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New York State Medicaid Update

THE OFFICIAL NEWSLETTER OF THE NEW YORK MEDICAID PROGRAM

Medicaid Begins Coverage for Hospital Emergency Room Observation Services



Effective April 1, 2011, New York State Medicaid, including Medicaid managed care and Family Health Plus (FHPlus) plans, will provide separate payment in certain situations for hospital observation services provided in a distinct observation unit, in addition to payment for the emergency room medical visit. Payment will be made under Ambulatory Patient Group 450 (APG). Medicaid payment for observation services is limited to patients who are seen, evaluated and admitted to the Observation Unit via the hospital's

emergency service and for whom a diagnosis and a determination concerning admission, discharge or transfer cannot be accomplished within eight hours of admission to observation status, but can reasonably be expected within 24 hours. In order to be reimbursed for observation services, a patient must be in observation status for a minimum of eight hours (with clinical justification). This is in addition to any time that the patient spent in the Emergency Room prior to admission to the observation unit. Hospitals may bill up to 24 hours of observation services, at which time the patient must be admitted as an inpatient or discharged. Medicaid will not reimburse for direct admits to observation (CPT/HCPCS code G0379).

The Department of Health is in the process of adopting regulations governing the operation of Observation Units. In the interim, to obtain Medicaid payment for such observation services, facilities must have a waiver approved by the Office of Health Systems Management (OHSM), Division of Certification and Surveillance (to initiate this process, please contact OHSM staff at 518-402-1003). Waivers are issued on a site specific basis. The OHSM waiver criteria are listed at the end of this article. **Medicaid will not reimburse for observation services provided at hospital facilities that have not received a Department of Health waiver to provide such services.** -continued on page 3-



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POLICY & BILLING GUIDANCE

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Medicaid Begins Coverage for Hospital Emergency Room Observation Services

The following Medicaid payment policy and reimbursement criteria will apply concerning Medicaid payment for observation services in an observation unit. Required documentation for Medicaid payment for observation unit services includes:

- ▶ *a clinical justification for observation status;*
- ▶ *a working diagnosis;*
- ▶ *any tests or treatments administered while the patient is in observation status;*
- ▶ *progress notes by a responsible Physician, PA or NP; and*
- ▶ *final disposition of the patient from the observation unit.*



Billing Guidelines and Requirements

Observation services should be billed under APG rate code 1402 and CPT/HCPCS code G0378 (hospital observation service, per hour). The number of hours in observation status must be coded in the units of service field of the claim line on which G0378 is coded. The appropriate CPT/HCPCS codes for all ancillary services provided to the patient while in observation status should also be reported on the claim. Facilities should code G0378 only when the length of stay in the observation unit is for 8 or more hours. If the length of stay in the observation unit is less than 8 hours, the observation portion of the stay is not reimbursable by Medicaid and the observation code should not be reported on the APG claim.

Only those hours that the patient is actually in the observation unit may be billed with G0378. Significant procedures or high intensity ancillaries (MRI, PET scans, CT scans) will cause G0378 to package, meaning it will not be paid separately. Low level ancillaries (X-rays, laboratory tests) and drugs will not cause G0378 to package and observation will be paid separately.

Observation unit services end when the patient is admitted as an inpatient, or is discharged from the hospital. If the patient is admitted to inpatient status, only the inpatient admission may be submitted for payment and the emergency room services and associated observation services should not be billed to Medicaid. If the patient must be transferred to another facility, the emergency room and observation services may be submitted for payment. **-continued on next page-**



POLICY & BILLING GUIDANCE

(continued from page 3)

Medicaid Begins Coverage for Hospital Emergency Room Observation Services

Managed care organizations (MCOs) may choose to utilize a criteria-based assessment tool for determining whether the observation stay is medically necessary. Approval of observation services may be subject to either prior authorization or a retrospective review process.

Observation Services Billing Examples

Hours in ED	Hours in Observation Unit	Provider Billing
3 hours	6 hours	Payment for ED visit only - do not report observation services on the APG claim.
3 hours	9 hours	Payment for ED visit and Observation (9 units)
8 hours	24 hours	Payment for ED visit and Observation (24 units)
8 hours	4 hours	Payment for ED visit only - do not report observation services on the APG claim.

