed their concern that requiring an additional six college credits in pedagogy for all STEM pathway candidates would present a disincentive to college faculty to pursue this career change. Members of the Committee also noted that college faculty with a master's degree in science, technology, engineering or math and two years of teaching experience at the post secondary level teaching this subject would possess the skills needed to begin to teach at the high school level.

Based on the Board's December discussion, the Department proposed an alternative to the six semester hours of college course work that allows a college faculty member to obtain a Transitional G certificate under the condition that the employing school district provide mentoring and at least 70 hours of professional development targeted toward appropriate pedagogical skills to the candidate during the course of their employment with the district. Accordingly, the proposed amendment allows a candidate to choose one of the following expedited pathways: (1) commence teaching with a Transitional G certificate with these supports from the school district, or (2) the candidate may complete the six semester hours of college course work in pedagogy to qualify for the initial certificate.

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

The Department has also added language to the regulation to require the employing school district, for a teacher holding a Transitional G certificate, to have a plan for mentoring and instructional support during the teacher's service on the transitional certificate. This is in addition to the required 70 or more hours of professional development targeted toward appropriate pedagogical skills.

2. COMMENT: One comment indicated that it is not reasonable to expect that in-service staff development will actually be targeted toward the individual. In-district (or BOCES) professional development is designed for individuals who have already been prepared through an accredited college or university teacher preparation program. At the very minimum, the pedagogical core needs to be developed and delivered through an accredited college or university teacher preparation program.

DEPARTMENT RESPONSE: Individual college faculty coming through the STEM pathway will bring different levels of teaching experience and skill. Some may have many years of teaching experience and others may only have the required two years.

The language added to the current proposed regulation requires the local school leadership to assess the supports needed by the teacher and to provide appropriate instructional support including targeted professional development activities.

The implementation of the new teacher performance evaluation system will also support this approach in the future by requiring performance evaluations of all teachers using the Regents approved teaching standards as a common base. School leaders will be required to address areas where a teacher's improvement is needed as a part of that process.

While realizing that resources for all districts and BOCES are tight, the Network Teams that are formed in the BOCES and some districts will be working with all districts to provide quality professional development activities for teachers. These efforts will substantially add to the resources devoted to professional development system wide.

3. COMMENT: One comment indicated that "similar to requirements for clinically rich teacher preparation pilot programs, prior to assigning individuals to a classroom, schools employing that individual under the Transitional G Certificate should specify the mentoring plan. Candidates

should be assigned a teacher-mentor and a support team including the school principal or designee and a school curriculum supervisor or specialist. Schools should document that the plan was implemented as a requirement for the individual to obtain the Initial Certificate.”

DEPARTMENT RESPONSE: The Department has revised the regulation in response to this comment to require the school district that is employing the Transitional G candidate to create and maintain a plan for mentoring, appropriate instructional support and at least 70 hours of professional development targeted toward appropriate pedagogical skills, over the two years of employment.

NOTICE OF ADOPTION

Technical Amendment of Section 100.2(ee)(2)

I.D. No. EDU-09-11-00007-A

Filing No. 435

Filing Date: 2011-05-17

Effective Date: 2011-06-01

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

Action taken: Amendment of section 100.2(ee)(2) of Title 8 NYCRR.

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

Subject: Technical amendment of section 100.2(ee)(2).

Purpose: To add language that was inadvertently omitted in a previous rule making.

Text or summary was published in the March 2, 2011 issue of the Register, I.D. No. EDU-09-11-00007-EP.

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

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

Assessment of Public Comment

The agency received no public comment.

PROPOSED RULE MAKING NO HEARING(S) SCHEDULED

Customized Packaging of Prescription Drugs

I.D. No. EDU-22-11-00005-P

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

Proposed Action: Amendment of section 29.7 of Title 8 NYCRR.

Statutory authority: Education Law, sections 207, 6504, 6506(1), 6508(1), 6509(9) and 6510(1)

Subject: Customized packaging of Prescription Drugs.

Purpose: Authorizes pharmacists to repack drugs in customized patient packaging provided that certain requirements are met.

Text of proposed rule: 1. Paragraph (15) of subdivision (a) of section 29.7 of the Rules of the Board of Regents is amended, effective August 10, 2011, as follows:

(15)(i) Repacking of drugs in a pharmacy, except by a pharmacist or under his/her immediate and personal supervision. Labels on repacked drugs shall bear sufficient information for proper identification and safety. A repacking record shall be maintained, including the name, strength, lot number, quantity and name of the manufacturer and/or distributor of the drug repacked, the date of the repacking, the number of packages prepared, the number of dosage units in each package, the signature of the person performing the packaging operation, the signature of the pharmacist who supervised the repacking, and such other identifying marks added by the pharmacy for internal recordkeeping purposes. Drugs repacked for in-house use only shall have an expiration date of 12 months, or 50 percent of the time remaining to the manufacturer's expiration date, whichever is less, from the date of repacking. For the repacking of drugs by manufacturers and wholesalers, the provisions of parts 210 and 211 of title 21, Code of Federal Regulations (1984 edition, Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402: 1984, available at New York State Board of Pharmacy, [Room 3035, Cultural Education Center, Albany, NY 12230] 89 Washington Avenue, 2nd Floor, Albany,

NY 12234), shall apply. Repacking records shall be maintained for five years and shall be made available to the department for review and copying.

(ii) Repacking drugs in customized patient medication packages (patient med-pak or patient medication package) unless the following conditions are complied with:

(a) medications are packaged in moisture-proof containers that are either non-reclosable or are designed to show evidence of having been opened;

(b) medications are dispensed in containers that bear a label affixed to the immediate container in which the medications are dispensed in accordance with section 6810(1) of the Education Law. Such label shall include:

(1) all information required by Education Law section 6810(1);

(2) the name, strength, physical description or identification, and quantity of each medication;

(3) the address and telephone number of the dispenser;

(4) an expiration date for the customized patient medication package, which shall not be longer than the shortest recommended expiration date of the medications included therein, provided that in no event shall the expiration date be more than 60 days from the date of preparation of the package and shall not exceed the shortest expiration date on the original manufacturer's bulk containers for the dosage forms included therein;

(5) a separate identifying serial number for each of the prescription orders for each of the drug products contained in the customized patient medication package and, unless such number provides complete information about the customized patient medication package, a serial number for the customized patient medication package itself; and

(6) any other information, including storage instructions or any statements, or warnings required for the medications contained in the package.

(c) medications shall not be repackaged for or reissued to any patient other than to the patient for whom they are originally dispensed;

(d) medications shall not be dispensed in customized patient medication packages, without the consent of the patient, the patient's caregiver, or the prescriber, and the patient or caregiver shall be properly instructed in the use of such packages, in how to identify each medication, and in the steps to be taken in the event one of the medications is discontinued or the therapy otherwise altered;

(e) controlled substances shall not be dispensed in customized patient medication packages;

(f) medications that are unstable or therapeutically incompatible shall not be dispensed in customized patient medication packages; and

(g) a record of each customized patient medication package shall be maintained by the pharmacist. Each record shall contain:

(1) the name and address of the patient;

(2) the serial number of the prescription order for each medication contained therein, or other means of individualized tracking system acceptable to the Department;

(3) the name of the manufacturer or labeler for each medication contained therein;

(4) information identifying or describing the design, characteristics, or specifications of the customized patient medication package sufficient to allow subsequent preparation of an identical customized patient medication package for the patient;

(5) the date of preparation of the customized patient medication package and the expiration date that was assigned;

(6) any special labeling instructions; and

(7) the name or initials of the pharmacist who prepared the customized patient medication package.

Text of proposed rule and any required statements and analyses may be obtained from: Christine Moore, New York State Education Department, 89 Washington Avenue, Room 146, Albany, New York 12234, (518) 473-8296, email: cmoore@mail.nysed.gov

Data, views or arguments may be submitted to: Peg Rivers, New York State Education Department, 89 Washington Avenue, Room 979, Albany, New York 12234, (518) 408-1189, email: privers@mail.nysed.gov

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

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 to supervise the practice of the professions.

Subdivision (1) of section 6508 of the Education Law provides that state boards for the professions shall assist the Board of Regents and Department on matters of professional licensing.

