

Pursuant to the State Administrative Procedure Act Section 207 and 202-d, the Department of Health invites public comment on the continuation or modification of the following rules. Public comments will be accepted for 45 days from the date of publication in the State Register and should be submitted to Katherine Ceroalo, Bureau of Program Counsel, Regulatory Affairs Unit, Corning Tower, Room 2438, Empire State Plaza, Albany, NY 12237 by email at REGSQNA@health.ny.gov.

Title 10 NYCRR - Three Year Review

Amendment of Section 9.1 of Title 10 (Prohibit Additional Synthetic Cannabinoids)

Statutory Authority:

Public Health Law Section 225

Description of the regulation:

In 2012, the Department issued 10 NYCRR Part 9, which addressed the emergent threat to public health by prohibiting the possession, manufacture, distribution, sale or offer of dangerous synthetic cannabinoids and other substances.

Identification and addition of new synthetic cannabinoids to the regulation simplified and enhanced the efforts of local governments to control these dangerous chemicals. The regulation should continue without modification.

Amendment of Parts 58 and 34 of Title 10 (Patient Access of Laboratory Test Results)

Statutory Authority:

Public Health Law Sections 576 and 587

Description of the regulation:

Part 58 contains the clinical laboratory and blood bank regulations and Part 34 establishes business practices that clinical laboratories must follow. 10 NYCRR § 58-1 (Clinical Laboratories), 58-8 (HIV Testing) and 34-2 (Laboratory Business Practices) had stated that laboratory test results cannot be reported directly to the patient unless written authorization is first provided by the physician or authorized person. 10 NYCRR § 58-8.4 and 10 NYCRR § 34-2.11 were amended to be consistent with new federal rules that provide individuals direct access to their laboratory test reports. The regulation should continue without modification.

**Amendment of Subpart 58-2 of Part 58 of Title 10
(Blood Banks)**

Statutory Authority:

Public Health Law Section 3121(5)

Description of the regulation:

Subpart 58-2 describes requirements for blood banks and laboratories performing immunohematology testing. The amendments were necessitated by advances in medical technology and the need to codify practice standards and eliminate obsolete requirements, afford regulated parties with greater flexibility in complying with department regulations, clarify regulatory intent, and provide for safe transfusion of blood components during interfacility transport of patients. Future amendments will likely be required to align the department's rules with new federal requirements that may be established to define requirements when new therapies and procedures are established in the field.

**Amendment of Subpart 66-1 of Title 10
(School Immunization Requirements)**

Statutory Authority:

Public Health Law Sections 2164 and 2168

Description of the regulation:

Subpart 66-1 of Title 10 effectuate the provisions and purposes of Public Health Law Sections 2164, regarding school immunization requirements, and 2168, regarding the statewide immunization information system. Subpart 66-1 was updated in 2015 to make the regulations consistent with current immunization recommendations. The regulation should continue without modification; however, revisions may be necessary in the future if pending Departmental proposals are approved.

**Amendment of Section 80.138 of Title 10
(Opioid Overdose Programs)**

Statutory Authority:

Public Health Law Section 3309

Description of the regulation:

The Commissioner of Health is authorized under Section 3309 of the Public Health Law to establish standards for approval of an opioid overdose prevention program. Section 80.138 of Title 10 sets forth the structure of the New York State Department of Health's Opioid Overdose

Program which outlines the responsibilities of a registered provider trained to administer a drug that negates or neutralizes in whole or in part the pharmacological effects of an opioid in the body. This regulation sets forth the requirements of a registered provider and the responsibilities required under the program. The regulation should continue without modification.

**Amendment of Subpart 86-10 of Title 10
Rate Rationalization for Community Residences (CRs)/Individualized Residential
Alternatives (IRAs) Habilitation and Day Habilitation**

Statutory Authority:

Public Health Law Section 201

Description of the regulation:

Provides for updating the cost base of the rate calculation. The regulation should continue without modification.

**Amendment of Subpart 86-11 of Title 10
Rate Rationalization for Intermediate Care Facilities for Persons with Developmental Disabilities
(ICF/DDs)**

Statutory Authority:

Public Health Law Section 201

Description of the regulation:

Provides for updating the cost base of the rate calculation. The regulation should continue without modification.

**Addition of Subpart 86-12 to Title 10
(Outpatient Services Licensed Under the Mental Hygiene Law)**

Statutory Authority:

Sections 26 and 111(a) of part H of chapter 59 of the laws of 2011

Description of the regulation:

Utilization threshold limits established by OASAS, OMH, and OPWDD in conjunction with DOH to help control service utilization. The regulation should continue without modification.

**Amendment of Section 98-1.16(c) and Addition of Subpart 98-3 to Title 10
(Audited Financial Statements for Managed Care Organizations)**

Statutory Authority:

Public Health Law Sections 4403(2) & 4403(f)(7)

Description of the regulation:

The purpose of this regulation is to extend audit and reporting standards to all managed care organizations (MCOs) certified under Article 44 of the Public Health Law. The regulation applies to MCOs (Prepaid Health Services Plans, HIV Special Needs Plans and Managed Long Term Care Plans) (PHSPs, HIV SNPs and MLTCPs) that were not included under the Department of Financial Services Regulation 118. This ensures that all MCOs authorized to operate under Article 44 adhere to the same financial reporting requirements and standards in the filing of audited financial statements. The regulation should continue without modification.

**Addition of Section 400.25 to Title 10
(Disclosure of Quality and Surveillance Related Information)**

Statutory Authority:

Public Health Law Sections 2803 and 2805-t

Description of the regulation:

The regulation provides that every facility with an operating certificate shall make available to the public nursing quality indicators including staffing, patient outcomes and data regarding complaints filed with any state or federal agency. The regulation should continue without modification.

**Addition of Part 404 to Title 10
(Integrated Outpatient Services)**

Statutory Authority:

Public Health Law Section 2803

Description of the regulation:

The Integrated Outpatient Services regulations were issued jointly by DOH (10 NYCRR Part 404), the Office of Mental Health (14 NYCRR Parts 598), and the Office of Alcoholism and Substance Abuse Services (14 NYCRR Part 825), effective January 1, 2015, to permit a provider licensed or certified by one agency to provide services under the jurisdiction of a second agency at one of its sites without an additional license or certification. The regulation should continue without modification.

**Amendment of Part 757 of Title 10
(Chronic Renal Dialysis Services)**

Statutory Authority:

Public Health Law Section 2803

Description of the regulation:

These regulations mirror the CMS Conditions for Coverage for End Stage Renal Disease Services (ESRD). The Chronic Renal Dialysis Services regulations which were in effect in NYS prior to 2015 were out of date as they were an adaptation of the 1988 CMS ESRD regulations. These amendments incorporated the most recent Federal dialysis regulations. Part 757 also incorporated (by reference), important infection control recommendation from the CDC, established standards for pediatric dialysis, established more stringent regulations for testing of dialysis water, emergency preparedness, and established facility staffing responsibilities that are consistent with SED practice acts.

