

RULE REVIEW

Department of Health

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

Addition of Part 4 to Title 10
(Protection Against Legionella)

Statutory Authority:

Public Health Law Section 225(5)(a)

Description of the regulation:

The addition of Part 4 includes two subparts. Subpart 4-1 established requirements for cooling towers related to their registration, record-keeping, Legionella culture testing, disinfection, maintenance, inspection, and certification. Subpart 4-2 established requirements for maintenance, monitoring, recordkeeping, and disinfection/control measures, as needed, of potable water systems in general hospitals and residential health care facilities under the statutory authority of Article 28 Section 3401 of Public Health Law.

The regulation should be amended. Following three years of implementation, the Department identified the need for several technical amendments for both subparts to revise and clarify provisions. The amendments will improve implementation of and compliance with elements of Part 4.

Amendment of Subpart 7-2 of Title 10
(Children's Camps)

Statutory Authority:

Public Health Law Section 225

Description of the regulation:

The amendments to Subpart 7-2 implemented Chapter 501 of the Laws of 2012, which established the NYS Justice Center for the Protection of People with Special Needs (Justice Center) to strengthen and standardize the safety net for vulnerable people that receive care from New York's Human Services Agencies and Programs. The regulation provides provisions for staff hiring, training, and incident management at children's camps for children with developmental disabilities. Additionally, some health and safety protections that were limited to qualifying camps for children with developmental disabilities were extended to any camp enrolling a child with a developmental or other disability. The regulation should continue without modification.

Amendment of Section 16.25 and Addition of Section 16.59 of Title 10

(Computed Tomography (CT) Quality Assurance)

Statutory Authority:

Public Health Law Section 225

Description of the regulation:

Section 16.25(a) was amended to include the criteria for a medical misadministration involving computed tomography equipment. Section 16.59 contains requirements for use of computed tomography equipment (for medical diagnostic use). The regulation should continue without modification.

Amendment of Sections 22.3 and 22.9 of Title 10

(Supplementary Reports of Certain Birth Defects for Epidemiological Surveillance; Filing)

Statutory Authority:

Public Health Law Sections 206(1)(d), 225(5)(t) and 2733

Description of the regulation:

The amendment to Section 22.3 of Title 10 expanded birth defect reporting requirements to physicians, nurse midwives, and other practitioners authorized to diagnose birth defects. The amendment to Section 22.9 of Title 10 clarified that birth defect reports shall be filed with the Bureau of Environmental and Occupational Epidemiology. The regulation should continue without modification.

Amendment of Part 23 of Title 10

(Sexually Transmitted Diseases (STDs))

Statutory Authority:

Public Health Law Sections 225(4), 2304, 2311 and 2312

Description of the regulation:

This regulation allows New York counties to bill a third party for the Article 23-covered sexually transmitted disease (STD) services. Counties must seek third party coverage or indemnification if the patient provides evidence of insurance coverage, but patients can always receive diagnosis and treatment as specified in 10 NYCRR Part 23 even if they do not provide such evidence. The regulation should continue without modification.

Addition of Section 40-2.24 to Title 10

(Zika Action Plan; Performance Standards)

Statutory Authority:

Public Health Law Sections 602, 603 and 619

Description of the regulation:

The Department will consider amending the regulations to transfer Zika-related requirements to 10 NYCRR Part 44, which addresses eligibility for state aid reimbursement for approved vector surveillance and control programs.

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 specifies dose- and grade-level school immunization requirements and Immunization Information System reporting requirements as authorized by Public Health Law Sections

2164 and 2168. The regulations were amended in 2014 and again in 2016 to comply with current national immunization recommendations and medical and public health knowledge.

The regulations should be regularly updated to reflect changes in Advisory Committee on Immunization Practices (ACIP) recommendations and schedules. The ACIP meets three times a year to vote on updated immunization recommendations, and issues updated immunization schedules annually.

Amendment of Section 69-1.2 of Title 10
(New York State Newborn Screening Panel)

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. Section 69-1.2 lists the diseases and conditions to be tested.

The Department's Newborn Screening Program continues to perform testing on newborns and continually updates the panel of tests that are performed. The regulation was recently amended to 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. As such, the regulation should continue without modification.