Subdivision (9) of section 6509 of the Education Law authorizes the Board of Regents to promulgate rules defining unprofessional conduct in the professions.

Subdivision (1) of section 6510 the Education Law establishes the labeling requirements for prescriptions.

2. LEGISLATIVE OBJECTIVES:

The proposed amendment authorizes pharmacists to repackage drugs in customized patient packaging provided that certain requirements are met. If such conditions are not met, the proposed amendment defines such pharmacy practice as unprofessional conduct. The proposal incorporates recognized practice standards and protections for purity, potency and labeling of medications.

3. NEEDS AND BENEFITS:

The proposed amendment authorizes medications to be repackaged in customized patient medication packages, with the consent of the patient, the patient's caregiver, or the prescriber. The proposal would encourage patient compliance with complex medication protocols.

4. COSTS:

- (a) There are no additional costs to state government.
- (b) There are no additional costs to local government.
- (c) Cost to private regulated parties. The proposed amendment will not impose any additional costs on private regulated parties. Instead, the proposed amendment may provide cost-savings to regulated parties.
- (d) There are no additional costs to the regulating agency.

5. LOCAL GOVERNMENT MANDATES:

The proposed amendment relates solely to the repackaging of drugs in customized patient medication packages and the definition of unprofessional conduct in the practice of pharmacy and does not impose any programs, service, duty, or responsibility upon local governments.

6. PAPERWORK:

The proposed amendment requires that medications in customized patient medication packages be dispensed in containers that bear a label affixed to the immediate container in accordance with section Education Law section 6810(1). The label shall include the following information:

- (1) all information required by Education Law section 6810(1);
- (2) the name, strength, physical description or identification, and quantity of each medication;
- (3) the address and telephone number of the dispenser;
- (4) an expiration date for the customized patient medication package, which shall not be longer than the shortest recommended expiration date of the medications included therein, provided that in no event shall the expiration date be more than 60 days from the date of preparation of the package and shall not exceed the shortest expiration date on the original manufacturer's bulk containers for the dosage forms included therein;
- (5) a separate identifying serial number for each of the prescription orders for each of the drug products contained in the customized patient medication package and, unless such number provides complete information about the customized patient medication package, a serial number for the customized patient medication package itself; and
- (6) any other information, including storage instructions or any statements, or warnings required for the medications contained in the package.

A record of each customized patient medication package shall also be maintained by the pharmacist. The record must contain the following information:

- (1) the name and address of the patient;
- (2) the serial number of the prescription order for each medication contained therein, or other means of individualized tracking system acceptable to the Department;
- (3) the name of the manufacturer or labeler for each medication contained therein;
- (4) information identifying or describing the design, characteristics, or specifications of the customized patient medication package sufficient to allow subsequent preparation of an identical customized patient medication package for the patient;
- (5) the date of preparation of the customized patient medication package and the expiration date that was assigned;
- (6) any special labeling instructions; and
- (7) the name or initials of the pharmacist who prepared the customized patient medication package.

The patient or caregiver must be properly instructed in the use of such packages, in how to identify each medication, and in the steps to be taken in the event one of the medications is discontinued or the therapy otherwise altered.

7. DUPLICATION:

The proposed amendment does not duplicate other existing state or federal requirements.

8. ALTERNATIVES:

There are no viable alternatives to the proposed amendment and none were considered.

9. FEDERAL STANDARDS:

Federal standards do not apply, nor does the proposal exceed federal standards.

10. COMPLIANCE SCHEDULE:

The proposed amendment is intended to become effective August 10, 2011.

Regulatory Flexibility Analysis

(a) Small Businesses:

1. EFFECT OF RULE:

The proposed amendment authorizes, but does not require, pharmacists to repackage drugs in customized patient packaging provided that certain requirements are met. If such conditions are not met, the proposed amendment defines such pharmacy practice as unprofessional conduct. The proposal incorporates recognized practice standards and protections for purity, potency and labeling of medications. The proposed amendment may impact small businesses, i.e., pharmacies across the State with fewer than 100 employees.

2. COMPLIANCE REQUIREMENTS:

The proposed amendment requires that medications in customized patient medication packages be dispensed in containers that bear a label affixed to the immediate container in accordance with section Education Law section 6810(1). The label shall include the following information:

- (1) all information required by Education Law section 6810(1);
- (2) the name, strength, physical description or identification, and quantity of each medication;
- (3) the address and telephone number of the dispenser;
- (4) an expiration date for the customized patient medication package, which shall not be longer than the shortest recommended expiration date of the medications included therein, provided that in no event shall the expiration date be more than 60 days from the date of preparation of the package and shall not exceed the shortest expiration date on the original manufacturer's bulk containers for the dosage forms included therein;
- (5) a separate identifying serial number for each of the prescription orders for each of the drug products contained in the customized patient medication package and, unless such number provides complete information about the customized patient medication package, a serial number for the customized patient medication package itself; and
- (6) any other information, including storage instructions or any statements, or warnings required for the medications contained in the package.

A record of each customized patient medication package shall also be maintained by the pharmacist. The record must contain the following information:

- (1) the name and address of the patient;
- (2) the serial number of the prescription order for each medication contained therein, or other means of individualized tracking system acceptable to the Department;
- (3) the name of the manufacturer or labeler for each medication contained therein;
- (4) information identifying or describing the design, characteristics, or specifications of the customized patient medication package sufficient to allow subsequent preparation of an identical customized patient medication package for the patient;
- (5) the date of preparation of the customized patient medication package and the expiration date that was assigned;
- (6) any special labeling instructions; and
- (7) the name or initials of the pharmacist who prepared the customized patient medication package.

The patient or caregiver must be properly instructed in the use of such packages, in how to identify each medication, and in the steps to be taken in the event one of the medications is discontinued or the therapy otherwise altered.

3. PROFESSIONAL SERVICES:

The proposed regulation will not require pharmacies to engage professional services.

4. COMPLIANCE COSTS:

Because the packaging of medications in customized patient medication packages is voluntary, there is no obligation on the part of pharmacies to participate, and, therefore, there are no mandated compliance costs. For those pharmacies that choose to make such packaging available to their customers, the recordkeeping and labeling costs are minimal since the pharmacies would be required to keep the same or similar information even if the drugs were dispensed in the traditional manner. The costs for the technology to provide customized packaging for prescription drugs is wide ranging. Manual systems can be obtained for approximately \$1,000, while very sophisticated systems used for high-volume, rapid dispensing

can cost up to \$200,000. However, costs per unit decrease over time with volume as this form of packaging replaces traditional dispensing in vials that can cost as much as 50 cents per vial.

5. ECONOMIC AND TECHNOLOGICAL FEASIBILITY:

For those pharmacies, including those that are classified as small businesses, that choose to make customized patient medication packaging available to their clients, the proposed regulation will likely be implemented by the use of available technology. See above "Compliance Costs" for the economic impact of the regulation.

6. MINIMIZING ADVERSE IMPACT:

The proposed amendment authorizes medications to be repackaged in customized patient medication packages, with the consent of the patient, the patient's caregiver, or the prescriber. The proposal would encourage patient compliance with complex medication protocols. The labeling and recordkeeping requirements listed above are necessary to comply with existing laws and standards and to ensure patient safety. Additionally, because the use of customized packaging is voluntary on the part of the pharmacy, individual pharmacies have the option of choosing not to provide such packaging.

7. SMALL BUSINESS PARTICIPATION:

Comments on the proposed rule were solicited from statewide organizations representing all parties having an interest in the practice of pharmacy, nursing and medicine. Included in this group were members of the State Board of Pharmacy, educational institutions and professional associations representing the pharmacy, nursing and medical professions, such as the Pharmacists Society of the State of New York, the New York State Council of Health System Pharmacists, and the New York State Board for Nursing. These groups, which include representatives of small businesses, have been provided notice of the proposed rule making and opportunity to comment on the regulations.

(b) Local Governments:

The proposed amendment relates solely to the repackaging of drugs in customized patient medication packages and the definition of unprofessional conduct in the practice of pharmacy and does not impose any programs, service, duty, or responsibility upon 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 rule would apply to 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. Of the 22,344 pharmacists registered by the State Education Department, 2,821 pharmacists report their permanent address of record is in a rural county. In addition, the rule would apply to pharmacies, 779 of which are located in rural counties.