The regulation should continue but will need to be modified in the future. A new modality, Nursing Home Dialysis, has been approved by CMS. The Federal regulations have not been amended yet. CMS has developed draft guidance describing the requirements and we await final guidance from CMS for surveillance of this type of dialysis.

Addition of Part 1004 and Amendment of Subpart 55-2 of Title 10 (Medical Use of Marihuana)

Statutory Authority:

Public Health Law Section 3369-a

Description of the regulation:

This regulation establishes rules of the Medical Marijuana Program pursuant to the Compassionate Care Act. Part 1004 regulates the participation and registration of practitioners; the issuance of certifications; application for registration as a certified patient or designated caregiver; applications, general requirements, manufacturing and dispensing requirements, security requirements, and operations of registered organizations; laboratory testing requirements for medical marihuana; pricing, medical marihuana marketing and advertising by registered organizations; reporting dispensed medical marihuana products; prohibitions of the use of approved medical marihuana products in certain places; reporting requirements for registered practitioners, certified patients and designated caregivers; proper disposal of medical marihuana products by certified patients or designated caregivers; general prohibitions, practitioner prohibitions, and designated caregiver prohibitions and protections.

The enactment of the Compassionate Care Act required the establishment of Part 1004 which describes requirements for the medical use of marihuana. These regulations cover a variety of areas for the use of medical marihuana including, but not limited to, requirements for practitioners, certified patients, registered organizations, and dispensing facilities. Section 1004.14 establishes laboratory testing requirements of medical marihuana products and require the analysis of medical marihuana in accordance with subpart 55-2. Subpart 55-2 describes

requirements for environmental laboratories performing testing on environmental samples originating from New York. Subpart 55-2 was amended to add a new section, 55-2.15, that describes the requirements for environmental laboratories performing testing of medical marijuana. The regulation should continue without modification.

Title 18 NYCRR - Three Year Review

**Amendment of Sections 505.14 and 505.28 of Title 18
Personal Care Services Program (PCSP) and Consumer Directed Personal Assistance Program
(CDPAP)**

Statutory Authority:

Social Services Law Sections 363-a(2), 365-a(2)(e) & 365-f and Public Health Law
Section 201(1)(v)

Description of the regulation:

Provides guidance for program and personal care rates. The regulation should continue
without modification.

Title 10 NYCRR - Five Year Review

Amendment of Sections 2.59, 405.3, 415.19, 751.6, 763.13, 766.11 and 793.5 of Title 10 (Prevention of Influenza Transmission by Healthcare and Residential Facility and Agency Personnel)

Statutory Authority:

Public Health Law Sections 225, 2803, 3612 and 4010

Description of the regulation:

This regulation requires certain healthcare workers who are unvaccinated for influenza during the time when the Commissioner declares influenza to be prevalent to wear surgical or procedure masks. It also requires covered healthcare facilities and entities to report their personnel influenza vaccination rates. The regulation should continue without modification.

Amendment of Part 16 of Title 10 (Quality Assurance Requirements for Medical Use of Radioactive Material and Radiation Therapy)

Statutory Authority:

Public Health Law Section 225(5)

Description of the regulation:

Requires facilities that provide radiation therapy services become accredited by the American College of Radiology (ACR) or the American College of Radiation Oncology (ACRO). In addition, updates to the quality assurance requirements for radiation therapy were implemented. The regulation should continue without modification.

Amendment of Section 35.4 of Title 10 (Death Certificates)

Statutory Authority:

Public Health Law Section 4100(2)

Description of the regulation:

The regulation governs when a death record may be disclosed and provides that, after January 1, 1988, all death certificate forms shall contain a confidential section which shall list the cause and circumstances of death. A certified copy or certified transcript of a death certificate, upon specific request by the spouse, sibling, children, or parents of the deceased or the lawful representative of such person(s) shall be entitled to a certified copy of certified transcript of a death certificate. The regulation also authorizes the release of a death certificate

upon request by municipal, State or Federal agencies for statistical or official purposes, when needed for medical, epidemiological or scientific research approved by the State Health Commissioner, or pursuant to a court order, a demonstrated legal right, or a claim of a demonstrated medical need by an applicant. The regulation should continue without modification.

**Amendment of Subpart 72-1 of Title 10
(Tanning Facilities)**

Statutory Authority:

Public Health Law Sections 3551 and 3554

Description of the regulation:

The regulation defines the term ‘tanning facility’ and requires facility operators to obtain a biennial permit to operate from the permit issuing official (PIO) having jurisdiction in the county where the tanning facility is located. Facility inspection and enforcement standards are established, as well as, operation standards for tanning facilities including age restrictions for use of ultraviolet radiation devices, requirements for patron identification, warning and consent requirements, operation and maintenance of physical facilities and equipment, use of protective eyewear during tanning and general operator responsibilities. The regulation should continue without modification.

**Amendment of Part 80 of Title 10
(Electronic Prescribing, Dispensing and Recordkeeping of Controlled Substances)**

Statutory Authority:

Public Health Law Section 3308(2)

Description of the regulation:

The regulations allow practitioners to electronically write and transmit prescriptions for controlled substances; permit pharmacies to receive, dispense, maintain and archive records of these electronic prescriptions; allow pharmacists to endorse a pharmacy’s electronic record with an electronic signature and other required information for refills of controlled substances; and authorize a pharmacist to document an oral prescription for controlled substances to an electronic record. The regulation should continue without modification.

**Amendment of Part 80 of Title 10
(Prescription Monitoring Program)**

Statutory Authority:

Public Health Law Article 33, Sections 3333, 3343-a and 3371

Description of the regulation:

The regulations require electronic reporting of prescription information from pharmacies and dispensing practitioners for controlled substances, to the New York State Department of Health, within 24 hours of delivery of the prescription.

Practitioners are required to consult the Prescription Monitoring Program (PMP) Registry prior to prescribing for or dispensing to a patient any controlled substance listed on schedule II, III, or IV, for the purpose of reviewing that patient's controlled substance history. A practitioner may authorize a designee to consult the prescription PMP Registry on his or her behalf, provided that the ultimate decision as to whether or not to prescribe or dispense a controlled substance remains with the practitioner.

The regulation ensures that practitioners are aware of other controlled substance prescriptions that their patients have recently received and avoid over-prescribing, misuse or abuse of controlled substances.

The legislation also authorizes the sharing of confidential data with statutorily identified entities. The regulation should continue without modification.

