York issued an Order for Summary Action banning the sale and distribution of certain products containing synthetic cathinone (a category of phenethylamines). On March 28, 2012, the Commissioner of Health of the State of New York issued an Order for Summary Action banning the sale and distribution of products containing synthetic cannabinoids. These Commissioner's Orders, unlike this regulation, are not enforceable by local governments or criminal authorities, and the sole enforcement mechanism for violations of the Order is a civil enforcement proceeding for an injunction and civil penalties through the State Attorney General. In addition, the Commissioner's Orders do not prohibit possession or manufacture of some synthetic phenethylamines and/or synthetic cannabinoids. Further, the Commissioner's Orders are only binding on and enforceable against those individuals and entities who received personal service of the Commissioner's Orders.

On July 9, 2012 President Barack Obama signed a Bill (S.3187) into law which, in relevant part, enacted the federal Synthetic Drug Abuse Prevention Act of 2012. The law banned the sale and distribution of products containing most of the types of synthetic phenethylamines and synthetic cannabinoids identified in this regulation by placing them on the federal schedule I list of substances under the federal Controlled Substances Act (21 U.S.C. § 812[c]). This regulation does not conflict because the federal law does not provide for state and local authority enforcement.

Alternatives:

The alternative of continued sole reliance on the May 20, 2011 and March 28, 2012 Commissioner's Orders was considered. Promulgating this regulation, however, was decided upon in order to provide enhanced enforcement authority and regulatory authority for state and local governments to more effectively address this emergent and expanding public health threat.

Federal Standards:

The New York regulation is broader than the recent federal Synthetic Drug Abuse Prevention Act of 2012 in that it covers additional classes of stimulant compounds. Further, it anticipates future synthesis of stimulant compounds not yet developed, specifically cannabinoid receptor agonists. Analysis methodologies will need to be developed as additional related compounds are synthesized.

Compliance Schedule:

Regulated parties should be able to comply with these regulations effective upon filing with the Secretary of State.

Regulatory Flexibility Analysis

Effect of Rule:

The rule will affect only the small businesses which are engaged in selling products containing certain harmful substances known as synthetic phenethylamines and synthetic cannabinoids. At this time, it is not possible to determine the number of small businesses that sell these products. However, in 2011 and 2012, Commissioner's Orders were issued banning certain synthetic phenethylamines and synthetic cannabinoids and resulted in approximately 7,000 establishments being served with one or both of such Orders by public health authorities.

This regulation affects local governments by establishing a minimum standard regarding the possession, manufacture, distribution, sale or offer of sale of synthetic phenethylamines and synthetic cannabinoids. Local governments have the power and duty to enforce the provisions of the State Sanitary Code, including this new Part, utilizing any civil and criminal remedies that may available. PHL §§ 228, 229, 309(1)(f) and 324(e).

Pursuant to PHL § 228, the State Sanitary Code establishes a minimum standard for health and sanitation. Under that same authority, local governments are empowered to establish a local sanitary code that is more restrictive than the State Sanitary Code. Many local governments already have local sanitary codes that are more restrictive than the State Sanitary Code.

Compliance Requirements:

Small businesses must comply by not engaging in any possession, manufacturing, distribution, sale or offer of sale of synthetic phenethylamines and synthetic cannabinoids.

Local governments must comply by enforcing the State Sanitary Code. Local boards of health may impose civil penalties for a violation of this regulation of up to $2,000 per violation, pursuant to PHL § 309(1)(f). Pursuant to PHL § 229, local law enforcement may seek criminal penalties for a first offense of up to $250 and 15 days in prison, and for each subsequent offense up to $500 and 15 days in prison.

Professional Services:

Small businesses will need no additional professional services to comply.

Local governments, in certain instances where local governments enforce, will need to secure laboratory services for testing of substances.

Compliance Costs:

Costs to Private Regulated Parties:

The regulation imposes no new costs for private regulated parties.

Costs to State Government and Local Government:

Any enforcement costs incurred by State and local governments cannot be predicted, but are likely to be offset by fines and penalties imposed pursuant to Public Health Law. Moreover, any such costs will be further offset by a reduction in emergency responder, law enforcement, health care and other State and local resources currently being used to respond to and address the negative effects of usage of the prohibited substances.