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

The proposed amendment requires that medications in customized patient medication packages be dispensed in containers that bear a label affixed to the immediate container in accordance with section Education Law section 6810(1). The label shall include the following information:

- (1) all information required by Education Law section 6810(1);
- (2) the name, strength, physical description or identification, and quantity of each medication;
- (3) the address and telephone number of the dispenser;
- (4) an expiration date for the customized patient medication package, which shall not be longer than the shortest recommended expiration date of the medications included therein, provided that in no event shall the expiration date be more than 60 days from the date of preparation of the package and shall not exceed the shortest expiration date on the original manufacturer's bulk containers for the dosage forms included therein;
- (5) a separate identifying serial number for each of the prescription orders for each of the drug products contained in the customized patient medication package and, unless such number provides complete information about the customized patient medication package, a serial number for the customized patient medication package itself; and
- (6) any other information, including storage instructions or any statements, or warnings required for the medications contained in the package.

A record of each customized patient medication package shall also be maintained by the pharmacist. The record must contain the following information:

- (1) the name and address of the patient;
- (2) the serial number of the prescription order for each medication contained therein, or other means of individualized tracking system acceptable to the Department;
- (3) the name of the manufacturer or labeler for each medication contained therein;
- (4) information identifying or describing the design, characteristics, or

specifications of the customized patient medication package sufficient to allow subsequent preparation of an identical customized patient medication package for the patient;

- (5) the date of preparation of the customized patient medication package and the expiration date that was assigned;
- (6) any special labeling instructions; and
- (7) the name or initials of the pharmacist who prepared the customized patient medication package.

The patient or caregiver must be properly instructed in the use of such packages, in how to identify each medication, and in the steps to be taken in the event one of the medications is discontinued or the therapy otherwise altered.

3. COSTS:

The proposed amendment does not impose any additional costs on regulated parties.

4. MINIMIZING ADVERSE IMPACT:

The rules make no exception for individuals or pharmacies in rural areas. The Department has determined that the proposed regulation should apply to all pharmacists and pharmacies, no matter their geographic location, to ensure a standard of practice across the State. Because of the nature of the proposed rule, alternative approaches for rural areas were not considered.

5. RURAL AREA PARTICIPATION:

Comments on the proposed rule were solicited from statewide organizations representing all parties having an interest in the practice of pharmacy, nursing and medicine. Included in this group were members of the State Board of Pharmacy, educational institutions and professional associations representing the pharmacy, nursing and medical professions, such as the Pharmacists Society of the State of New York, the New York State Council of Health System Pharmacists, and the New York State Board for Nursing. These groups, which have representation in rural areas, have been provided notice of the proposed rule making and opportunity to comment on the regulations.

Job Impact Statement

The proposed amendment relates to the definition of unprofessional conduct in the practice of the profession of pharmacy and will not adversely impact jobs and employment opportunities. Because it is evident from the nature of the proposed amendment that it will not affect job and employment opportunities, no affirmative steps were needed to ascertain that fact and none were taken. Accordingly, a job impact statement is not required and one has not been prepared.

Department of Environmental Conservation

EMERGENCY/PROPOSED RULE MAKING NO HEARING(S) SCHEDULED

Recreational Harvest Regulations for Black Sea Bass

I.D. No. ENV-22-11-00006-EP

Filing No. 440

Filing Date: 2011-05-17

Effective Date: 2011-05-17

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

Proposed Action: Amendment of Part 40 of Title 6 NYCRR.

Statutory authority: Environmental Conservation Law, sections 11-0303, 13-0105 and 13-0340-f

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

Specific reasons underlying the finding of necessity: These regulations are necessary for New York to remain in compliance with the Fishery Management Plan (FMP) for Summer Flounder, Scup and Black Sea Bass as adopted by the Atlantic States Marine Fisheries Commission (ASMFC), to avoid potential federal sanctions for lack of compliance with such plan, and to optimize recreational fishing opportunities available to New Yorkers.

Each member state of ASMFC is expected to promulgate regulations that comply with FMPs adopted by ASMFC. These regulations are needed

to properly manage the State’s recreational fisheries and prevent the State from exceeding the State’s recreational harvest limit, as assigned by the FMP. Failure by a state to adopt, in a timely manner, necessary regulations may result in a determination of non-compliance by ASMFC and the imposition of federal sanctions on the particular fishery in that state. A closure, for example, of the New York black sea bass fishery could result in significant adverse impacts to the State’s economy. New York State must adopt regulations that are in compliance with the FMP and prevent the recreational harvest of black sea bass from exceeding the State’s assigned limits for that species.

The promulgation of this regulation as an emergency rule making is necessary because the normal rule making process would not promulgate these regulations in the time frame necessary to prevent the fishing season from opening on May 22, one of the provisions of the 2010 regulations. If this rule making were to be promulgated by the normal rule making process, it would not be effective until several months after the target date for the opening of the fishing season. If recreational anglers were allowed to harvest black sea bass under the provisions of the 2010 regulations, it is very likely that New York anglers would exceed the 2011 black sea bass quota assigned to New York State. The State then could be found out of compliance by ASMFC, resulting in federal sanctions and a moratorium. It is in the best interests of New York State’s recreational fishing industry to remain in compliance with ASMFC black sea bass requirements by not promulgating the proposed regulation through the normal rule making process.

Subject: Recreational harvest regulations for black sea bass.

Purpose: To maximize recreational angler opportunities for black sea bass while staying in compliance with the ASMFC and MAFMC.

Text of emergency/proposed rule: Existing subdivision 40.1(f) of 6 NYCRR is amended to read as follows:

Species Striped bass through Scup (porgy) all other anglers remain the same. Species Black sea bass is amended to read as follows:

40.1(f) Table A - Recreational Fishing.

Species	Open Season	Minimum Length	Possession Limit
Black sea bass	[May 22] June 13 - Oct. [11] and Nov. 1 - Dec. 31	[12.5]13" TL	[25]10

Species American shad through Oyster toadfish remain the same.

This notice is intended: to serve as both a notice of emergency adoption and a notice of proposed rule making. The emergency rule will expire August 14, 2011.

Text of rule and any required statements and analyses may be obtained from: John D. Maniscalco, New York State Department of Environmental Conservation, 205 North Belle Mead Road, Suite 1, East Setauket, NY 11733, (631) 444-0437, email: jdmanisc@gw.dec.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.

Additional matter required by statute: Pursuant to the State Environmental Quality Review Act, a negative declaration is on file with the department.

Regulatory Impact Statement

1. Statutory authority:

Environmental Conservation Law (ECL) sections 13-0105 and 13-0340-f authorize the Department of Environmental Conservation (DEC or department) to establish by regulation the open season, size, catch limits, possession and sale restrictions and manner of taking for black sea bass.

2. Legislative objectives:

It is the objective of the above-cited legislation that DEC manages marine fisheries to optimize resource use for commercial and recreational harvesters consistent with marine fisheries conservation and management policies, and interstate fishery management plans.

3. Needs and benefits:

These regulations are necessary for New York to maintain compliance with the Interstate Fishery Management Plan (FMP) for Black Sea Bass as adopted by the Atlantic States Marine Fisheries Commission (ASMFC). New York, as a member state of ASMFC, must comply with the provisions of the Interstate Fishery Management Plans adopted by ASMFC. These FMPs are designed to promote the long-term sustainability of quota managed marine species, preserve the States’ marine resources, and protect the interests of both commercial and recreational fishermen. All member states must promulgate any necessary regulations that implement the provisions of the FMPs to remain in compliance with the FMPs. If ASMFC determines a state to be in non-compliance with a specific FMP, the state may be subject to a complete prohibition on all fishing for the as-

sociated species in the waters of the non-compliant state until the state comes into compliance with the FMP.

Under the FMP for black sea bass, ASMFC will assign New York an annual harvest for black sea bass for the 2011 recreational season. The 2011 quota will be smaller than the 2010 quota. Under existing regulations, it is likely that New York will overharvest the 2011 assigned take of black sea bass by recreational anglers. The proposed regulations will decrease the duration of the 2011 recreational black sea bass season, increase the minimum size limit, and decrease the bag limit to prevent New York State recreational anglers from overharvesting the reduced quota. According to a report released by National Oceanic and Atmospheric Administration Fisheries, recreational fishing in New York generated \$424 million in total sales in 2006. Black sea bass is a popular fish taken by recreational harvesters in New York.