**Amendment of Sections 80.131 and 80.133 of Title 10
(Electronic Prescriptions and Records for Hypodermic Needles and Hypodermic Syringes)**

Statutory Authority:

Public Health Law Section 3381

Description of the regulation:

Hypodermic needle and syringe regulations removed the barriers to prescribing and dispensing of needles and syringes. The regulations provide greater access to needles and syringes by the patient by allowing pharmacists to receive oral prescriptions from the agent of the practitioner; allowing practitioners to authorize necessary refills with no limits; allowing prescriptions to be valid for longer than a 6-month period; and allowing a refill to be transferred to another pharmacy for dispensing, based on the patient's request. The regulation should continue without modification.

**Repeal of Section 85.45 of Title 10 and Section 506.4 of Title 18
(Orthodontic Screening)**

Statutory Authority:

Public Health Law Sections 201 and 206 & Social Services Law Sections 363-a and 365-a(2)

Description of the regulation:

Section 506.4 describes the location of the review criteria, the age limitations, and the practitioner qualifications for the orthodontic benefit. The regulation should continue without modification.

**Amendment of Sections 86-1.2 and 86-1.4 of Title 10
(Audits of Institutional Cost Reports)**

Statutory Authority:

Public Health Law Section 2807-c (35)

Description of the regulation:

Section 86-1.2 describes the financial and statistical data filing requirements for hospitals. Section 86-1.4 describes the audit requirements/process for the financial and statistical data filed by hospitals. The regulation should continue without modification.

**Amendment of Part 405 of Title 10
(Hospital Pediatric Care)**

Statutory Authority:

Public Health Law Section 2803(2)

Description of the regulation:

These regulations established minimum general hospital standards for administration, radiology/nuclear medicine, respiratory, emergency, surgical and anesthesia services, including new requirements for pediatric intensive and emergency care (Parts 405.3, 405.6, 405.7, 405.9, 405.15, 405.12, 405.17, 405.19, 405.20, 405.22). The regulation should continue without modification.

**Amendment of Parts 405 and 751 of Title 10
(Adverse Event Reporting Via NYPORTS System)**

Statutory Authority:

Public Health Law Sections 2803(2), 2805-1 and 2805(m)

Description of the regulation:

Part 405.8 Adverse event reporting

Part 405.8 requires general hospitals to report certain adverse events to the Department within a specified timeframe. Part 405.8 provides the definitions of the adverse events. The definitions are consistent with National Quality Forum (NQF) definitions, which the Department partially adopted in July 2011. Part 405.8 requires the Hospital to conduct an investigation of certain adverse events, and to submit an electronic version of the investigation to the Department within a specified timeframe. Part 405.8 states the investigation must identify and analyze the circumstances surrounding the event, and must develop and implement measures to prevent recurrence and to improve the overall quality of patient care.

Part 751.10 Adverse event reporting

Part 751.10 requires Diagnostic and Treatment Centers (D&TCs) to report certain adverse events to the Department within a specified timeframe. Part 751.10 provides the definitions of the adverse events. The definitions are consistent with National Quality Forum (NQF) definitions, which the Department partially adopted in July 2011. Part 751.10 requires the D&TC to conduct an investigation of certain adverse events, and to submit an electronic version of the investigation to the Department within a specified timeframe. Part 751.10 states the investigation must identify and analyze the circumstances surrounding the event, and must develop and implement measures to prevent recurrence and to improve the overall quality of patient care.

The language in the current versions of the regulations are consistent with national standards (National Quality Forum Never Events, and Joint Commission Sentinel Events). The regulations hold Article 28 Hospitals and D&TCS accountable for correcting systematic problems that contribute to an adverse event. The regulation should continue without modification.

Amendment of Sections 405.2 and 405.4 of Title 10 (Hospital Sepsis Protocols)

Statutory Authority:

Public Health Law Sections 2800 and 2803

Description of the regulation:

Parts 405.2 and 405.4 were amended and enacted on May 1, 2013 to require all hospitals licensed to operate in New York State to have in place and implement evidence-based protocols for the early identification and treatment of severe sepsis and septic shock. These amendments were made in response to the high prevalence and mortality rate of sepsis.

The sepsis regulations at part 405.4 as initially drafted include guidelines and a definition of sepsis that are no longer consistent with current international guidelines. The Office of Quality and Patient Safety, Office of the Medical Director has proposed an amendment that will refine the definition of sepsis and the guidelines for treatment to assure consistency with current evidence. In addition, a revision is proposed to ensure the Department's ability to receive data through different intake options in the future should the need arise due to bandwidth issues, i.e. poor network speeds, or due to contractual or funding constraints related to the current process of data intake through IPRO's secure web portal. The regulation at part 405.2 is not affected by the changes proposed to part 405.4 and therefore should continue without modification.

Amendment of Parts 763 and 766 of Title 10 (Certified Home Health Agency (CHHA) and Licensed Home Care Services Agency (LHCSA) Requirements)

Statutory Authority:

Public Health Law Section 3612

Description of the regulation:

These regulations will be amended to reflect the enactment of legislation authorizing the performance of advanced tasks by Advanced Home Aides supervised by nurses employed by CHHAS, LHCSAS, hospice programs, or enhanced assisted living residences (Chapter 471 of the Laws of 2016).

**Amendment of Section 910.2 of Title 10
(Language Assistance and Official New York State Prescription Form Requirements)**

Statutory Authority:

Public Health Law Section 281(2)

Description of the regulation:

Language barriers and the inability to read or understand prescription information can pose health risks to patients with limited English proficiency (LEP). Amendments to Section 281 of the Public Health Law require Official New York State Prescription (ONYSRx) forms and electronic prescriptions to include a section that allows prescribers to indicate whether an individual is limited English proficient and, if so, the preferred language of the patient.

Contents related to the ONYSRx form or electronic prescription, to meet the legislative mandate for LEP, was described and defined in detail. The regulation should continue without modification.

**Addition of Part 1002 to Title 10
(Limits on Executive Compensation and Administrative Expenses in Agency Procurements)**

Statutory Authority:

Social Services Law Sections 363-a(2) and Public Health Law Sections 201 & 206(3)

Description of the regulation:

Limits administrative expenses and executive compensation. The regulation should continue without modification.

Title 18 NYCRR - Five Year Review

Amendment of Section 360-2.4 of Title 18 (Medicaid Eligibility)

Statutory Authority:

Public Health Law Sections 201 and 206 & Social Services Law Section 363-a

Description of the regulation:

Description of the regulation: Establishes time frames under which the social services district must determine an applicant's Medicaid eligibility. In general, it is within 45 days from the date of the application, subject to certain exceptions. The regulation also establishes the periods of time when coverage is available.

The regulation should continue without modification.

Amendment of Parts 486 and Part 487 of Title 18 (Adult Homes)

Statutory Authority:

Social Services Law Sections 460-d, 461, and 461-e

Description of the regulation:

Effective January 16, 2013, regulations Section 486.7 of Part 486 and Part 487 of Title 18 of the Official Compilation of Codes, Rules and Regulations of the State of New York, were amended and adopted. The regulations affect New York State's adult homes. Specifically, the amended regulations provide definitions for the following: persons with serious mental illness; transitional adult homes; alternative community settings; community services; mental health census; housing contractors; and community transition coordinator.