Amendment of Part 75 and Addition of Appendix 75-C of Title 10
(Standards for Individual Onsite Water Supply and Individual Onsite Wastewater Treatment Systems)

Statutory Authority:
Public Health Law Section 201(1)(l)
Description of the regulation:

The amendment updated certain terms to conform with nationally-recognized nomenclature; clarified the standards and requirements for individual onsite wastewater treatment systems; established provisions requiring that onsite wastewater treatment systems plans be prepared by a design professional; and included new minimum water quality standards for individual onsite water supply systems. The regulation should continue without modification.

Amendment of Part 89 of Title 10
(Practice of Radiologic Technology)

Statutory Authority:
Public Health Law Sections 3504, 3507(2) and 3507(7), 3510(1)(g)
Description of the regulation:

The amendment of Part 89 included the following: authorization of dental assistants, (exempt persons Section 89.30) with specific training and under the direct supervision of a dentist, to use cone beam computed tomography equipment; the inclusion of manual air insufflation to the practice of radiologic technology (Section 89.2); and a revision to the continuing education requirements for radiologic technologists (Section 89.20) to allow the 48 credits to be obtained at any time during the four year registration period to replace the previous requirement of 12 credits per year. The regulation should continue without modification.

Amendment of Sections 80.136 and 800.5 of Title 10
(Controlled Substances for EMS Agency Agent and Requirements for an Advanced Life Support System)

Statutory Authority:
Public Health Law Sections 3002, 3011(4), 3308 and 3390
Description of the regulation:
Section 80.136 amended requirements for the maintenance and

administration of controlled substances used by all Advanced Life Support agencies in order to make them consistent with Section 800.5 that deals with individuals with previous criminal convictions or offenses. This regulation added the requirement that ALS agents providing care must be licensed to obtain and administer controlled substances per state protocols. This provides accountability and ensures safeguarding the handling of controlled substances to patients as they are transported to hospitals. The regulation should continue without modification.

Amendment of Subpart 86-2 of Title 10
(Neurodegenerative Specialty Rates)

Statutory Authority:
Public Health Law Section 2808-2(c)
Description of the regulation:

This regulation pertains to specialized programs for the Centers of Excellence providing care specifically to patients diagnosed with Huntington's disease (HD) and Amyotrophic Lateral Sclerosis (ALS). Facilities which have been approved to operate discrete units specifically designated for the purpose of providing specialized programs for HD and ALS residents as established pursuant to section 415.41 of this Title shall have separate and distinct payment rates. The regulation should continue without modification.

Addition of Subpart 86-13 to Title 10

(Rationalization – Prevocational Services (Site-Based and Community-Based), Respite (Hourly and Free-standing), Supported Employment and Residential Habilitation (Family Care))

Statutory Authority:
Public Health Law Section 201

Description of the regulation:
Rate Methodology for Prevocational Services (Site-Based and Community-Based), Respite (Hourly and Free-standing), Supported Employment and Residential Habilitation (Family Care)). The regulation should continue without modification.

Addition of Part 300 to Title 10
(Statewide Health Information Network for New York (SHIN-NY))

Statutory Authority:
Public Health Law Sections 201, 206(1) and (18-a)(d), 2800, 2803, 2816, 3600, 3612, 4000, 4010, 4400, 4403, 4700 and 4712

Description of the regulation:
These regulations relate to the Statewide Health Information Network for New York (SHIN-NY), and specifically the Qualified Entities (also known as regional health information organizations or RHIOS). The regulations establish a statewide collaboration process to develop SHIN-NY policy guidance. The regulation should continue without modification.

Addition of Section 405.33 to Title 10
(Extended Mammography Hours for General Hospitals and Hospital Extension Clinics)

Statutory Authority:
Public Health Law Sections 2800 and 2803

Description of the regulation:
This amendment requires hospitals and their extension sites that provide mammography services to extend their hours, at least 4 hours per week on at least 2 days per week. The goal of the regulation to provide women with better access to mammography services, before and after work hours and during the weekend. The provisions allow the Department to grant a waiver should compliance with this requirement be unlikely or impossible to meet. The regulation should continue without modification.