The promulgation of this regulation is necessary for DEC to remain in compliance with the FMP for black sea bass. The regulatory changes in this emergency rule are calculated, and have been approved by ASMFC. The proposed rule will allow New York State recreational anglers to achieve the harvest level provided by the 2011 quota, yet prevent these anglers from exceeding the assigned black sea bass quota. New York State would remain in compliance with the FMP.

Specific amendments to the current regulations include the following:

1. Black sea bass: Implement an open season for the black sea bass recreational fishery from June 13 through October 1 and November 1 through December 31, a 13.0 inch minimum size limit, and a 10 fish bag limit. This represents a loss of 32 days from the fishing season, a 0.5 inch increase in minimum size, and a substantial decrease of the bag limit from 25 fish.

4. Costs:

(a) Cost to State government:

There are no new costs to state government resulting from this action.

(b) Cost to local government:

There will be no costs to local governments.

(c) Cost to private regulated parties:

There are no new costs to regulated parties resulting from this action. However, the reduced season length and more restrictive management measures will decrease angler participation in the recreational black sea bass fishery. This is likely to decrease revenues for party/charter boat operators and sales at bait and tackle shops.

(d) Costs to the regulating agency for implementation and continued administration of the rule:

The department will incur limited costs associated with both the implementation and administration of these rules, including the costs relating to notifying recreational harvesters, party and charter boat operators and other recreational support industries of the new rules.

5. Local government mandates:

The proposed rule does not impose any mandates on local government.

6. Paperwork:

None.

7. Duplication:

The proposed amendment does not duplicate any state or federal requirement.

8. Alternatives:

“No Action” Alternative (no amendment to black sea bass regulations)

- The “no action” alternative would leave current black sea bass regulations in place. Under existing regulations, it is likely that New York recreational anglers will exceed the 2011 assigned harvest. If New York doesn’t take steps to reduce harvest, the state could be found out of compliance with the Fishery Management Plan by the Atlantic States Marine Fisheries Commission and subject federally imposed sanctions. This alternative was rejected.

9. Federal standards:

The amendments to Part 40 are in compliance with the ASMFC and Regional Fishery Management Council FMPs.

10. Compliance schedule:

Regulated parties will be notified by mail, through appropriate news releases and via DEC’s website of the changes to the regulations. The emergency regulations will take effect upon filing with the Department of State.

Regulatory Flexibility Analysis

1. Effect of rule:

The Atlantic State Marine Fisheries Commission (ASMFC) facilitates cooperative management of marine and anadromous fish species among the fifteen Atlantic Coast member states. The principal mechanism for implementation of cooperative management of migratory fish is the ASMFC’s Interstate Fishery Management Plans (FMPs) for individual species or groups of fish. The FMPs are designed to promote the long-term health of these species, preserve resources, and protect the interests of both commercial and recreational fishers.

ASMFC requires New York State to reduce its recreational black sea

bass harvest by 39 percent and this may impact the State's recreational fishing industry. Those most affected by the proposed rule are recreational anglers, licensed party and charter boat businesses, and retail and wholesale marine bait and tackle shops operating in New York State. There were 502 licensed party and charter boats in 2010, and an unknown number of bait and tackle shops. Approximately 300,000 recreational marine fishing licenses were sold in 2010. Local party and charter boat businesses and bait and tackle shops will lose many customers who target black sea bass during the spring. Party and charter boat businesses and bait and tackle shops may rely on the patronage of recreational anglers who target black sea bass for the income it provides and may see a reduction in their earnings once the regulations are in place.

There are no local governments involved in the recreational fish harvesting business, nor do any participate in the sale of marine bait fish or tackle. Therefore, no local governments are affected by these proposed regulations.

2. Compliance requirements:

None.

3. Professional services:

None.

4. Compliance costs:

There are no initial capital costs that will be incurred by a regulated business or industry to comply with the proposed rule.

5. Economic and technological feasibility:

The proposed regulations do not require any expenditure on the part of affected businesses in order to comply with the changes. The changes required by the proposed regulations may reduce the income of party and charter businesses and marine bait and tackle shops because of the reduction in the number of days available for recreational fishers to take black sea bass.

There is no additional technology required for small businesses, and this action does not apply to local governments; there are no economic or technological impacts for either.

6. Minimizing adverse impact:

The promulgation of this regulation is necessary for DEC to maintain compliance with the FMPs for black sea bass and to avoid a punitive closure of the black sea bass fisheries and the economic hardship that would ensue with such a closure. Since these regulatory amendments are consistent with federal and Interstate FMPs, DEC anticipates that New York State will remain in compliance with the FMPs.

The department consulted with the Marine Resources Advisory Council (MRAC) and other individuals who chose to share their views on black sea bass recreational management measures. There was no consensus but a majority was in favor of the proposed regulation.

Ultimately, the maintenance of long-term sustainable fisheries will have a positive effect on employment for the fisheries in question, including party and charter boat fisheries as well as wholesale and retail bait and tackle shops and other support industries for recreational fisheries. Failure to comply with FMPs and take required actions to protect our natural resources could cause the collapse of a stock and have a severe adverse impact on the commercial and recreational fisheries for that species, as well as the supporting industries for those fisheries. These regulations are being proposed in order to provide the appropriate level of protection and allow for harvest consistent with the capacity of the resource to sustain such effort.

7. Small business and local government participation:

The department received recommendations from the MRAC, which is comprised of representatives from recreational and commercial fishing interests. The proposed regulations are also based upon comments received from recreational fishing organizations, party and charter boat owners and operators, retail and wholesale bait and tackle shop owners, recreational anglers and state law enforcement personnel. There was no special effort to contact local governments because the proposed rule does not affect them.

Rural Area Flexibility Analysis

The Department of Environmental Conservation has determined that this rule will not impose an adverse impact on rural areas. There are no rural areas within the marine and coastal district. The black sea bass fishery is entirely located within the marine and coastal district, and is not located adjacent to any rural areas of the state. Further, the proposed rule does not impose any reporting, recordkeeping, or other compliance requirements on public or private entities in rural areas. Since no rural areas will be affected by the proposed amendments of 6 NYCRR Part 40, a Rural Area Flexibility Analysis is not required.

Job Impact Statement

1. Nature of impact:

The promulgation of this regulation is necessary for the Department of Environmental Conservation (DEC) to maintain compliance with the Fishery Management Plan for Black Sea Bass, to avoid potential federal

sanctions for lack of compliance with such plan, and to optimize recreational fishing opportunities available to New Yorkers. The proposed rule will reduce the recreational season for black sea bass by 32 days and decrease the opportunities anglers will have to take large amounts of fish home.

Many currently licensed party and charter boat owners and operators, as well as bait and tackle businesses, will be affected by these regulations. Due to the reduction in the number and appeal of fishing days for black sea bass, there may be a corresponding reduction of the number of fishing trips and bait and tackle sales during the upcoming fishing season.

2. Categories and numbers affected:

In 2010, there were 502 licensed party and charter businesses in New York State. There were also a number of retail and wholesale marine bait and tackle shop businesses operating in New York; however, DEC does not have a record of the actual number. The number of recreational fishers in New York has been estimated by the National Marine Fisheries Service to be just over 714,000 in 2010. However, this Job Impact Statement does not include them in this analysis, since fishing is recreational for them and not related to employment.

3. Regions of adverse impact:

The regions most likely to receive any adverse impact are within the marine and coastal district of the State of New York. This area included all the waters of the Atlantic Ocean within three nautical miles from the coast line and all other tidal waters within the state, including Long Island Sound and the Hudson River up to the Tappan Zee Bridge.