In addition, the amended regulations, among other things:

- Modify admission and retention requirements for all adult homes regarding individuals with serious mental illness;
- Define adult homes with a certified capacity of 80 beds or more, in which 25% or more of the resident population are persons with serious mental illness, as "transitional adult homes;"
- Require every operator of a transitional adult home to submit a compliance plan designed to bring the facility's mental health census to a level that is under 25 percent of the resident population over a reasonable period of time, through the lawful discharge of residents with appropriate community services to alternative community settings;

- Expand the requirements for the completion of mental health evaluations, and make authority to complete a mental health evaluation subject to DOH approval;
- Set forth requirements for quarterly statistical reporting by transitional adult homes;
- Provide for additional record keeping requirements for all adult homes; and
- Set forth penalties for provider non-compliance.

The regulation should continue without modification.

**Amendment of Section 505.3 of Title 18
(Authority to Collect Pharmacy Acquisition Cost)**

Statutory Authority:

Social Services Law Sections 363-a(2) and 367-a(9)(b) & Public Health Law Sections 201(1)(v) and 206

Description of the regulation:

Per 505.3(f)(4), each pharmacy enrolled in the Medicaid program shall provide the department, in such manner, for such periods, and at such times as the department may require, with the drug acquisition cost, as defined in paragraph 505.3(a)(3), of prescription drugs. The regulation should continue without modification.

Title 10 NYCRR - Ten Year Review

Amendment of Part 11 of Title 10 NYCRR - Qualifications of Local Health Personnel

Statutory Authority:

Public Health Law Sections 225(4) and (5) and 206(1)(9)(a)

Description of the regulation:

Part 11 of the State Sanitary Code provides job descriptions and minimum qualifications for public health personnel working in county and city health departments. Changes made to the Part 11 in 2008 include:

Revised job descriptions and/or minimum qualifications for the following titles:

GENERAL PROVISIONS
LOCAL HEALTH OFFICER
COMMISSIONER OF HEALTH
MEDICAL DIRECTOR OF COUNTY PHYSICALLY HANDICAPPED
CHILDREN'S PROGRAMS
PUBLIC HEALTH NURSE 1
PUBLIC HEALTH NURSE 2
ENVIRONMENTAL HEALTH DIRECTOR
PUBLIC HEALTH ENGINEER
PUBLIC HEALTH SANITARIAN
PUBLIC HEALTH TECHNICIAN
PUBLIC HEALTH NUTRITIONIST
PUBLIC HEALTH EDUCATOR
PUBLIC HEALTH SOCIAL WORKER
PUBLIC HEALTH DIRECTOR
PUBLIC HEALTH EPIDEMIOLOGIST

The regulation should continue without modification.

Amendment of Section 66-1.2 of Part 66 of Title 10 NYCRR - Immunization Registry

Statutory Authority:

Public Health Law Section 2168

Description of the regulation:

Section 66-1.2 of Title 10 define authorized users of the New York State Immunization Information System (NYSIIS) and the Citywide Immunization Registry (CIR), mandated NYSIIS and CIR reporters, reporting requirements including information to be reported, methods of reporting, exceptions to reporting requirements, and timeliness of reporting, methods of

accessing immunization data, maintenance of security and confidentiality, and the provision of NYSIIS information to registrants' families or guardians. The regulation should continue without modification.

Amendment of Sections 86-1.55, 86-1.62 and 86-1.63 of Title 10 NYCRR - DRGs, SIWs, Trimpoints and the Mean LOS

Statutory Authority:

Public Health Law Sections 2803(2), 2807(3), 2807-c(3) and (4)

Description of the regulation:

These represented the annual update of SIWs, DRGs and Length of Stays required under the statute. These regulations were repealed effective 12/1/2009 with the implementation of the new reform regulations.

Addition of new section 86-2.38 of Title 10 NYCRR - Rate Enhancement/Pay for Performance

Statutory Authority:

Public Health Law Section 2808(22)

Description of the regulation:

The nursing home incentive payments regulation provides for additional payments to nursing homes (in the form of a rate enhancement) that exceed defined quality standards. One set of awards was for (1) the best overall performers during the evaluation period (calendar year 2007) and (2) best improvement in performance in pressure ulcer care (comparison of performance from July 1, 2006-June 30, 2007 to performance from July 2007, June 2008). A nursing home could receive an award in both categories. Nursing homes that received a deficiency for substandard quality of care or were in the bottom quarter percentile of all eligible nursing homes during the periods under review were not eligible for these incentives. The regulation should continue without modification.

Addition of new Subpart 86-8 to Title 10 NYCRR - APGs Outpatient Reimbursement

Statutory Authority:

Public Health Law Section 2807(2)(a)

Description of the regulation:

Established regulations for the new APG reimbursement system effective 12/1/2008 forward. The Department is considering amendments to the regulation.

Addition of new Subpart 86-9 to Title 10 NYCRR - Limited Home Care Services Agencies

Statutory Authority:

Public Health Law Sections 2803, 2807, 2808

Description of the regulation:

The regulation enables licensed adult home and enriched housing program operators under contract to local departments of social services (LDSS) to be reimbursed by the New York State Medical Assistance (MA) program for providing specified home care services to eligible persons under Title XIX of the Social Security Act. The services that may be provided for which the operator may be reimbursed by MA are personal care services, the administration of medications, and the application of sterile dressings by a registered nurse. The regulation should continue without modification.

Amendments to Sections 98-2.2, 98-2.6 and 98-2.10 of Subpart 98-2 of Title 10 NYCRR - External Appeals of Adverse Determinations

Statutory Authority:

Public Health Law Sections 4910 – 4916

Description of the regulation:

Subpart 98-2 codifies requirements and responsibilities for health plans and certified external appeal agents to afford enrollees and providers independent external review of health plan determinations that a requested service was not medical necessary. Section 98-2.2 provides definitions for certain words and terms used in this Subpart. Section 98-2.6 describes certified external appeal agents' prohibited material affiliations and conflicts of interest. Section 98-2.10 describes the responsibilities of certified external appeal agents to process external appeal requests.

The Subpart should be revised to reflect changes to Article 49 of the Public Health Law. These revisions will be promulgated in conjunction with revisions to Department of Financial Services regulations at 11 NYCRR 410.