Economic and Technological Feasibility:

Although there will be an impact on small businesses that sell these products, the prohibition is justified by the extremely dangerous nature of these products.

Although the costs of local enforcement are not precisely known at this time, the benefits to public health are anticipated to outweigh any such costs. Regarding technical feasibility, as new designer drugs become available, new tests will need to be developed.

This regulation is necessary to protect public health. It is as narrowly tailored as possible while still addressing the public health threat.

Minimizing Adverse Impact:

The New York State Department of Health will assist local government, e.g. consultation, coordination and providing information and updates on its website.

Small Business and Local Government Participation:

Local governments are aware of and have been involved in notifying certain small businesses regarding prior Commissioner's Orders on this same matter.

Cure Period:

Violation of this regulation can result in civil and criminal penalties. In light of the magnitude of the public health threat posed by these substances, the risk that some small businesses will not comply with regulations and continue to make or sell or distribute the substance justifies the absence of a cure period.

Rural Area Flexibility Analysis

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

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

Job Impact Statement

Nature of the Impact:

The Department of Health does not expect there to be a positive or negative impact on jobs or employment opportunities.

Categories and Numbers Affected:

The Department anticipates no negative impact on jobs or employment opportunities as a result of the amended rule.

Regions of Adverse Impact:

The Department anticipates no negative impact on jobs or employments opportunities in any particular region of the state.

Minimizing Adverse Impact:

Not applicable.

Office of Medicaid Inspector General

NOTICE OF ADOPTION

Withholding of Payments; Incorporation by Reference

I.D. No. MED-21-12-00001-A

Filing No. 797

Filing Date: 2012-08-06

Effective Date: 2012-08-22

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

Action taken: Amendment of sections 518.7 and 518.9 of Title 18 NYCRR.

Statutory authority: Public Health Law, section 32

Subject: Withholding of payments; Incorporation by reference.

Purpose: To amend regulations governing the withholding of Medicaid payments in accordance with federal requirements.

Text of final rule: Section 518.7 of title 18 of NYCRR is amended to read as follows:

518.7 Withholding of payments.

(a) *Basis for withholding.*

(1) The department may withhold payments under the program, in whole or in part, when it has [reliable information that] *determined* that a provider [is involved in fraud or willful misrepresentation involving claims submitted to the program; or] has abused the program or *has* committed an unacceptable practice. [Reliable information] *The department's determination that a provider has abused the program, or has committed an unacceptable practice* may consist of preliminary findings by the department's audit or utilization review staff of unacceptable practices or significant overpayments, information from a State professional licensing or certifying agency of an ongoing investigation of a provider involving fraud, abuse, professional misconduct or unprofessional conduct, or information from a State investigating or prosecutorial agency or other law enforcement *organization* [agency] of an ongoing investigation of a provider for fraud or criminal conduct involving the program. The department may withhold payment of current and future claims to the provider and any affiliate.

(2) The department must withhold payments under the program, in whole or in part, when it has determined or has been notified that a provider is the subject of a pending investigation of a credible allegation of fraud unless the department finds good cause not to withhold payments in accordance with 42 C.F.R. 455.23. A credible allegation of fraud is an allegation that has indicia of reliability and has been verified by the department, or the Medicaid fraud control unit, or another State agency, or law enforcement organization.

(i) Whenever the department initiates a withholding, in whole or in part, in relation to a pending investigation of a credible allegation of fraud, the department must make a fraud referral to the Medicaid fraud control unit. If the Medicaid fraud control unit does not accept the referral, then the department may refer the matter to another law enforcement organization.

(ii) The fraud referral made under this paragraph must be in writing and provided to the Medicaid fraud control unit or other law enforcement organization not later than the next business day after the withhold is enacted.

(b) Notice of the withholding will [usually] be given [prior to or contemporaneously with the withholding; however, in no event will notice of the withholding be given more than] *within* five days of [after the withholding of payments] *taking such action unless requested in writing by a law enforcement organization to delay such notice.* The notice will describe the reasons for the action, but need not include specific information concerning an ongoing investigation.