4. Minimizing adverse impact:

In the development of the proposed rule making, DEC consulted with the Marine Resources Advisory Council and many individuals who chose to share their views on black sea bass recreational management measures to the DEC. In the long-term, the maintenance of sustainable fisheries will have a positive affect on employment for the fisheries in question, including party and charter boat owners and operators, wholesale and retail bait and tackle outlets and other support industries for recreational fisheries. Any short-term losses in participation and sales will be offset by the restoration of fishery stocks and an increase in yield from well-managed resources. Protection of the black sea bass resource is essential to the survival of the party and charter boat businesses and bait and tackle shops that are sustained by these fisheries. These regulations are designed to protect stocks while allowing appropriate harvest, to prevent over-harvest and to continue to rebuild stocks and maintain them for future utilization.

NOTICE OF ADOPTION

Sanitary Condition of Shellfish Lands

I.D. No. ENV-10-11-00005-A

Filing No. 439

Filing Date: 2011-05-17

Effective Date: 2011-06-01

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

Action taken: Amendment of Part 41 of Title 6 NYCRR.

Statutory authority: Environmental Conservation Law, sections 13-0307 and 13-0319

Subject: Sanitary Condition of Shellfish Lands.

Purpose: To reclassify underwater lands to allow the harvest of shellfish.

Text of final rule: 6 NYCRR Part 41, Sanitary Condition of Shellfish Lands, is amended to read as follows:

Existing Section 41.0 through sub-paragraph 41.2(b)(2)(v) remains unchanged.

Existing sub-paragraph 41.2(b)(3)(i) is repealed.

New subparagraphs 41.2(b)(3)(i) through 41.2(b)(3)(iii) are adopted to read as follows:

(i) *Long Island Sound.*

(a) *All that area of Long Island Sound, including tributaries, lying northerly and westerly of a line extending northeasterly from the northernmost point of land at Prospect Point to the northernmost point of land at Matinecock Point; and, thence continuing in a northeasterly direction on a true bearing North 18 degrees East (magnetic bearing North 30 degrees East) from Matinecock Point to the New York-Connecticut State boundary.*

(b) *All tributaries of Long Island Sound, including Frost Creek, between Matinecock Point and Middle Chimney west of Oak Neck Point (local names, local landmarks).*

(ii) *Hempstead Harbor.*

(a) *All that area of Hempstead Harbor, including tributaries, lying southerly of a line extending northeasterly from the westernmost*

chimney on the seaward side of the large brown house (situated on the bluff within Sands Point Park and Preserve) located approximately 1300 yards northwesterly of Mott Point, to the western end of the rock jetty at Red Spring Point, on the opposite eastern shoreline, and then continuing along the northeasterly side of said jetty to the shore. Said jetty forms the northern enclosure of the private marina serving The Legend Yacht and Beach Club Community on Pembroke Drive, Glen Cove (local names, local landmarks).

(b) All that area of East Creek (the tidal creek and wetlands) located southerly of Prospect Point.

(c) All that area of West Pond and outer Hempstead Harbor lying southerly and easterly of a line extending northerly from the westernmost end of the rock jetty, located southerly of the mouth of West Pond, to the westernmost end of the rock jetty with adjacent wooden walkway, located on Dosoris Island, northerly of the mouth of West Pond (local names, local landmarks).

(d) All that area of Hempstead Harbor lying within 250 yards of the seaward end of the rock jetty at the City of Glen Cove's Crescent Beach at the foot of Crescent Beach Road, on the eastern shore of Hempstead Harbor (local names, local landmarks).

(iii) Dosoris Pond. All that area of Dosoris Pond.

Existing subparagraph 41.2(b)(4)(i) is repealed.

New subparagraph 41.2(b)(4)(i) is adopted to read as follows:

(i) Long Island Sound.

(a) All that area of Long Island Sound, including tributaries, lying northerly and westerly of a line extending northeasterly from the northernmost point of land at Prospect Point to the northernmost point of land at Matinecock Point; and, thence continuing in a northeasterly direction on a true bearing North 18 degrees East (magnetic bearing North 30 degrees East) from Matinecock Point to the New York-Connecticut State boundary.

(b) All tributaries of Long Island Sound, including Frost Creek, between Matinecock Point and Middle Chimney west of Oak Neck Point (local names, local landmarks).

Existing subparagraphs 41.2(b)(4)(ii) through 41.2(b)(4)(iv) are renumbered as 41.2(b)(4)(iv) through 41.2(b)(4)(vi).

New subparagraphs 41.2(b)(4)(ii) through 41.2(b)(4)(iii) are adopted to read as follows:

(ii) Hempstead Harbor.

(a) All that area of Hempstead Harbor, including tributaries, lying southerly of a line extending northeasterly from the westernmost chimney on the seaward side of the large brown house (situated on the bluff within Sands Point Park and Preserve) located approximately 1300 yards northwesterly of Mott Point, to the western end of the rock jetty at Red Spring Point, on the opposite eastern shoreline, and then continuing along the northeasterly side of said jetty to the shore. Said jetty forms the northern enclosure of the private marina serving The Legend Yacht and Beach Club Community on Pembroke Drive, Glen Cove (local names, local landmarks).

(b) All that area of East Creek (the tidal creek and wetlands) located southerly of Prospect Point.

(c) All that area of West Pond and outer Hempstead Harbor lying southerly and easterly of a line extending northerly from the westernmost end of the rock jetty, located southerly of the mouth of West Pond, to the westernmost end of the rock jetty with adjacent wooden walkway, located on Dosoris Island, northerly of the mouth of West Pond (local names, local landmarks).

(d) All that area of Hempstead Harbor lying within 250 yards of the seaward end of the rock jetty at the City of Glen Cove's Crescent Beach at the foot of Crescent Beach Road, on the eastern shore of Hempstead Harbor (local names, local landmarks).

(iii) Dosoris Pond. All that area of Dosoris Pond.

Renumbered subparagraphs 41.2(b)(4)(iv) through 41.2(b)(4)(vi) remain unchanged.

Final rule as compared with last published rule: Nonsubstantive changes were made in section 41.2(b)(3)(ii) and (4)(ii).

Text of rule and any required statements and analyses may be obtained from: William Hastback, NYSDEC, Bureau of Marine Resources, Shellfisheries Section, 205 N Belle Mead Rd, Suite 1, East Setauket, NY 11733, (631) 444-0477, email: wghastba@gw.dec.state.ny.us

Additional matter required by statute: Pursuant to the State Environmental Quality Review Act, a negative declaration is on file with DEC.

Revised Regulatory Impact Statement

This statement explains why a revised consolidated Regulatory Impact Statement is not required to accompany this Notice of Adoption. The change made to the last published rule retains the current uncertified designation for approximately 20 acres of state underwater lands but does not affect the reclassification of approximately 2500 acres of state underwater lands as certified for the harvest of shellfish and does not

necessitate a revision to the previously published Regulatory Impact Statement.

Revised Regulatory Flexibility Analysis

This statement explains why a revised consolidated Regulatory Flexibility Analysis is not required to accompany this Notice of Adoption. The change made to the last published rule retains the current uncertified designation for approximately 20 acres of state underwater lands but does not affect the reclassification of approximately 2500 acres of state underwater lands as certified for the harvest of shellfish and does not necessitate a revision to the previously published Regulatory Flexibility Analysis.

Revised Rural Area Flexibility Analysis

The change made to the last published rule does not necessitate a revision to the previously published Rural Area Flexibility Analysis statement which determined that no rural areas are affected by the proposed rule.

Revised Job Impact Statement

This statement explains why a revised consolidated Job Impact Statement is not required to accompany this Notice of Adoption. The change made to the last published rule retains the current uncertified designation for approximately 20 acres of state underwater lands but does not affect the reclassification of approximately 2500 acres of state underwater land as certified for the harvest of shellfish and does not necessitate a revision to the previously published Job Impact Statement.

Assessment of Public Comment

The New York State Department of Environmental Conservation (the department) proposed to amend 6NYCRR, Part 41 "Sanitary Condition of Shellfish Lands" to reclassify areas that were designated as uncertified (closed) for the harvest of shellfish to certified (open) year-round. The reclassification is based on a sanitary survey which included identification of actual and potential pollution sources, collection and examination of water samples and the evaluation of water quality data which determined the area meets the bacteriological standards for certified shellfish lands. A small area of approximately 20 acres, initially included in the initial proposed rule to reclassify approximately 2500 acres as certified for the harvest of shellfish, will be excluded from the reclassification and will remain uncertified based on new information.