Amendment of Section 415.13, addition of subdivision 415.2(u) and addition of subdivision 415.26(k) to Title 10 - Feeding Assistants in Nursing Homes

Statutory Authority:

Public Health Law Sections 2800 and 2803

Description of the regulation:

This regulation amends § 415.13 (c) (1) to exclude feeding assistants from the definition of nurse aide. The addition of subdivision (d) to § 415.13 (which is referenced in subdivision [u]

of Section 415.2) defines the term “feeding assistant” and sets forth the circumstances under which a feeding assistant may be used, consistent with federal requirements. Subdivision (k) of § 415.26 describes the feeding assistant training course that feeding assistants are required to complete pursuant to paragraph (2) of subdivision (d) of § 415.13 and 42 CFR § 483.35 (h) (i). The training course requires a minimum of 15 hours (as opposed to the federally-required minimum of eight hours) of training for feeding assistants and includes all federally-required topics. This regulation should continue without modification.

Amendment of Sections 763.12, 766.10 and 766.12 of Title 10 NYCRR - Licensed Home Care Services Agency Reporting

Statutory Authority:

Public Health Law Sections 3612(3) and (6)

Description of the regulation:

This regulation implements the provisions of Public Health Law (PHL) §§3612 (3) and (6). Under § 763.12 and § 766.12, certified home health care agencies (CHHAs) and licensed home care services agencies (LHCSAs) are required to submit annual reports that must include reports on the type, frequency and reimbursement for services provided, including reimbursement from federal and state agencies. Subdivision (c) of § 763.12 requires CHHAs to provide all information necessary to any LHCSA that subcontracts with the CHHA to allow the LHCSA to file its annual report. Subdivision (h) of § 766.10 establishes a cap on administrative and general costs for LHCSAs equal to the cap on administrative and general costs applied to CHHAs, in accordance with subdivision seven of PHL § 3614. The regulation should continue without modification.

Addition of a new Part 910, amendment of existing sections 85.21 & 85.22, repeal of existing sections 85.23 & 85.25, & amendment of Part 80 of Title 10 NYCRR, amendment of existing section 505.3 & repeal of existing sections 528.1 & 528.2 of Title 18 NYCRR - Enactment of a Serialized New York State Prescription Form

Statutory Authority:

Public Health Law Sections 206 and 3308(2)

Description of the regulation:

Public Health Law Section 21 defined the use of the Official New York State Prescription Form as it applies to all medications issued by New York State licensed practitioners. The corresponding Part 910 regulations established definitions, minimum standards for registration to utilize the prescription forms, a system for ordering and tracking the serialized forms, safeguards and storage of the forms by registered practitioners and institutional dispensers, and dispensing upon prescription forms. Official New York State Prescription Program forms are still in use. The regulation should continue without modification.

Addition of new Part 1001 within Title 10 NYCRR - Assisted Living Residences

Statutory Authority:

Public Health Law Section 4662(1)

Description of the regulation:

This regulation implements Public Health Law Article 46-B, which creates new licensure and certification categories for assisted living residences (ALRs), entities that provide or arrange for housing, on-site monitoring and personal care services and/or home care services in a home-like setting. An operator of an ALR must be certified as an adult home or enriched housing program. In addition to its obligations to residents under that certificate, the ALR operator must have an individualized service plan for each resident and provide prospective residents, residents and their representatives with significant residency agreements and disclosure information. ALR operators will also have additional or different requirements with regard to case management and staff qualifications and training. The regulation should be updated to conform to current standards.

Title 18 NYCRR - Ten Year Review

Amendment of paragraph 505.3(b)(1) of Title 18 NYCRR - Non-Prescription Emergency Contraceptive Drugs

Statutory Authority:

Public Health Law Sections 201(1)(v) and 206(1)(f); Social Services Law, Section 365-a(2)

Description of the regulation:

This rule allows for Federal Drug Administration (FDA) approved non-prescription emergency contraceptive drugs to be dispensed by a pharmacy without a fiscal order for women 18 years of age and older. This was enacted to allow women, 18 years of age and older, to have access to this time sensitive medication. It is critical for women to take emergency contraceptive drugs within 72 hours, although ideally within 12 hours, of unprotected intercourse.

The regulation should continue with modification to conform to current standards.

Addition of paragraph 505.8(g)(6) to Title 18 NYCRR - Payment for Nursing Services Provided to Medically Fragile Children (RAU # 07-11) Effective: 4/16/08

Statutory Authority:

Social Service Law Section 367-r(1-a)

Description of the regulation:

This regulation provides that Medicaid reimbursement for private duty nursing services furnished to medically fragile children will be made at an enhanced rate. The regulation should continue without modification.

Title 10 NYCRR - Fifteen Year Review

Amendment to Section 2.1 (Effects of Smallpox Vaccination)

Statutory Authority:

Public Health Law Sections 225(4) and (5)(a), (g), and (h) authorize the Public Health and Health Planning Council to establish, and from time to time amend, the Sanitary Code with respect to preserving and improving public health in the State and to designate those communicable diseases deemed dangerous to public health. Further, the Public Health and Health Planning Council is authorized to establish the reporting standards associated with such reports, and those diseases for which specimens shall be submitted to approved laboratories.

Description of the regulation:

Cases of vaccinia infection due to contact transmission or other complications resulting from vaccination must be reported immediately to the local health department (which would then notify the Department).

In the event that a reimplementations of smallpox vaccination is necessary, it is critical that adverse events due to vaccination be reported, monitored and treated. This requirement must remain in place as an important piece of the response to a bioterrorism event in NYS. The regulation should continue without modification.

Amendment of Part 2.1(a), (b) and (c), 2.5, 2.10 (Reportable Communicable Disease List and Quarantine Authority)

Statutory Authority:

Public Health Law Sections 225(4) and (5)(a), (g), and (h) authorize the Public Health and Health Planning Council to establish, and from time to time amend, the Sanitary Code with respect to preserving and improving public health in the State and to designate those communicable diseases deemed dangerous to public health. Further, the Public Health and Health Planning Council is authorized to establish the reporting standards associated with such reports, and those diseases for which specimens shall be submitted to approved laboratories.

Description of the Regulation:

Section 2.1 lists diseases that physicians are required report, and section 2.5 lists diseases for which physicians need to submit specimens for laboratory examination.

The regulation should be modified to require the reporting of new diseases of public health importance and the submission of needed laboratory specimens.

Amendment to Subpart 5-1 of Title 10 (Public Water Systems - Revised Maximum Contaminant Level (MCL) - Propylene Glycol)

Statutory Authority:

Public Health Law, Sections 201 and 225

Description of the regulation:

This amendment revised the Maximum Contaminant Level (MCL) for Propylene Glycol in water delivered to any user of a public water system, to 1.0 mg/L. This amendment should continue without modification.

Amendment to Subpart 5-1 of Title 10 (Public Water Systems - Revised Maximum Contaminant Level (MCL) - MTBE)

Statutory Authority:

Public Health Law, Sections 201 and 225

Description of the regulation:

This amendment revised the Maximum Contaminant Level (MCL) for Methyl-tertiary-butyl-ether (MTBE) in water delivered to any user of a public water system, to 0.010 mg/L. The amendment should continue without modification.