Addition of Section 415.41 to Title 10
(Specialized Programs for Residents with Neurodegenerative Diseases)

Statutory Authority:
Public Health Law Section 2803(2)
Description of the regulation:
Provides for a discrete unit with a planned array of services, staff-

ing, equipment and physical facilities designed to serve individuals with Neurodegenerative Diseases. The program shall provide goal-directed, comprehensive and interdisciplinary services directed at attaining or maintaining the individual at his or her highest practicable level of physical, affective, behavioral, psychosocial and cognitive functioning. The regulation should continue without modification.

Amendment of Sections 700.2 and 717.3, Part 793 and Part 794 of Title 10

(Hospice Operational Rules)

Statutory Authority:

Public Health Law Section 4010(4)

Description of the regulation:

Chapter 471 also amended PHL §§ 2899(6) and 2899-a(9) to add hospices to the definition of provider types required to conduct criminal history record checks (CHRCs) on employees hired on or after April 1, 2018, which will allow such employees to be added to the Home Care Services Worker Registry. This regulation should continue without modification.

Title 18 NYCRR - Three Year Review

Amendment of Parts 487 and 488 of Title 18

(Standards for Adult Homes and Adult Care Facilities Standards for Enriched Housing)

Statutory Authority:

Part 487 – Social Services Law, Sections 20, 34, 131-o, 460 460-a, 460-g, 461, 461-a and 461-h and Part 488 - Sections 20(3)(d), 34(3)(f), 131-o, 460 and 461

Description of the regulation:

Regulation amendments addressed New York State Justice Center for the Protection of People with Special Needs (Justice Center) requirements. Specifically, the amendments:

- Added definitions to support Justice Center requirements;
- Added occurrences which would constitute a reportable incident;
- Clarify a facility's obligations regarding what incidents must be investigated and by whom;
- Removed outdated references to the State Commission on Quality of Care for the Mentally Disabled;
- Addressed when reports must be made to the Justice Center;
- Added a requirement for staff training in the identification of reportable incidents and facility reporting requirements; and
- Clarify responsibilities related to consulting the Staff Exclusion List

The regulation should continue without modification.

Amendment of Sections 505.14 and 505.28 of Title 18

(Immediate Needs for Personal Care Services and Consumer Directed Personal Assistance)

Statutory Authority:

Social Services Law Sections 363-a(2), 365-a(2)(e), 365-f

Description of the regulation:

The regulations expedite Medicaid eligibility determinations for Medicaid applicants with immediate needs for Personal Care Services (PCS) or Consumer Directed Personal Assistance (CDPA) and, for those Medicaid applicants with immediate needs for either service who are determined eligible for Medicaid, require the provision of PCS and CDPA, as appropriate, pending the individuals' enrollment in a managed care provider or MLTC plan. The regulation should continue without modification.

Title 10 NYCRR - Five Year Review

Amendment of Section 1.31 of Title 10

(Disclosure of Confidential Cancer Information)

Statutory Authority:

Public Health Law Sections 225(4) and 2402

Description of the regulation:

This regulation provides for confidentiality of reports of cancer made pursuant to Public Health Law § 2401 and also provides for

disclosure of such reports to effectuate the purposes of Public Health Law Article 24. The regulation should continue without modification.

Amendment of Section 2.59 of Title 10

(Prevention of Influenza Transmission by Healthcare and Residential Facility and Agency Personnel)

Statutory Authority:

Public Health Law Sections 225, 2800, 2803, 3612 and 4010

Description of the regulation:

This amendment requires staff of Department of Health licensed facilities to annually receive immunization against influenza. Those staff that do not receive an immunization against influenza must wear a surgical mask when present in areas where patients are present. The facility must also report numbers of immunized and unimmunized staff to the Department upon request.