Note: Medicare's payment policy for observation services is different than that utilized by Medicaid. Nevertheless, Medicaid will continue to reimburse the Medicare Part B coinsurance amounts (to the extent permitted by State statute) for dually-eligible recipients.

Questions? Please call the Division of Financial Planning and Policy at (518) 473-2160 for any additional information or questions about Medicaid coverage policy for observation services.



EMERGENCY DEPARTMENT OBSERVATION UNIT SERVICES

Application and Review Criteria For Regulatory Waiver of Eight-Hour ED Length of Stay Limitation for Patients Assigned to Observation Units

The application must include a summary of the program proposed, that includes:

1. Program goals and objectives for the observation unit, which must include use of the unit only for observation, diagnosis and stabilization of those patients for whom diagnosis and a determination concerning admission, discharge, or transfer cannot be accomplished within eight hours, but can reasonably be expected within twenty-four hours.
2. Clinical Criteria/Indicators for Assignment and Discharge/Exclusion Criteria.
3. Clear Statement/Description of Oversight and Accountability, which must provide for:
 - a. Organization of the observation unit under the direction and control of the Emergency Service;
 - b. The integration of the observation unit and its services with the emergency service and other related services of the hospital; and
 - c. Medical staff adoption of policies and to assure appropriate use of the observation unit.
4. Description of the Physical Space, which must include:
 - a. The size and location of the unit and number of beds. The total number of observation unit beds in a hospital shall be limited to five percent of the hospital's certified bed capacity, and shall not exceed forty, provided that in a hospital with less than 100 certified beds, an observation unit may have up to five beds.
 - b. A distinct physical space separate from the rest of the emergency service, except in a hospital designated as a critical access hospital pursuant to subpart F of part 485 of Title 42 of the Code of Federal Regulations or a sole community hospital pursuant to section 412.92 of Title 42 of the Code of Federal Regulations or any successor provisions.
 - c. Whether or not construction is required, a certification from a licensed architect or engineer, in a form specified by the Department, that the space complies with the applicable provisions of Parts 711 and 712-2 and section 712-2.4 of 10 NYCRR (Chapter 2.2, "Specific Requirements for General Hospitals," of Part 2, "Hospitals," of Guidelines for Design and Construction of Health Care Facilities, 2010 edition).
 - d. To the extent that construction is required for the observation unit, compliance with Part 710 of 10 NYCRR.

-continued-



POLICY & BILLING GUIDANCE

(continued from page 5)

Emergency Department Observation Unit Services

Application and Review Criteria For Regulatory Waiver of Eight-Hour ED Length of Stay Limitation for Patients Assigned to Observation Units

5. Defined staffing plan that:
 - a. Provides for staff appropriately trained and in sufficient numbers to meet the needs of patients in the observation unit;
 - b. At a minimum, provides for oversight of the medical care of the patients assigned to the observation unit by a physician, nurse practitioner, or physician assistant. The physician, nurse practitioner, or physician assistant assigned to oversee the observation unit must be immediately available to meet the needs of patients in the observation unit and must not be assigned concurrent duties that will interfere with such availability.

6. Quality Review/Improvement Activities – to be established by hospital, but may include:
 - a. Tracking inpatient admissions from the observation unit;
 - b. Reducing returns to the ED;
 - c. Reducing any hospital admissions within 7 days of discharge from the observation unit;
 - d. Sample chart reviews/review of all deaths following an observation unit stay;
 - e. Patient satisfaction/assessment tool.

7. Hospitals operating observation units pursuant to waivers granted by the Department prior to May 1, 2011, may continue to operate those units consistent with the terms of their waivers.

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

Economic and Technological Feasibility:

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

Minimizing Adverse Impact:

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

Small Business and Local Government Participation:

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

Rural Area Flexibility Analysis

Types and Estimated Number of Rural Areas:

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

Reporting, Recordkeeping and Other Compliance Requirements and Professional Services:

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

Costs:

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

Minimizing Adverse Impact:

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

Rural Area Participation:

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

Job Impact Statement

Nature of Impact:

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

Categories and Numbers Affected:

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

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

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

Regions of Adverse Impact:

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

Minimizing Adverse Impact:

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

Self-Employment Opportunities:

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

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

Observation Unit Operating Standards

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

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

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

Statutory authority: Public Health Law, section 2803

Subject: Observation Unit Operating Standards.