Amendments to Subpart 58-8 (HIV Testing)

Statutory Authority:

Public Health Law section 576

Description of the regulation:

Subpart 58-8 promotes the public health, safety and welfare by establishing minimum standards for clinical laboratory testing and reporting of test results to detect human immunodeficiency virus (HIV) and to monitor infected individuals. Amendments may be required in the future to address updated technologies and revise testing algorithms for the management of HIV.

Amendment to Sections 66-1.1 and 66-1.3 (Seventh Grade Hepatitis B School Entry)

Statutory Authority:

Public Health Law Section 2164

Description of the regulation:

The rule requires children entering the seventh grade to receive adequate doses of hepatitis B vaccine.

Hepatitis B is a serious, vaccine preventable disease that can lead to liver cancer. According to the Centers for Disease Control and Prevention approximately 70% of hepatitis B infections occur in late adolescence and early adulthood. It is very important that children attending NY schools who have not been vaccinated against hepatitis B in infancy receive this immunization before they reach the age when they are most likely to become infected. The rule should continue without modification.

Amendment to Sections 66-1.1 and 66-1.3 (Varicella Vaccine for School Entry)

Statutory Authority:

Public Health Law Section 2164

Description of the regulation:

The rule requires all children entering kindergarten to have received adequate doses of varicella (chickenpox) vaccine.

Varicella, or chickenpox, is a highly contagious and potentially serious vaccine preventable disease that was once a common illness in young children. Use of the vaccine to prevent varicella has significantly reduced the incidence of this disease in recent years. Children attending school in NY must be protected against this disease, as it is easily transmitted in a school setting. In addition, if an individual reaches adolescence or adulthood without having been vaccinated, the occurrence of natural disease could have even more serious consequences. These regulations should be updated to conform to updated standards and to establish vaccination schedules.

Amendment of Section 69-1.2 (Newborn Screening-Testing for Phenylketonuria & Other Diseases and Conditions)

Statutory Authority:

Public Health Law Section 2500-a

Description of the regulation:

The regulation designates diseases or conditions for the state's newborn screening panel, in accordance to the Department's mandate to prevent infant and child mortality, morbidity, and diseases and disorders of childhood, in keeping with the Legislature's public health aims of early identification and timely medical intervention for all the State's youngest citizens. New York State Public Health Law Section 2500-a authorizes the Commissioner of Health to designate additional diseases or conditions for inclusion in the Newborn Screening Program test panel by regulation. The most recent amendment, effective October 19, 2016, modified the newborn screening panel by adding adrenoleukodystrophy (ALD) and Pompe disease.

Amendments will be proposed that will reflect recent recommendations by the Department of Health and Human Services Advisory Committee on Heritable Disorders in Newborns and Children related to improving timeliness in newborn screening programs. Addition of other diseases or conditions may also be required in the future.

Amendments to Part 1000

Statutory Authority:

Public Health Law Section 2995-a

Description of the regulation:

The rule sets forth the requirements for collecting and presenting information on New York's licensed and registered physicians for purposes of the New York State Physician Profile. The regulation should be amended to update definitions and clarify and update requirements.

Title 10 NYCRR - Twenty Year Review

Amendment to Subpart 5-1 of Title 10 (Public Water Systems)

Statutory Authority:

Public Health Law Sections 201 and 225

Description of the regulation:

This regulation incorporated the federal EPA Phase V drinking water standards for certain organic and inorganic chemicals into the state sanitary code. To ensure compliance with federally mandated regulations, amendments to Subpart 5-1 were made to incorporate specific Maximum Contaminant Levels for six inorganic and eight organic contaminants in water, which is delivered to any user of a public water system. This regulation should continue without modification.

Amendment to Subparts 6-1 and 6-2 (Swimming Pools and Bathing Beaches)

Statutory Authority:

Public Health Law Sections 225(5) and 1340-1342

Description of the regulation:

The revisions to the regulations (1) clarify lifesaving equipment requirements; (2) provide flexibility in determining the number of toilet and handwashing facilities at swimming pools and bathing beaches and guidelines for determining the location of such facilities at bathing beaches; (3) accept ozone as a supplement to chlorine or bromine disinfection systems; and (4) require installation of a minimum of two main drains at pools and spas, which provides additional protection for bathers against suction entrapment and hair entanglement. The amendments should continue without modification.

Amendment to Section 35.8 (Form and Content of Certificates)

Statutory Authority:

Public Health Law Sections 4100(1)(c), 4132(1) and 4141(1).

Description of the regulation:

This regulation establishes a basis for the electronic preparation and filing of birth and death certificates. It supports the efforts of the Department of Health to electronically file vital records certificates. No changes in this regulation are required at this time.

Amendment to Subpart 58-2 (Blood Banks)

Statutory Authority:

Public Health Law Section 3121(5)

Description of the regulation:

Subpart 58-2 describe requirements for blood banks and laboratories performing immunoematology testing. The regulation establishes standards for the proper collection, processing, fractionation, storage, distribution and supply of human blood or blood products for use in transfusion. The most recent amendment, effective September 27, 2015, were necessitated by advances in medical technology and the need to codify practice standards and eliminate obsolete requirements, afford regulated parties with greater flexibility in complying with department regulations, clarify regulatory intent, and provide for safe transfusion of blood components during interfacility transport of patients.

Future amendments will likely be required to align the Department's rules with new federal requirements that may be established and to define requirements when new therapies and procedures that are established in the field.

Amendment to Part 71 (Requirements for Vent-Free Gas Space Heating Appliances)

Statutory Authority:

Public Health Law Section 206(1)(r).

Description of the regulation:

Public Health Law Section 206(1)(r) requires and authorizes DOH to promulgate regulations to implement Section 322-c(a)(ii) of the General Business Law. The stated purpose of this rule is to protect public health, safety and welfare by specifying requirements for vent-free gas space heating appliances offered for sale or sold in New York State. The requirements are intended: to caution customers about the proper installation, sizing, maintenance and use of vent-free gas space heaters through mandatory shipping carton labels; to provide consumers with information on the carbon monoxide and nitrogen dioxide emissions from these units; and to assist consumers with selecting appropriately sized units based on heat output.

The regulation should be amended to update requirements for appliance shipping carton labels, based on data and literature since the last regulation review.

Amendment of Section 77.7 (Registered Residents - Funeral Directing)

Statutory Authority:

Section 3401(1) of the Public Health Law authorizes the Commissioner of Health to adopt rules and regulations not inconsistent with law as may be necessary in the performance of his/her duties and in the administration of Article 34 (Funeral Directing) of the Public Health

Law and to govern and regulate the conduct and transaction of the business and practice of funeral directing, undertaking and embalming.

Section 3400(k) of the Public Health Law defines a "registered resident" in a manner consistent with the regulation.