The NYSDOH Prevention of Influenza Transmission by Healthcare and Residential Facility and Agency Personnel regulation became effective on 11/19/2014. The regulation requires that during the influenza season (the period of time during which influenza is prevalent as determined by the Commissioner), all healthcare and residential facilities and agencies regulated under Articles 28, 36, and 40 of public health law shall ensure that all personnel not vaccinated against influenza for the current influenza season wear a surgical or procedure mask while in areas where patients or residents are typically present except under certain circumstances outlined in the regulation. Covered healthcare facilities, residential facilities, and agencies also must report the number and percentage of personnel that have been vaccinated against influenza for the current influenza season.

The regulation should continue without modification.

Amendment of Section 12.3 of Title 10

(Administration of Vitamin K to Newborn Infants)

Statutory Authority:

Public Health Law Sections 225

Description of the regulation:

The amendment expanded the time window for the administration of vitamin K to newborn infants to within six hours of birth. This time frame remains consistent with the most recent 2012 American Academy of Pediatrics Policy Statement. Expanding the time frame for administration of vitamin K continues to promote and support early initiation and exclusive breastfeeding during the birth hospitalization. The regulation should continue without modification. The regulation should continue without modification.

Repeal of Parts 39 and 40 and Addition of Part 40 of Title 10

(State Aid for Public Health Services: Counties and Cities)

Statutory Authority:

Public Health Law Sections 201, 602, 603, 619, 2201, 2202, and 2276

Description of the regulation:

Title 10 NYCRR Subpart 39 "General Provisions Regarding the Payment of State Aid" was repealed in its entirety. To be consistent and in conjunction with amendments contained in the 2013-14 enacted State Budget which became effective on April 1, 2013, all of the relevant provisions of Part 39 have been incorporated into the amended 10 NYCRR Subpart 40-1.

Title 10 NYCRR Subpart 40-1 "State Aid for Public Health Services: Counties and Cities" was amended in its entirety to comply and maintain consistency with the Public Health Law Article 6 statute changes enacted as part of the 2013 New York State Budget. With the inclusion of the relevant provisions of the repealed 10 NYCRR Subpart 39, this subpart describes a clear and concise description of the administrative processes involved in the State Aid Application and how the local health departments will apply and be reimbursed for State Aid.

Title 10 NYCRR Subpart 40-2 "Performance Standards for Basic Public Health Services and Minimum Requirements of Municipal Public Health Services Plans" was amended in its entirety to comply and maintain consistency with Public Health Law Article 6 statute changes enacted as part of the 2013 New York State Budget. This

subpart was simplified and modernized. References to the Municipal Public Health Services Plan and the Fee and Revenue Plan were eliminated. This subpart describes the performance standards and requirements for core public health services provided by the local health departments to reflect current best practices and minimum program requirements for State Aid reimbursement.

In general, this regulation should continue without modification. It was developed jointly with considerable input from the New York State Association of County Officials and pertinent State programs to maintain consistency with the statute changes in Public Health Law Article 6. Specific sections may be updated as needed.

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 specifies dose- and grade-level school immunization requirements and Immunization Information System reporting requirements as authorized by Public Health Law Sections 2164 and 2168. The regulations were amended in 2014 and again in 2016 to comply with current national immunization recommendations and medical and public health knowledge.

The regulations should be regularly updated to reflect changes in Advisory Committee on Immunization Practices (ACIP) recommendations and schedules. The ACIP meets three times a year to vote on updated immunization recommendations, and issues updated immunization schedules annually.

Addition of Subpart 69-10 to Part 69 of Title 10
(NYS Medical Indemnity Fund)

Statutory Authority:

Public Health Law Section 2999-j

Description of the regulation: These regulations govern the Medical Indemnity Fund administration, including enrollment of qualified plaintiffs, definitions of qualified health care costs, and payments from the fund. The regulation should continue without modification.

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

Statutory Authority:

Public Health Law Sections 3309

Description of the regulation:

The regulation achieves the following: 1) expanded provider eligibility so as to include institutions of higher education; business, trade, technical and occupational schools; and a wider range of local government agencies than was previously permitted; 2) elimination of an unnecessary recordkeeping requirement; 3) a clear definition of "affiliated prescribers"; and 4) an improved framing of training within the context of the regulated programs. The regulation should continue without modification.