(c) The notice of withholding must:

(1)*(i)* state that the payments are being withheld in accordance with [42 C.F.R. 455.23 and] this section; *and*

(ii) in cases where there is a pending investigation of a credible allegation of fraud state that the payments are being withheld in accordance with 42 C.F.R. 455.23;

(2) state that the withholding is for a temporary period only and recite the circumstances under which the withholding will be terminated;

(3) specify whether the withholding applies to all or only some claims and identify which claims if not all claims are involved; and

(4) advise of the right to submit written arguments and documentation in opposition to the withholding and how to submit them *in accordance with subdivision (e) of this section*.

(d) The withholding may continue only temporarily.

(1) When initiated by the department prior to issuance of a draft audit report or notice of proposed agency action, the withholding will not continue for more than 90 days unless a written draft audit report or notice of proposed agency action is sent to the provider. Issuance of the draft report or notice of proposed action may extend the withholding until an amount reasonably calculated to satisfy the overpayment is withheld, pending a final determination on the matter.

(2) When initiated by the department after issuance of a draft audit report or notice of proposed agency action, the withholding will not continue for more than 90 days unless a written final audit report or notice of agency action is sent to the provider. Issuance of the report or notice of action may extend the withholding until an amount reasonably calculated to satisfy the overpayment is withheld, pending a final determination on the matter.

(3) When initiated by another State agency or law enforcement organization, the withholding may continue until the agency or prosecuting authority determines that there is insufficient evidence to support an action against the provider or its affiliate, or until the agency or criminal proceedings are completed.

(4) When initiated by the department when it has determined or has been notified that a provider is the subject of a pending investigation of a credible allegation of fraud all withholding actions will be temporary and will not continue after either of the following:

(i) The department, or the Medicaid fraud control unit, or other law enforcement organization determines that there is insufficient evidence of fraud by the provider.

(ii) Legal proceedings related to the provider's alleged fraud are completed.

(e) Appeals.

(1) A provider or its affiliate that is the subject of the withholding is not entitled to an administrative hearing, but may, within 30 days of the date of the notice, submit written arguments and documentation that the withhold should be removed.

(2) Within 60 days of receiving written arguments or documentation in response to a withhold, the department will review the determination and notify the provider or its affiliate of the results of that review. After the review, the determination to impose a withhold may be affirmed, reversed or modified, in whole or in part.

(3) A decision by the department to affirm, reverse or modify a withhold on appeal shall not be a determination of the merits of any investigation initiated by another State agency, the Medicaid fraud control unit, or other law enforcement organization.

Section 518.9 of title 18 of NYCRR is amended to read as follows:

518.9 Incorporation by reference.

The provisions of the Code of Federal Regulations which have been incorporated by reference in this Part have been filed in the Office of the Secretary of State of the State of New York, the publication so filed being the booklet entitled: Code of Federal Regulations, title 42, Parts 455.23, revised as of October 1, [2008] *2011*, published by the Office of the Federal Register, National Archives and Records Administration, as a special edition of the Federal Register. The regulations incorporated by reference may be examined at the Office of the Department of State, 99 Washington Ave, Albany, NY 12231 at the law libraries of the New York State Supreme Court and the New York State, and at the Office of the Medicaid Inspector General, Office of Counsel, 800 N. Pearl Street, Albany, New York 12204. They may also be purchased from the Superintendent of Documents, Government Printing Office Washington, DC 20402. Copies of the Code of Federal Regulations are also available at many public libraries and bar association libraries.

Final rule as compared with last published rule: Nonsubstantive changes were made in section 518.7(a)(1).

Text of rule and any required statements and analyses may be obtained from: Michael D'Allaird, Esq., Office of the Medicaid Inspector General, 800 North Pearl Street, Albany, New York 12204, (518) 402-1434, email: Michael.D'Allaird@omig.ny.gov

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

The change made to the last published rule does not necessitate a revision to the RIS, RFA, RAFA or JIS because it was a non-substantial change made for the purposes of correcting a technical error in the publication of the proposed rule, and does not require any changes to the RIS, RFA, RAFA, or JIS.