Description of the regulation:

These amendments clarify the duties of registered residents in the practice of funeral directing and clarify the role of registered residents, funeral directors and undertakers regarding supervision of an interment or cremation. This clarification was necessary due to confusion among the funeral directing industry about what registered residents may do. By eliminating the confusion, the industry can better utilize this personnel resource and registered residents can find employment under appropriate supervision, for their mandated supervision period. Additionally, subparagraph (h) places specific limits on the residents regarding their interaction with client families and the public to ensure protection for the customer and eliminate the possibility of consumer confusion. Because the benefits of the regulatory amendment continue to be realized, continuance of the regulation is warranted with modification.

Amendment of Sections 80.1, 80.46, 80.64, 80.67, 80.69, 80.70, 80.73 and 80.75 (Physician's Assistants Controlled Substances)

Statutory Authority:

The authority for the promulgation of these regulations comes in Public Health Law, Sections 3701(1), (6) and 3308(2).

The definition of practitioner who is permitted to dispense, administer or conduct research with respect to a controlled substance in the course of a licensed professional practice or research license, including a physician assistant, is provided for in Section 3302(29) of the Public Health Law.

Description of the regulation:

The above regulation governs the prescribing, dispensing, and administration of controlled substances in a variety of circumstances by practitioners, including physician assistants. In 1998, the definitions of "authorized practitioner" and "practitioner" in 10 NYCRR Section 80.1(a) were amended to add physician assistants to the categories of licensed practitioners who can lawfully prescribe controlled substances in New York State. This regulation permits physician assistants to perform an activity for which they are well trained while providing the necessary regulatory safeguards for controlled substances required of all practitioners.

In 2006, section 80.46 was further amended to bring into conformity with an amendment to Public Health Law, Section 3703 (1). In this law a physician's assistant's written medical order for the administration of a controlled substance in a hospital setting is required to be

countersigned by his or her supervising physician only if deemed necessary by the supervising physician or the hospital.

In 2007, Public Health Law, Section 3703 (3) was amended to authorize physician assistants to prescribe controlled substances, including Schedule II, when acting in good faith and in the physician assistant's lawful scope of practice.

These regulations continue to appropriately govern the prescribing, dispensing and administration of controlled substances by physician assistants and reflect all the changes in this period of time. This regulation should continue without modification.

Amendment of 86-1.88 (Distribution of Regional Professional Education Pools)

Statutory Authority:

Public Health Law Section 2807-m

Description of the regulation:

Clarifies the definitions and data collection time frames for making distributions from the Regional Professional Education Pool to teaching general hospitals. This regulation was repealed as part of the inpatient reimbursement reform regulatory package.

Amendment to 86-1.89 (Supplemental Distribution of Regional Professional Education Pools)

Statutory Authority:

Public Health Law Section 2807-m(5)

Description of the regulation:

Describes the graduate medical education reform goals and methodology for receiving supplemental distributions from the Regional Professional Education Pool. This regulation was repealed as part of the inpatient reimbursement reform regulatory package.

Amendment to Part 128 (New York City Watershed)

Statutory Authority:

Public Health Law Section 1100

Description of the regulation:

These rules and regulation govern those activities in the New York City watershed that threaten the quality of the water supply of the numerous upstate communities and the City of New York.

They help insure compliance with the Federal and State drinking water standards by providing a comprehensive watershed protection program. The goal and intent of these rules and regulations to protect the public health by averting future contamination to and degradation of the water supply and by remediating existing sources of pollution or degradation of the New York City water supply.

This regulation is under review for potential amendment.

Amendment of Section 405.4, 405.5 and 405.10 (Hospital Medical Records)

Statutory Authority:

The authority for the promulgation of this regulation is contained in Section 2803(2) of the Public Health Law which authorizes the Public Health and Health Planning Council to adopt and amend rules and regulations, subject to the approval of the Commissioner, to implement the purposes and provisions of Article 28 of the Public Health Law, and to establish minimum standards governing the operation of health care facilities.

Description of the regulation:

These amendments are intended to establish criteria and safeguards for hospital usage of modern data communications technology and to update provisions for the acceptance of verbal orders. The amendments permit hospitals to use the most current electronic and computer technology for the transmission and storage of information. It includes safeguards for author identification/authentication and security and confidentiality of records. It also clarifies standards for the use of telephone orders. These are important advances in giving hospitals the flexibility to operate an effective and efficient medical records unit and continuance of these regulations is warranted. This regulation was updated to allow verbal orders to be authenticated by not only the ordering practitioner, but also by other practitioners responsible for the care of the patient within 48 hours rather than “as soon as possible” consistent with federal requirements that had a sunset date of January 26, 2012. The Centers for Medicare and Medicaid Services (CMS) permanently adopted their provisions.

These regulations were amended on May 17, 2017 to comply with CMS regulatory changes which permit more flexibility in the authentication of verbal orders. The recent amendment removed the requirement for co-signature of verbal orders within 48 hours, allowing the hospital, in their policy and procedures, to create a policy on authentication of such orders which defies the acceptable time frame. This is consistent with CMS regulatory changes

This regulation should continue without modification.

Amendment of Sections 405.8 and 405.11 (Infection Control Standards and Reporting)

Statutory Authority:

The authority for the promulgation of this regulation is contained in Sections 2803(2) and 2819 of the Public Health Law. PHL Section 2803 authorizes the Public Health and Health Planning Council to adopt and amend rules and regulations, subject to the approval of the Commissioner, to implement the purposes and provisions of Article 28 of the Public Health Law, and to establish minimum standards governing the operation of health care facilities. PHL Section 2819 sets forth the provision for hospital acquired infection reporting.

Description of the Regulation:

These amendments are intended to streamline reporting requirements for infection outbreaks and reorganize and update infection control standards focusing on outcome rather than processes. Unnecessary bureaucratic requirements have been eliminated so the regulations can focus on promotion of safe and effective infection control practices and appropriate reporting of untoward events.

These Department is considering amendments to these regulations to establish requirements for hospitals to report select hospital acquired infections.

Amendment of Sections 405.20, 670.4, 709.5, 711.4, 711.10, 715.16, 755.1 and 755.2 (Ambulatory Surgery)

Statutory Authority:

Public Health Law Sections 2801-a(10)(a) and 2803(2)(a).

Description of the regulation:

The regulation updated the need methodology for ambulatory surgery services and changes the definitions of hospital-based ambulatory surgery services and of extension clinics. These amendments promoted efficiency, accessibility and quality in the operation of Ambulatory Surgery Centers. The regulation should continue without modification.

Amendment of Paragraph 405.24(h) (Pet Therapy in Hospitals)

Statutory Authority:

The authority for the promulgation of this regulation is contained in Section 2803(2) of the Public Health Law which authorizes the Public Health and Health Planning Council to adopt and amend rules and regulations, subject to the approval of the Commissioner, to implement the purposes and provisions of Article 28 of the Public Health Law, and to establish minimum standards governing the operation of health care facilities.