Comments were received from several individuals and one municipality.

Comment: All those who submitted comments expressed agreement with the intent of the proposed rule to reclassify approximately 2500 acres as certified for the harvest of shellfish and that it would be beneficial to commercial and recreational harvesters.

Department's response: The department concurs.

Comment: The department should look into the cause of bathing beach closures due to elevated bacteria levels at the City of Glen Cove's Crescent Beach.

Department's response: The department concurs. Recently collected water quality data documented elevated fecal coliform levels in a small creek that discharges to Hempstead Harbor near the City of Glen Cove's bathing beach at the foot of Crescent Beach Road on the eastern shore of the Harbor. Those findings, in conjunction with water quality data provided by the county health department, require the department to amend its initial proposed rule making. The department's amended rule making will retain the existing uncertified classification in an area comprising approximately 20 acres around the mouth of the small creek. That area is located within a 250-yard radius centered on the seaward end of the rock jetty immediately adjacent to the municipal beach at the foot of Crescent Beach Road. That area is currently uncertified and will remain uncertified (closed) for the harvest of shellfish, to protect public health, under the amended rule.

Comment: The department should limit harvesting to weekdays to avoid conflicts with recreational boaters in the area proposed for reclassification as certified for the harvest of shellfish.

Department's response: The department does not concur. The department does not believe that it is necessary to limit shellfish harvesting to weekdays only to avoid conflicts with recreational boating on weekends. Shellfish harvesting is permitted seven days per week in approximately 1 million acres of certified area and the department has not received reports of conflicts with increased recreational boating activities on weekends. The department has no information to indicate that shellfish harvesting in this area is more likely to result in conflicts than in other certified areas where shellfish harvesting and recreational boating take place.

Comment: The department should defer reclassification of the area until December to avoid conflicts with recreational boaters in the area during the summer months.

Department's response: The department does not concur. The department believes that it is not appropriate to delay reclassification of the area until December. As previously stated, the department has no information

to support the assertion that there will be conflicts between commercial shellfish harvesters, who typically work onboard stationary boats, and recreational boaters. Additionally, deferring the reclassification until December would adversely affect recreational harvesters who typically harvest shellfish during the months when weather and water temperatures are warmer. It would also adversely affect part-time commercial harvesters who work during the summer months for extra income.

Comment: The department should impose a daily harvest limit on the amount of shellfish that can be harvested in this area to prevent the price of shellfish from being depressed by excessive supply.

Department's response: The department does not concur. Regulations specify daily harvest limits to manage particular shellfish resources, such as surfclams and bay scallops. The department does not have the authority to limit shellfish harvests for economic or market purposes. The department can not address concerns about the market price of shellfish. Commercial harvesters are free to determine how much shellfish they can take each day and subsequently sell to wholesale buyers, retail markets or food service establishments based on their communications and relationships with the purchasers of the shellfish they harvest. The environmental conservation law specifies to whom an individual possessing a valid shellfish diggers permit, or valid class D shippers permit, may sell the shellfish the individual harvests from certified shellfish lands.

Comment: If there is a substantial amount of shellfish resources in the area, harvesters may work on weekends and may improperly store their weekend catch until Monday.

Department response: The department does not concur. Harvesters currently harvest shellfish on weekends, including Sundays, in certified areas in state waters and within several Long Island towns. Harvesters have several options for selling their catch. Harvesters may sell their catch to a state permitted shellfish dealer. Harvesters who hold a Class "D" shellfish shipper permit issued by the department may sell their own catch to retail food stores or restaurants within Nassau and Suffolk Counties, many of which are open on weekends, including Sundays. All holders of a New York State shellfish diggers permit are provided with a copy of "Shellfish Harvesting, Handling and Storage." This document summarizes proper handling and storage methods for shellfish and provides a link to the web page with the complete regulations in 6 NYCRR, Part 42 "Sanitary Control over Shellfish." Those regulations specify in detail how commercial shellfish harvesters are required to properly tag, store and handle their catch, including the requirement to place shellfish under refrigeration within a specified number of hours after harvest to prevent excessive growth of bacteria. Harvesters who do not comply with the regulations on handling and storage are subject to fines and possible revocation of their permit.

Comment: There is little access to the area in the form of boat ramps and dock space in Hempstead Harbor.

Department response: The department does not concur. Three municipal boat launching ramps provide access directly to Hempstead Harbor. The Town of Oyster Bay allows non-residents to use the town boat ramp at Tappen Marina for a daily fee during the summer season, approximately Memorial Day through Labor Day, but charges no fee during the remainder of the year. The City of Glen Cove allows non-residents to use the city boat ramp at Garvies Point Road for a daily fee during the summer season, Memorial Day through Labor Day, but charges no fee during the remainder of the year. Commercial shellfish harvesters who currently work in the certified area of Long Island Sound immediately east of Matinecock Point are known to travel to that area by boat from Oyster Bay Harbor, Cold Spring Harbor or the Huntington-Northport Bay Complex where there are additional municipal boat launching ramps in the Towns of Oyster Bay and Huntington. The northeasternmost section of outer Hempstead Harbor that is proposed for reopening is immediately adjacent to the currently certified area lying east of Matinecock Point. Therefore, harvesters traveling by boat from the east, through Long Island Sound, have access to outer Hempstead Harbor by traveling a few more minutes to the south and west around Matinecock Point. Additionally there is one town marina on the eastern shore of Hempstead Harbor with dock space for over 150 boats and two private marinas with dock space for more than 400 boats in Glen Cove Creek, a tributary of Hempstead Harbor, at which harvesters may pay a fee to dock their boats. The Town marina has resident and non-resident fee schedules for marina patrons.

Comment: The department should do a small survey of shellfish resources in the area.

Department's response: The department does not have the resources to perform a scientifically valid survey that could accurately determine the extent of shellfish resources in the area.

PROPOSED RULE MAKING NO HEARING(S) SCHEDULED

Otter Creek Trail System Assembly Area

I.D. No. ENV-22-11-00003-P

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

Proposed Action: Addition of section 190.32 to Title 6 NYCRR.

Statutory authority: Environmental Conservation Law, sections 1-0101(1), (3)(b), 3-0301(1), (b), (2)(m), 9-0105(1) and (3)

Subject: Otter Creek Trail System Assembly Area.

Purpose: To protect natural resources and public safety.

Text of proposed rule: A new section 190.32 is added to 6 NYCRR to read as follows:

190.32 Otter Creek Trail System Assembly Area

(a) *Description.* For purposes of this section, Otter Creek Trail System Assembly Area means those State lands located in Independence River State Forest (Lewis Reforestation Area 35) lying east of the Erie Canal Road (Chase's Lake Road) and west of the Adirondack park boundary. Said Otter Creek Trail System Assembly Area shall be hereinafter referred to as the "Assembly Area". In addition to other applicable general provisions of this Part, the following provisions apply to the Assembly Area. In the event of a conflict, these specific provisions shall control.

(b) Camping.

(1) Immediately upon arrival at the Assembly Area each camping party shall complete all required information on a self-issuing camping permit. The Department portion of the camping permit shall be placed in the provided drop box. The camping party's portion of the camping permit shall be displayed on the dashboard of the vehicle identified on the camping permit at all times.

(2) Each camping party is limited to a maximum of nine persons. All members of the camping party shall be listed on the camping permit and shall occupy a single site.

(3) Camping permits are valid for a maximum of 14 consecutive nights after which all members of the camping party shall vacate the facility for a minimum of five calendar days.

(4) Camping sites shall be occupied by at least one or more members of the registered camping party every night during the duration of the permit.

(5) Camping in the overflow area of the Assembly Area (hereinafter referred to as "overflow area") is limited to no more than three consecutive nights.

(6) Any use of the Assembly Area by any person who is not a member of a registered camping party is considered day-use. Day-use shall be from 7:00 a.m. to 10:00 p.m. unless otherwise posted. No day-users are allowed in the facility after 10:00 p.m. and before 7:00 a.m.

(c) *Horses and Llamas. Definition.* For the purpose of this section, horse(s) shall mean the entire family of equidae and llama(s) shall mean all new world camelids, llamas, alpacas, guanacos, and vicunas.