Assessment of Public Comment

The Office of the Medicaid Inspector General (OMIG) received comments from seven (7) organizations on its proposed rulemaking amending 18 NYCRR § 518.7 & § 518.9 to conform with federal requirements. Comments were highly detailed. Criticisms centered mainly on (1) the definition of a ''credible allegation of fraud'' not expressly referencing the department's commitment to review each allegation carefully, judiciously and on a case-by-case basis; (2) assertions that the proposed rulemaking went beyond the federal regulations and guidance; (3) the sufficiency of notice provisions; (4) the lack of a an administrative hearing right on the withhold; and (5) the sufficiency of parameters in the regulation relative to the Medicaid Fraud Control Unit's (MFCU) or other law enforcement organization's investigation of the credible allegation of fraud. The OMIG acknowledges these concerns. However, in drafting this rulemaking the OMIG verified that its provisions are consistent with federal regulations and relevant guidance. To clarify, the OMIG will review and verify all of the facts and circumstances of an allegation of fraud carefully, judiciously and on a case-by-case basis before initiating a withholding pursuant to this rulemaking. The OMIG will consider all relevant factors when evaluating a pending investigation of a credible allegation of fraud and the application of good cause exceptions. The OMIG will coordinate with the MFCU, other law enforcement organizations and agency partners with regard to enforcement of this rulemaking. We believe this rulemaking as written comports with due process and complies with federal regulations and associated guidance. The OMIG made no substantive changes to this rulemaking as a result of reviewing and assessing the public comments. However, the OMIG did make a non-substantive technical correction to 18 NYCRR § 518.7(a)(1). To clarify the term ''law enforcement agency'' has been deleted and replaced with the term ''law

enforcement organization''. A full assessment of public comments will be posted on the OMIG's website at the following address: http://www.omig.ny.gov.

Office of Mental Health

EMERGENCY/PROPOSED RULE MAKING NO HEARING(S) SCHEDULED

Medical Assistance Payments for Comprehensive Psychiatric Emergency Programs (CPEP)

I.D. No. OMH-34-12-00003-EP
Filing No. 796
Filing Date: 2012-08-06
Effective Date: 2012-08-06

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

Proposed Action: Amendment of Part 591 of Title 14 NYCRR.

Statutory authority: Mental Hygiene Law, sections 7.09(b) and 31.04(a)

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

Specific reasons underlying the finding of necessity: The proposed rule implements an increase in the Medicaid fees paid to Comprehensive Psychiatric Emergency Programs (CPEPs) operated by hospitals licensed by the Office of Mental Health pursuant to Article 31 of the Mental Hygiene Law, and by the Department of Health pursuant to Article 28 of the Public Health Law. The Medicaid fee increase is effective July 1, 2012. This increase will preserve program funding and will enable CPEPs to sustain programs and continue to provide assistance to individuals in need of emergency psychiatric services. Since this proposed regulation has significant impact upon public health, safety and general welfare, the proposed rule warrants emergency filing.

Subject: Medical Assistance Payments for Comprehensive Psychiatric Emergency Programs (CPEP).

Purpose: To increase Medicaid fees paid to CPEPs effective July 1, 2012.

Text of emergency/proposed rule: Section 591.5 of Title 14 NYCRR is amended to read as follows:

Effective [April 1, 2011] *July 1, 2012,* reimbursement for comprehensive psychiatric emergency programs under the medical assistance program shall be in accordance with the following fee schedule:

Brief emergency visit	$[83.71] *181.00*
Full emergency visit	[491.59] *1,060.00*
Crisis outreach service visit	[491.59] *1,060.00*
Interim crisis service visit	[491.59] *1,060.00*

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 November 3, 2012.