Description of the regulation:

This amendment establishes the parameters under which hospitals may establish and operate organized animal visitation or animal-assisted therapy programs. Such programs have proven to be of medical benefit to some patients; especially patients undergoing rehabilitation.

The regulations ensure that such programs are safe and consider the well-being of patients affected both directly and indirectly as well as the animals. Department of Health staff who review patient complaints and perform routine hospital surveys have not identified any problems associated with this regulation and the continuance of this regulation is warranted. This regulation should continue without modification.

Amendment of Paragraph 405.24(i) (Sterility Assurance)

Statutory Authority:

The authority for the promulgation of this regulation is contained in Section 2803(2) of the Public Health Law which authorizes the Public Health and Health Planning Council to adopt and amend rules and regulations, subject to the approval of the Commissioner, to implement the purposes and provisions of Article 28 of the Public Health Law, and to establish minimum standards governing the operation of health care facilities.

Description of the regulation:

Under these regulations, hospitals are given the right to implement an alternative process of assuring the sterility of supplies and equipment known as "event related sterility assurance". Such process has been endorsed by the Association for the Advancement of Medical Instrumentation and the Joint Commission on the Accreditation of Healthcare Organizations as an effective way to ensure sterility of supplies and equipment. Since adoption of this amendment, Department of Health staff have not identified any problems related to the implementation of this process. Continuance of this regulation is warranted. This regulation should continue without modification.

Amendment of Section 415.37 and Repeal of 422 (Services for Residents with AIDS)

Statutory Authority:

Public Health Law Section 2803(2)(a)

Description of the regulation:

These regulations reflect the additional experience required of the health professionals to adequately care for residents with HIV/AIDS and the corresponding staffing levels for rendering such care. These regulations should continue without modification.

Amendment of Section 710.1 (Project Cost Thresholds for CON Administrative Review and Full Review)

Statutory Authority:

Public Health Law Sections 2802(2) and 2803(2)(a)

Description of the regulation:

The rule helped streamline and focus the CON process on project proposals that have a significant impact on how and where Article 28 providers deliver care. This rule was amended in 2010 and 2017 to further raise the project cost thresholds for administrative and full review. This regulation should continue without modification.

Amendment of Section 710.1 (Conversion of Article 28 Beds)

Statutory Authority:

Public Health Law Section 2803

Description of the regulation:

This regulation sought to reduce costs for providers by removing the requirement for CON review of bed conversions within certain categories of services for which the hospital is an approved provider. This regulation should continue without modification.

Amendment of Section 710.1 (CON Requirements for Article 28 Extension Clinics)

Statutory Authority:

Public Health Law Sections 2802(2) and 2803(2)(a)

Description of the regulation:

This regulation permits CON administrative review for extension clinics regardless of location relative to the main facility. The previous modification to the regulation removed a non-essential regulatory requirement applicable to extension clinics of hospitals and diagnostic and treatment centers. The regulation promotes efficiency in the operation of such clinics services without compromising service quality. This regulation should continue without modification.

Amendment of Parts 711, 712, 713, 714, 715 and 716 (Construction Regulations for Medical Facilities)

Statutory Authority:

Public Health Law Sections 2803(1) and (2803(2)

Description of the regulation:

The regulation updates referenced technical standards and allows providers greater flexibility in the design and construction of health care services. The regulations ensure that the initial construction of new medical facilities as well as their subsequent repair, maintenance, refurbishing and modernization conform to the latest architectural and engineering standards for the structure, dimensions and physical appointments of medical facility buildings. These several Parts were amended in 2010 to reflect updates of their referenced technical standards and changes in prevailing industry practices in health care facility design and construction. These regulations should be amended to reflect updated standards.

Amendment of Subdivision 800.20(c) (EMS Curricula Approval/Course Standards)

Statutory Authority:

The authority for promulgation of this regulation is contained in Section 3002(2) of the Public Health Law which authorizes the New York State Emergency Medical Services Council (SEMSCO), subject to approval by the Commissioner, to enact, amend and repeal rules and regulations establishing minimum standards for the training, examination and certification of prehospital care personnel.

Description of the regulation:

The regulations contained in Subdivision 800.20 establish the criteria for approval by the Department of EMS Course Sponsors (training academies) and standards by which Course Sponsors must provide prehospital education in New York State. This section also establishes the minimum standards for prehospital curricula for each level of prehospital certification. The regulations also describe EMS Course Sponsor responsibilities and standard operating procedures.

Proposed amendments to these regulations are under consideration to address the current environment and technology as well as reflect the current EMS education curricula. The surveillance portions of these provisions need to be strengthened to appropriately address the issues of quality, student rights and safety. This regulation should be continued without modification.

Title 18 NYCRR - Twenty Year Review

Amendment of Section 505.2 (Gender Reassignment)

Statutory Authority:

This is consistent with the Legislature's objective of providing high-quality medical assistance services to recipients under the Medicaid program. The Department has the responsibility of allocating available resources and assuring that services available are safe and effective. These treatments have not been proven to be safe and effective over the long term, and therefore have been eliminated from the list of covered services under the Medicaid program.

Description of the regulation:

The purpose of this regulation is to exclude payment for care, services, drugs or supplies rendered for the purpose of gender reassignment (also known as transsexual surgery) or any care, services drugs, or supplies intended to promote such treatment.

This regulation should continue without modification.

Amendment of Section 505.10 (Medicaid Transportation)

Statutory Authority:

Social Services Law Section 363 and Chapter 474 of the Laws of 1996

Description of the regulation:

The regulation clarified the ordering of Medicaid transportation services. The list of qualified orderers was expanded, as well as offering guidelines for the appropriate ordering of various modes of transportation. The change stated that the ordering practitioner should keep a record of the justification for the order, and that ordering practitioners may be subjected to monetary claims and/or program sanctions. The regulation clarified the Department's ability to establish reimbursement amounts for transportation services. The regulation listed the documentation needed in order for ambulette services to receive payment. These clarified Department policy, enabling providers and orderers to adhere to Medicaid rules.

This regulation should be updated to conform to amendments to Section 365-h of the Social Services Law (SSL). Additionally, the update should include emergency medical services guidelines and new quality standards expected of Medicaid transportation providers.

Amendment of Section 505.18 (Medicaid Billing for Certified School Counselors)

Statutory Authority:

Social Services Law Section 368-d

Description of the regulation:

The Department is developing amendments to this regulation. Certified School Counselors are no longer considered Medicaid qualified providers. The only Medicaid qualified providers for psychological counseling for disabled children with an Individualized Education Program (IEP) are psychiatrists, psychologists, and licensed clinical social workers (LCSWs). Licensed master social workers (LMSWs) may also provide psychological counseling services when services are provided under the supervision of one of either a psychiatrist, psychologist, or a LCSW.