Addition of Subpart 83-2 to Title 10
(Certificate of Public Advantage)

Statutory Authority:

Public Health Law Section 2999-bb

Description of the regulation:

Public Health Law (PHL) Article 29-F sets forth the State's policy of encouraging appropriate collaborative arrangements among health care providers who might otherwise be competitors. The statute requires the New York State Department of Health (Department) to establish a regulatory structure allowing it to engage in appropriate state supervision as necessary to promote state action immunity under state and federal antitrust laws. The regulations establish a process for providers to apply for a Certificate of Public Advantage (COPA) for their collaborative arrangements such as mergers and clinical integration agreements. The regulation should continue without modification.

Amendment of Subpart 86-1 of Title 10

(Service Intensity Weights (SIWs) and Average Length-of-Stay (ALOS), Administrative Appeals and Out-of-State Providers)

Statutory Authority:

Public Health Law Section 2807-c(35)(c)

Description of the regulation:

These regulations will be updated with the rebasing of hospital inpatient rates.

Amendment of Section 86-1.16(c) of Subpart 86-1 of Title 10
(Reduction to Statewide Base Price)

Statutory Authority:

Public Health Law Section 2807-c(35)

Description of the regulation:

This regulation will be updated with the rebasing of hospital inpatient rates.

Amendment of Section 86-1.44 of Subpart 86-1 of Title 10
(Episodic Pricing for Certified Home Health Agencies)

Statutory Authority:

Public Health Law Section 3614(13)

Description of the regulation:

Effective for services provided on and after May 2, 2012, Medicaid payments for certified home health care agencies ("CHHA"), except for such services provided to children under eighteen years of age and except for services provided to a special needs population of medically complex and fragile children, adolescents and young disabled adults by a CHHA operating under a pilot program approved by the Department, shall be based on payment amounts calculated for 60-day episodes of care.

The regulation should be modified to remove March 31, 2019 as the end of the effective period, and this program should not sunset.

Addition of Section 86-1.46 to Title 10

(Empire Clinical Research Investigator Program (ECRIP))

Statutory Authority:

Public Health Law Section 2807-m

Description of the regulation:

The Empire Clinical Research Investigator Program (ECRIP), as set forth in Public Health Law § 2807-m, provides funding to eligible teaching hospitals for the purpose of training physicians in clinical research and to supporting projects that advance biomedical research in New York State. Regulations at 10 NYCRR § 86-1.46 set forth various provisions related to the distribution methodology for awards and other provisions governing the program.

Technical proposed changes are being drafted to amend 10 NYCRR § 86-1.46 to: (1) include other federal research grants and Patient-Centered Outcomes Research Institute (PCORI) grants as qualifying grants for Center Awards, in addition to NIH grants; (2) amend the time period for qualifying grants from one year to two years for Center Awards; (3) eliminate the provision that fellows to be funded under the proposed project may not have been previously funded by the teaching hospital within the past three years; and (4) eliminate Individual Awards.

Addition of Section 86-1.47 to Title 10

(Hospital Indigent Care Pool Payment Methodology)

Statutory Authority:

Public Health Law Section 2807-k(5-d)

Description of the regulation:

Regulation 86-1.47 is effective for the period January 1, 2019 through December 31, 2019.

Regulation 86-1.47 cites New York State's statutory authority to administer the Disproportionate Share Hospital (DSH) Program and the methodology for calculating annual Indigent Care Pool payments to New York's Article 28 hospitals. The DSH program reimburses hospitals that serve an unequal number of low-income Medicaid and uninsured patients with special needs. To be eligible for DSH, the Federal government requires an inpatient utilization rate for each hospital to be greater than 1%.

Because federal financial participation is available for aggregate ICP payments paid to the hospitals, the federal office of the Center for

Medicare and Medicaid Services (CMS) requires an approved State Plan Amendment (SPA) that defines the methodology for calculating the rate of ICP distributions to New York State hospitals. Procedures for the State's DSH process are then approved by CMS through the SPA.

Specific limits for the total DSH payments for both the State and the individual hospitals are contained in the legislation (Section 1923 of the Social Security Act and 42 USC 1396(r)). The statutory authority to make DSH payments pursuant to subdivision 5-d of section 2807-k of New York State's Public Health Law are made in accordance with this section. For purposes within section 2807-k(S-d), each hospital's relative uncompensated care need amount shall be determined in accordance with regulation 86-1.47.