Purpose: To provide operating standards for observation units.

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

405.19 Emergency services

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

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

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

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

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

(2) Physical Space:

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

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

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

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

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

(3) Staffing.

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

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

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

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

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

(5) Opening and Closure.

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

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

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

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

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

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

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

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

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

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

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

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

Regulatory Impact Statement**Statutory Authority:**

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

Legislative Objectives:

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

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

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

Current Requirements:

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

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

Needs and Benefits:

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

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

COSTS**Costs to Private Regulated Parties:**

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

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

Costs to Local Government:

There are no costs to local government.

Costs to the Department of Health:

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

Costs to Other State Agencies:

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

Local Government Mandates:

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

Paperwork:

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

Duplication:

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

Alternatives:

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

Federal Standards:

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

Compliance Schedule:

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

Regulatory Flexibility Analysis

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

Rural Area Flexibility Analysis

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

Job Impact Statement

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Section 59.9, as amended, provides for an effective period of four years for technical supervisor certification, an increase of two years. The responsibilities of a technical supervisor have been modified to reflect current practice. Notably, the duty to conduct field inspections has been eliminated, as has the responsibility to provide expert

New York State Department of Health
Division of Health Facility Planning/Bureau of Architectural & Engineering Facility Planning

**ARCHITECTURAL AND ENGINEERING CERTIFICATION FOR OBSERVATION UNITS IN
EXISTING ARTICLE 28 SPACE WITHOUT CONSTRUCTION**

Date: _____

NYS Department of Health/Office of Health Systems Management
Division of Health Facility Planning
Bureau of Architectural and Engineering Facility Planning
433 River Street, 6th Floor
Troy, New York 12180-2299

Re: Name: _____
Location: _____
Description: _____

To the New York State Department of Health:

I hereby certify that:

1. I have been retained by the above-named facility, to evaluate whether its observation unit complies with applicable construction standards, codes and regulations, including the Guidelines for the Design and Construction of Health Care Facilities, 2010 Edition, published by The Facility Guidelines Institute.
2. I have ascertained that, to the best of my knowledge, information and belief, the above-referenced observation unit has been designed and constructed in compliance with the applicable provisions of the State Hospital Code -- 10 NYCRR Part 711 (General Standards for Construction) and Part 712, Subpart 712-2 and section 712-2.4 of this Title for construction projects approved or completed after January 1, 2011
3. I understand that if a component of this unit is inconsistent with the applicable provisions of the State Hospital Code (10 NYCRR Parts 711, 712), I shall bring this to the attention of Bureau of Architectural and Engineering Facility Planning of the New York State Department of Health prior to the opening of the unit.
4. I understand that the costs of any subsequent corrections necessary to achieve compliance with applicable requirements of 10 NYCRR Parts 711 and 712 when the prior work was not completed properly as certified herein, may not be considered allowable costs for reimbursement under 10 NYCRR Part 86.

Project Name	
Location	
Description	

Signature of Architect or Engineer

Name of Architect or Engineer

Professional New York State License Number

Business Address

The undersigned applicant understands and agrees that, notwithstanding this architectural/engineering certification the Department of Health shall have continuing authority to (a) inspect the space, and (b) to require correction of any deficiencies. The applicant shall have a continuing obligation to make any changes required by the Division to comply with the above- mentioned codes and regulations, whether or not physical plant construction or alterations have been completed.

:

Authorized Signature for Applicant

Date

Name

Title

STATE OF NEW YORK

County of _____

)
) SS:.
)

On the ___ day of _____ 20___, before me personally appeared _____, to me known, who being by me duly sworn, did depose and say that he/she resides at _____, that he/she is the _____ of the _____, the corporation described herein which executed the foregoing instrument; and that he/she signed his/her name thereto by order of the board of directors of said corporation.

(Notary) _____