(1) All horses entering the Assembly Area shall have documentation of a currently valid Coggins test performed in the current or previous calendar year and shall have been found negative for Equine Infectious Anemia. Out of state horses shall also have a valid 30 day Certificate of Health. All horses will have proof of a current rabies vaccination.

(2) All llamas entering the Assembly Area are required to have a valid Certificate of Veterinary Inspection, with the animals individually identified and proof of a current rabies vaccination.

(3) Any horse or llama remaining in the Assembly Area overnight, with the exception of the overflow area, shall be harbored in a DEC covered tie stall or, in the case of a stallion, in a stud stall.

(4) Stud stalls shall only be occupied by stallions.

(5) Horses or llamas shall not be tethered to trees anywhere in the Assembly Area.

(6) Horses or llamas shall not be run, galloped or cantered in the Assembly Area.

(7) Horses or llamas in the overflow area shall be harbored in, or tethered to their trailer or in a temporary corral.

(8) The use of temporary corrals is restricted to the cleared section of the overflow area.

(9) No person shall fail to maintain an orderly camp, including horse stalls. All manure shall be removed or deposited into designated manure pits.

(10) Washing of horses or llamas within the Assembly Area is prohibited.

(d) Animals and Household Pets.

(1) All animals, except household pets, horses and llamas, are prohibited.

(2) All household pets shall be confined on a leash or otherwise confined to restrict them to the campsite area of their owner.

(3) Dogs may be walked on a leash no more than six feet long provided they are under control at all times.

(4) No household pets shall be left unattended in the Assembly Area at any time.

(5) All household pets in the Assembly Area shall have proof of a current rabies vaccination.

(6) Household pet owners shall properly dispose of their pet's excrement in the designated manure pits.

(7) Disruptive or vicious animals and household pets shall be removed by their owner from the area whenever requested by Department or law enforcement personnel.

(e) General Provisions.

(1) No person shall possess alcoholic beverages in any container with a capacity greater than seven gallons at any time.

(2) Fires are only permitted in fire rings or fireplaces provided by the Department.

(3) Quiet hours shall be observed between 10:00 p.m. and 7:00 a.m.

(4) Generators may only be operated from 8:00 a.m. to 10:00 a.m. and from 4:00 p.m. to 8:00 p.m.

(5) The possession or use of fireworks of any nature is prohibited.

(f) Enforcement.

(1) No person shall fail to comply with a lawful instruction of an employee of the Department or law enforcement personnel.

(2) Violation of any provision of this Part shall be grounds to revoke the camping permit which includes the violator as a member of the camping party, removal of the violator from the Assembly Area and denial of any use of the Assembly Area by the violator for a period of seven days.

Text of proposed rule and any required statements and analyses may be obtained from: Robert Messenger, Chief Bureau of State Land Management, NYS DEC, 625 Broadway, Albany, New York 12233-4255, (518) 402-9428, email: rwmessex@gw.dec.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.

Additional matter required by statute: A Negative Declaration has been prepared in compliance with Article 8 of the Environmental Conservation Law.

Regulatory Impact Statement

1. Statutory authority

Environmental Conservation Law ("ECL") section 1-0101(3)(b) directs the Department to guarantee "that the widest range of beneficial uses of the environment is attained without risk to health or safety, unnecessary degradation or other undesirable or unintentional consequences." ECL section 3-0301(1)(b) gives the Department the responsibility to "promote and coordinate management of...land resources to assure their protection...and take into account the cumulative impact upon all such resources in...promulgating any impact upon all such resources...in promulgating any rule or regulation." ECL section 9-0105(1) authorizes the Department of Environmental Conservation to "exercise care, custody, and control" of State lands. ECL section 3-0301(2)(m) authorizes the Department of Environmental Conservation (DEC) to adopt rules and regulations "as may be necessary, convenient or desirable to effectuate the purposes of (the ECL)," and ECL 9-0105(3) authorizes DEC to "make necessary rules and regulations to secure proper enforcement of (ECL Article 9)."

2. Legislative objectives

In adopting various articles of the ECL, the legislature has established forest, fish, and wildlife conservation to be policies of the State and has empowered DEC to exercise care, custody, and control over certain State lands and other real property. Consistent with these statutory interests, the proposed regulations will protect natural resources and the safety and welfare of those who engage in recreational activities on the Otter Creek Trail System Assembly Area. The Department also has been provided authority by the Legislature to manage State owned lands (see ECL section 9-0105(1), and to promulgate rules and regulations for the use of such lands (see ECL section 3-0301(2)(m) and ECL section 9-0105(3)).

The proposed regulations will protect natural resources by requiring campers to complete a self issuing permit, as well as requiring horses and llamas to remain in the Assembly Area overnight. Additional provisions of the regulation will control the use of alcoholic beverages and generators as well as household pets using the area.

A Unit Management Plan (UMP) for this area will be completed in the future. During the planning process, revisions to the proposed regulations might be made. This would depend upon the need, for instance if management of the area can be improved as evidenced by use or as a result of public input.

3. Needs and benefits

The Otter Creek Trail System Assembly Area serves as the major trailhead for approximately a seventy mile complex of recreational trails designated for use by horses, mountain bikers and hikers. The trail system is located on two State reforestation areas as well as the adjoining Independence River Wild Forest. The Assembly Area also provides camping and equestrian related facilities. Because of unregulated use of this facility during peak periods, degradation of natural resources, particularly damage to vegetation and trees has occurred. In addition, social impacts, including overcrowding, boisterous behavior and pets, particularly dogs disturbing other users, must be controlled.

The major provisions of the proposed regulations that will control use on the Assembly Area include: requiring campers to complete a self-issuing permit; limiting the size of camping parties to groups of nine; requiring horses and llamas to remain in the Assembly Area overnight to be tethered in a DEC-provided covered tie stall or, in the case of a stallion, in a stud stall; tethering of horses and llamas in the Overflow Area to a trailer or to a temporary corral; restrictions on alcoholic beverages and household pets and allowing the operation of generators from 8:00 a.m. to 10:00 a.m. and from 4:00 p.m. to 8:00 p.m.

Additional regulations that may apply to the Assembly Area are covered under 6 NYCRR Part 190, Use of State Lands.

The proposed regulations relating to the self-issuing permit system provides a mechanism to limit the amount of use within the Assembly Area to a level within the area's capacity to withstand that use. In addition, it would provide the Department with valuable user data for the area. Limiting the size of camping groups to nine would lessen the potential for environmental damage to the area as well as limiting the potential for social impacts, such as inappropriate behavior causing disturbance to other users.

The proposed regulations require horses and llamas remaining in the Assembly Area overnight be tethered in a covered tie stall or horses in a stud stall as well as requiring horses and llamas in the Overflow Area be tethered to a trailer or to a temporary corral. This will provide protection to vegetation and trees in the Assembly Area by prohibiting tethering of horses and llamas to trees which can cause damage to bark. This is a potential problem, particularly during high peak use periods.

The proposed regulations will extend hours to allow generator use to accommodate users who are on the trails late in the day. The seven gallon container restriction on alcohol is necessary so that excessive drinking can be minimized. A 1/4 keg (7.75 gallons) is popular on this area among young adults, thus restricting the limit to seven gallons would not allow the 1/4 kegs. The regulation on household pets is necessary, particularly to control dogs in the Assembly Area.

The Department went beyond its initial responsibility regarding outreach. The following groups, as well as users, had the opportunity to review the draft regulations. As a result, further staff review along with public input resulted in some revisions to the regulations. These included establishing a self-issuing permit system, rather than the designation of campsites, eliminating the restriction on glass containers and changing the seven gallon container to only cover alcoholic beverages, allowing extended hours for generator use, allowing overnight camping in the Overflow Area for up to three nights, permitting the use of temporary corrals in the Overflow Area, and removing the requirement that stallions in stud stalls also have a tie stall assigned to them.

Individual members of the New York State Trails Council, New York State Horse Council, Upper Canada Equestrian Association, Ride New York and the Leatherstocking Riding Club received an announcement of the DEC's intent to propose this regulation, along with a request for preliminary comments. The proposed regulations were also posted at the facility with contact information to allow individual users of the facility the opportunity to comment.