Text of rule and any required statements and analyses may be obtained from: Sue Watson, NYS Office of Mental Health, 44 Holland Avenue, Albany, NY 12229, (518) 474-1331, email: Sue.Watson@omh.ny.gov

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

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

Regulatory Impact Statement

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

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

2. Legislative objectives: Articles 7 and 31 of the Mental Hygiene Law reflect the Commissioner's authority to establish regulations regarding mental health programs. Comprehensive Psychiatric Emergency Programs (CPEPs) provide a full range of psychiatric emergency services in a safe and comfortable environment to persons in need of such services. CPEPs are operated by hospitals licensed by the Office of Mental Health (Office) pursuant to Article 31 of the Mental Hygiene Law, and by the Department of Health pursuant to Article 28 of the Public Health Law. The proposed rule furthers the legislative intent under Article 7 by assuring the delivery of mental health services to persons with mental illness and facilitating financing procedures and mechanisms to support such a service delivery system.

3. Needs and benefits: The proposed amendments increase the Medicaid fees paid to CPEPs effective July 1, 2012. This increase is due to the conversion of Medicaid Disproportionate Share Funding and State Aid paid to CPEP programs to ''base'' Medicaid, and has been approved by the Director of the Division of Budget. It is anticipated that the increase in Medicaid fees paid to CPEPs will aid in program viability and enable CPEPs to continue to serve individuals in need of emergency psychiatric services.

4. Costs:

(a) Cost to State government: These regulatory amendments are not expected to result in any additional costs to State government. The estimated full annual impact of these regulatory amendments is estimated to be $11,981,223 (State share of $5,990,612), but these costs are expected to be offset by the conversions of Medicaid Disproportionate Share Funding and State Aid to ''base'' Medicaid.

(b) Cost to local government: These regulatory amendments are not expected to result in any additional costs to local government.

(c) Cost to regulated parties: These regulatory amendments are not expected to result in any additional costs to regulated parties.

5. Local government mandates: These regulatory amendments will not result in any additional imposition of duties or responsibilities upon county, city, town, village, school or fire districts.

6. Paperwork: This rule should not result in an increase in the paperwork requirements of providers.

7. Duplication: These regulatory amendments do not duplicate existing State or federal requirements.

8. Alternatives: The only alternative to the regulatory amendment which was considered was inaction. This alternative was rejected due to the need for the conversion of Medicaid Disproportionate Share Funding and State Aid to ''base'' Medicaid.

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

10. Compliance schedule: These regulatory amendments will be effective upon their adoption, and shall be deemed to have been effective on and after July 1, 2012.

Regulatory Flexibility Analysis

A Regulatory Flexibility Analysis for Small Businesses and Local Governments is not being submitted with this notice because the amended rule will not have an adverse economic impact upon small businesses or local governments. The purpose of the proposed rule is to increase the Medicaid fees paid to Comprehensive Psychiatric Emergency Programs (CPEPs) operated by hospitals licensed by the Office of Mental Health pursuant to Article 31 of the Mental Hygiene Law, and by the Department of Health pursuant to Article 28 of the Public Health Law. It is anticipated that the increase in Medicaid fees paid to CPEPs will aid in program viability and enable CPEPs to continue to serve individuals in need of emergency psychiatric services.

Rural Area Flexibility Analysis

The amendments to 14 NYCRR Part 591 are necessary to increase the Medicaid fees paid to Comprehensive Psychiatric Emergency Programs (CPEPs) operated by hospitals licensed by the Office of Mental Health pursuant to Article 31 of the Mental Hygiene Law, and by the Department of Health pursuant to Article 28 of the Public Health Law. It is anticipated that the increase in Medicaid fees paid to CPEPs will aid in program viability and enable CPEPs to continue to serve individuals in need of emergency psychiatric services. The proposed rule will not impose any adverse economic impact on rural areas; therefore, a Rural Area Flexibility Analysis is not submitted with this notice.

Job Impact Statement

A Job Impact Statement is not submitted with this notice because the purpose of the proposed rule is to increase the Medicaid fees paid to Comprehensive Psychiatric Emergency Programs (CPEPs) operated by hospitals licensed by the Office of Mental Health pursuant to Article 31 of the Mental Hygiene Law, and by the Department of Health pursuant to Article 28 of the Public Health Law. It is anticipated that the increase in Medicaid fees paid to CPEPs will aid in program viability and enable CPEPs to continue to serve individuals in need of emergency psychiatric services. There will be no adverse impact on jobs and employment opportunities as a result of this proposed rule.