The regulation should continue without modification.

Addition of New Section 86-2.40 to Subpart 86-2 of Title 10
(Statewide Pricing Methodology for Nursing Homes)

Statutory Authority:

Public Health Law Section 2808(2-c)

Description of the regulation:

The statewide Pricing methodology for nursing homes is the basis for which the nursing home FFS Medicaid reimbursement rates are calculated. The regulation should continue without modification.

Amendment of Section 86-4.16 of Title 10

(Capital Projects for Federally Qualified Health Centers (FQHCs))

Statutory Authority:

Public Health Law Section 2807-z(9)

Description of the regulation:

Establishes a payment methodology to reimburse federally qualified health centers (FQHCs) for the costs of capital projects with a total budget of less than \$3 Million exempt from certificate of need (CON) requirements. The regulation should continue without modification.

Addition of Subpart 86-10 to Title 10

Rate Rationalization for Community Residences (CRs) / Individualized Residential Alternatives (IRAs) Habilitation and Day Habilitation

Statutory Authority:

Social Services Law Section 363-a and Public Health Law Section 201(1)(v)

Description of the regulation:

Rate Methodology for Community Residences (CRs) / Individualized Residential Alternatives (IRAs) Habilitation and Day Habilitation. The regulation should continue without modification.

Addition of Subpart 86-11 to Title 10

Rate Rationalization for Intermediate Care Facilities for Persons with Developmental Disabilities (ICF/DDs)

Statutory Authority:

Social Services Law Section 363-a and Public Health Law Section 201(1)(v)

Description of the regulation:

Rate Methodology for Intermediate Care Facilities for Persons with Developmental Disabilities (ICF/DDs). Amend the regulation to add CRP Fees and Active Treatment. If no, please provide a brief description.

Amendment of Section 400.18 of Title 10

(Statewide Planning and Research Cooperative System (SPARCS))

Statutory Authority:

Public Health Law Section 2816

Description of the regulation:

This regulation provides for the reporting, maintenance, and disclosure of data in the Statewide Planning and Research Cooperative System (SPARCS), a data system containing health care claims of Public Health Law Article 28 health care facilities. The regulation was amended on January 30, 2019, and as amended should continue without modification.

Amendment of Section 400.21 and Repeal of Sections 405.43 and 700.5 of Title 10

(Advance Directives)

Statutory Authority:

Public Health Law Sections 2803, 2993 and 2994-t

Description of the regulation:

This regulation was adopted to update section 400.21 to reflect changes brought about by the Family Health Care Decisions act. Part 400 applies to multiple settings, allowing a repeal of 405.43 and 700.5. The regulation should continue without modification.

Amendment of Section 405.4 of Title 10

(Definition of Pediatric Severe Sepsis Update)

Statutory Authority:

Public Health Law Sections 2800 and 2803

Description of the regulation:

This amendment established the need for a hospital's medical staff to adopt and implement evidence based protocols for the identification and treatment of sepsis in adults and children. In addition, this section requires a hospital to annually report certain measures to the Department related to sepsis identification and treatment.

It should be noted that the Office of Patient Safety and Quality is undertaking a regulatory change that will affect this section. The regulation should continue without modification.

Amendment of Section 405.13, Repeal of Section 405.22 and Addition of new Sections 405.30 and 405.31 of Title 10

(Organ Transplant Provisions)

Statutory Authority:

Public Health Law Sections 2800 and 2803

Description of the regulation:

This amendment repeals provisions related to organ transplantation services out of Section 405.22 and creates two new sections dealing with organ transplant services/programs and living donor transplantation services. This change allowed program to clarify and expand requirements related to transplantation services. The regulation should continue without modification.

Amendment of Part 425 of Title 10

(Adult Day Health Care Programs and Managed Long Term Care)

Statutory Authority:

Public Health Law Sections 201(1)(v) and 2803(2) and Social Services Law Section 263-a

Description of the regulation:

10 NYCRR 425.1 through 425.23 set forth regulatory requirements for ADHCPs related to non-residential, medically supervised services for individuals with physical or mental impairment.