4. Costs

There will be no increased staffing, construction or compliance costs projected for State or local governments or to private regulated parties as a result of this rulemaking. Costs to the Department would be minimal, approximately \$300 for the necessary signage and printing costs for self issuing permits.

5. Local government mandates

This proposal will not impose any program, service, duty nor responsibility upon any county, city, town, village, school district or fire district.

6. Paperwork

Self-issuing permits will be required for overnight campers, however, this will not result in an increase in paperwork since these permits will replace the existing trail register system. It is possible there will be a slight increase in the number of citations issued by the Department during the first few months after the regulation takes effect, however this should also not result in an increase in paperwork and may offset some of the cost of new or additional signage. The regulations will not impose any additional reporting requirements or other paperwork on any private or public entity.

7. Duplication

There is no duplication, conflict, or overlap with State or Federal regulations.

8. Alternative approaches

Several alternatives were considered to determine which management strategies would best protect the resource and best serve the public using this facility.

The "No Action" alternative would continue to allow unregulated use of the facility and the adjoining trail system and would do nothing to provide protection to the natural resources of the area or the experience of visitors.

There were many variations of the proposed regulations considered. Staff considered additional regulations to control every aspect of use in the area but felt that the proposed regulations represented the "minimal tool" necessary for the management of this facility. Consideration was given to requiring users to obtain permits from the Lowville DEC Office prior to arrival, however, it was felt this would not only place an additional burden on users, but also on Department staff.

9. Federal standards

There is no relevant Federal standard governing the use of State lands.

10. Compliance schedule

The proposed rule with respect to the Otter Creek Trail System Assembly Area will become effective on the date of publication of the rulemaking in the New York State Register. No time is needed for regulated persons to achieve compliance with the regulations. Once the regulations are adopted, they are effective immediately.

Regulatory Flexibility Analysis

Regulatory Flexibility Analysis for Small Businesses and Local Governments is not submitted with these regulations because the proposal will not impose any reporting, recordkeeping or other compliance requirements on small businesses or local governments.

Since there are no identified cost impacts for compliance with the proposed regulations on the part of small businesses and local governments, they would bear no economic impact as a result of this proposal. The proposed regulation relates solely to protecting the natural resources and the public safety on the Otter Creek Trail System Assembly Area.

Rural Area Flexibility Analysis

A Rural Area Flexibility Analysis is not submitted with this proposal because the proposal will not impose any reporting, recordkeeping or other compliance requirements on rural areas. The proposed regulation relates solely to protecting the natural resources and the public safety on the Otter Creek Trail System Assembly Area.

Job Impact Statement

A Job Impact Statement is not submitted with this proposal because the proposal will have no substantial adverse impact on existing or future jobs and employment opportunities. The proposed regulation relates solely to protecting natural resources and the public safety on the Otter Creek Trail System Assembly Area.

Specific reasons underlying the finding of necessity, above, are as follows: This action is taken on an emergency basis pursuant to State Administrative Procedures Act (SAPA) § 202(6). The adequacy and reliability of the supply of electricity is essential to the public health, safety and general welfare of the citizens of New York. A failure to timely adopt the financing could potentially impair the ability of HTP to meet its construction schedule, and could adversely affect the availability of needed capacity for reliability in New York City. The access to new power supply sources, which HTP will provide, will be critical to maintain reliability as existing resources are retired or, in the event that generating facilities such as the Indian Point Nuclear Station are not re-licensed. As a result, compliance with the advance notice and comment requirements of SAPA § 202(1) would be contrary to the public interest, and the immediate authorization of the proposed financing is necessary for the preservation of the public health, safety and general welfare.

Subject: Approval for Hudson Transmission Partners, LLC to incur indebtedness and borrow up to \$750,000,000.

Purpose: To finance the construction of Hudson Transmission Partners, LLC's electric transmission facility.

Substance of emergency/proposed rule: The Public Service Commission adopted an order approving the petition by Hudson Transmission Partners, LLC (HTP) for approval to incur indebtedness, for a term in excess of twelve months, by borrowing up to \$750,000,000 to finance the construction of HTP's electric transmission facility.

This notice is intended: to serve as both a notice of emergency adoption and a notice of proposed rule making. The emergency rule will expire August 9, 2011.

Text of rule may be obtained from: Leann Ayer, Public Service Commission, 3 Empire State Plaza, Albany, New York 12223-1350, (518) 486-2655, email: leann_ayer@dps.state.ny.us

Data, views or arguments may be submitted to: Jaclyn A. Brilling, Secretary, Public Service Commission, 3 Empire State Plaza, Albany, New York 12223-1350, (518) 474-6530, email: secretary@dps.state.ny.us

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

Regulatory Impact Statement

A regulatory impact statement is 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.

Regulatory Flexibility Analysis

A regulatory flexibility analysis is 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.

Rural Area Flexibility Analysis

A rural area flexibility analysis is 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.

Job Impact Statement

A job impact statement is not submitted with this notice because the proposed rule is within the definition contained in section 102(2)(a)(ii) of the State Administrative Procedure Act.

(11-E-0215EP1)

Public Service Commission

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

Approval for Hudson Transmission Partners, LLC to Incur Indebtedness and Borrow Up to \$750,000,000

I.D. No. PSC-22-11-00002-EP

Filing Date: 2011-05-12

Effective Date: 2011-05-12

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

Proposed Action: The Public Service Commission adopted an order approving, on an emergency basis, the petition on behalf of Hudson Transmission Partners, LLC (HTP) to incur indebtedness, for a term in excess of twelve months, by borrowing up to \$750,000,000 to finance the construction of HTP's electric transmission facility.

Statutory authority: Public Service Law, sections 4(1), 5(2), 65(1), 66(1), (2), (4), (5) and 69

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

NOTICE OF ADOPTION

Amendments to 16 NYCRR Parts 10 and 255

I.D. No. PSC-22-10-00010-A

Filing No. 433

Filing Date: 2011-05-17

Effective Date: 2011-05-17

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

Action taken: Amendment of Parts 10 and 255 of Title 16 NYCRR.

Statutory authority: Public Service Law, sections 2(10), (11), 64, 65, 66, 71, 72, 72-a, 75 and 79

Subject: Amendments to 16 NYCRR Parts 10 and 255.

Purpose: To approve amendments to 16 NYCRR Parts 10 and 255.

Substance of final rule: The Commission, on October 14, 2010, adopted the Memorandum and Resolution approving amendments to 16 NYCRR Chapter I, Rules of Procedure, Subchapter A, General, Part 10, Referenced Material and Chapter III, Gas Utilities, Subchapter C, Safety, Part 255, Transmission and Distribution of Gas.

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

Text of rule may be obtained from: Leann Ayer, Public Service Commission, Three Empire State Plaza, Albany, New York 12223, (518) 486-2655, email: leann_ayer@dps.state.ny.us 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.

(09-G-0627SA1)

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

Whether to Permit the use of the Sensus AccuWAVE for use in Residential Gas Meter Applications

I.D. No. PSC-22-11-00004-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, deny or modify, in whole or in part, a petition filed by National Fuel Gas Distribution Corporation for the approval to use the Sensus accuWAVE diaphragm gas meter.

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

Subject: Whether to permit the use of the Sensus accuWAVE for use in residential gas meter applications.

Purpose: To permit gas utilities in New York State to use the Sensus accuWAVE diaphragm gas meter.

Substance of proposed rule: The Public Service Commission is considering whether to grant, deny or modify, in whole or part, the petition filed by National Fuel Gas Distribution Corporation to use the Sensus R275 accuWAVE diaphragm meter in residential natural gas meter applications.

Text of proposed rule and any required statements and analyses may be obtained by filing a Document Request Form (F-96) located on our website <http://www.dps.state.ny.us/f96dir.htm>. For questions, contact: Leann Ayer, Public Service Commission, Three Empire State Plaza, Albany, New York 10007, (518) 486-2655, email: leann_ayer@dps.state.ny.us

Data, views or arguments may be submitted to: Jaclyn A. Brillling, Secretary, Public Service Commission, Three Empire State Plaza, Albany, NY 10007, (518) 474-6530, email: Secretary@dps.state.ny.us

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

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

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

(11-G-0223SP1)