ADHCP services include nursing, transportation, leisure activities, physical therapy, speech pathology, nutrition assessment, occupational therapy, medical social services, psychosocial assessment, rehabilitation and socialization, nursing evaluation and treatment, coordination of referrals for outpatient health, and dental services.

The regulations should be amended to align with federal requirements of participation for Medicaid reimbursement.

Addition of Part 1003 and Amendment of Subpart 98-1 of Title 10

(Accountable Care Organizations)

Statutory Authority:

Public Health Law Article 29-E and Section 4403(2)

Description of the regulation:

Public Health Law (PHL) Article 29-E requires the Department of Health (Department) to establish a program governing the approval of Accountable Care Organizations. PHL § 2999-p defines an Accountable Care Organization (ACO) as "an organization of clinically integrated health care providers that work together to provide, manage, and coordinate health care (including primary care) for a defined population; with a mechanism for shared governance; the ability to negotiate, receive, and distribute payments; and accountability for the quality, cost, and delivery of health care to the ACO's patients" and

that has been issued a certificate of authority by the Department. The regulation should continue without modification.

Title 18 NYCRR - Five Year Review

Amendment of Section 360-3.7 of Title 18

(Presumptive Eligibility for Family Planning Benefit Program)

Statutory Authority:

Social Services Law Section 363-a

Description of the regulation:

The regulation establishes criteria for presumptive eligibility for the Family Planning Benefit Program to expand access to family planning services by easing the application process. The regulation should continue without modification.

Repeal of Subparts 360-10, 360-11 and Sections 300.12 and 360-6.7 and Addition of a New Subpart 360-10 to Title 18

(Medicaid Managed Care Programs)

Statutory Authority:

Public Health Law Sections 201 and 206 and Social Services Law Sections 363-a, 364-j, and 369-ee

Description of the regulation:

Subpart 360-10 identifies the Medicaid populations required to enroll and those that are exempt or excluded from enrollment, defines good cause reasons for changing/disenrolling from an MCO, or changing primary care providers (PCPs), adds enrollee fair hearing rights, adds marketing/outreach and enrollment guidelines, and identifies unacceptable practices and the actions to be taken by the State when an MCO commits an unacceptable practice.

18 NYCRR 360-10 should be amended to be consistent with the provisions of 42 CFR 438.

Amendment of Sections 487.4 and 488.4 of Title 18 and Section 1001.7 of Title 10

(Assisted Living Residences and Adult Care Facilities)

Statutory Authority:

Social Services Law Section 461 and Public Health Law Section 4662

Description of the regulation:

Regulations found at 10NYCRR Part 1001.7 address admission and retention standards for individuals residing in an assisted living residence and the enhanced assisted living residence.

The regulation requires modification related to the admission and retention requirements and aligning with statutory requirements.

Amendment of Section 505.5 of Title 18

(Expand Medicaid Coverage of Enteral Formula)

Statutory Authority:

Social Services Law Sections 363-a and 365-a(2)(g) and Public Health Law Section 201(1)(v)

Description of the regulation:

This section defines coverage criteria for enteral nutritional formula in the Medicaid program. Enteral nutritional formula is covered benefit for the medical conditions identified in the regulation. The regulation should continue without modification.

Amendment of Section 505.31(h) of Title 18

(Hearing Aids)

Statutory Authority:

Social Services Law Sections 363-a and 365-a(2) and Public Health Law Section 201(1)(v) and 206

Description of the regulation:

This Section defines hearing aid equipment and audiology services reimbursement by describing methodology for determining payment for equipment and services under the Medicaid benefit. The regulation should continue without modification.

Title 10 NYCRR - Ten Year Review

Amendment of Subpart 7-1 and Addition of New Subpart 7-4 of Part 7 of Title 10 - Temporary Residences and Mass Gatherings

Statutory Authority:

Public Health Law Section 225(5)

Description of the regulation:

Amended Subpart 7-1 of Title 10 NYCRR to: relocate sections pertaining to mass gatherings to a newly created Subpart 7-4; repeal sections pertaining to campgrounds (text previously moved to Subpart 7-3); repeal sections applicable to special provisions of hotels and motels and other requirements for employers; delete section reserved for mobile home parks; repeal text applicable to temporary residences and replace with newly drafted text. The regulation should continue without modification.

Addition of New Section 16.112 to Part 16 of Title 10 - Fingerprinting and Criminal Background Check Requirements for Unescorted Access to Radioactive Materials)

Statutory Authority:

Public Health Law Sections 225(5)(p) and (q)

Description of the regulation:

The addition of Section 16.112 required fingerprinting of individuals who are allowed unescorted access to large quantities of radioactive material. This provision was necessary to be compliant with the requirements of the United States Nuclear Regulatory Commission.

The regulation should be amended to reflect changes to the US Nuclear Regulatory Commission requirements in 10 CFR 37, Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material, which includes a requirement for fingerprinting at 10-year intervals, and revisions to the requirements of the persons who approve unescorted access to large quantities of radioactive material.

Amendment of Part 53 of Title 10 - Drinking Water State Revolving Fund

Statutory Authority:

Public Health Law Sections 1161 and 1162

Description of the regulation:

This regulation outlined rules and procedures for the New York State Department of Health to provide financial assistance to public water systems through the New York State Drinking Water State Revolving Fund (DWSRF). The DWSRF was created by Chapter 413 of the Laws of 1996 of the State of New York. Amendments were enacted in 2009 to facilitate the use of additional Federal Capitalization Grant funds provided to the program through the American Recovery and Reinvestment Act. The regulation should continue without modification.

Amendment of subdivisions 59.1(c) & 59.4(b) of Title 10 - Chemical Analyses of Blood, Urine, Breath or Saliva for Alcohol Content

Statutory Authority:

NYS Vehicle and Traffic Law, Section 1194(4)(c) and Dept. of Environmental Conservation Law, Section 11-1205(6)

Description of the regulation:

This regulation established standards for the chemical analyses of blood, urine, breath and saliva for alcoholic content, instrument approval, and operator permits, to ensure law enforcement agencies have the appropriate tools and proficiency in their use for effective enforcement of DWI prosecution laws. Subdivision 59.1(c) clarified that chemical tests/analyses includes breath tests conducted on breath analysis instruments approved by the commissioner and 59.4(b) lists approved instruments found on the Conforming Products List of Evidential Breath Alcohol Measurement Devices as established by the U.S. Department of Transportation/National Highway Traffic Safety Administration (NHTSA).

The Department continues to issue operator permits to law enforcement agencies that use breath analysis instruments approved by NHTSA. The regulation should continue without modification.

Subdivision 59.4(b) currently references the Conforming Products List of Evidential Breath Alcohol Measurement Devices as established by the U.S. Department of Transportation/National Highway Traffic Safety Administration (NHTSA), published in the Federal Register on March 11, 2010. This subdivision needs to be amended to reflect the most current List of Evidential Breath Alcohol Measurement Devices published in the Federal Register on November 2, 2017.

Amendment of Subparts 67-1 and 67-3 of Part 67 of Title 10 - Childhood Lead Poisoning Screening and Follow-up

Statutory Authority:

Public Health Law Section 206

Description of the regulation:

Subpart 67-1 was amended to lower the blood lead level threshold for requiring comprehensive case management services and environmental interventions from 20 micrograms per deciliter (mcg/dL) to 15 mcg/dL. Subpart 67-3 was amended to authorize the use of waived blood testing equipment by physician office laboratories and limited service laboratories, with reporting requirements to the Department. The regulations should continue without modification.

Addition of New Subpart 72-1 to Title 10 - Tanning Facilities

Statutory Authority:

Public Health Law Section 3551 and 3554

Description of the regulation:

The regulations established permit requirements, fees and standards for the safe and sanitary operation of ultraviolet (UV) tanning facilities.

These regulations should be amended. Governor Cuomo signed legislation on August 16, 2018 amending Public Health Law Article 35-A, to prohibit the use of commercial ultraviolet indoor tanning devices by minors, and modified the definition of Tanning Facility to include establishments that do not charge a direct or indirect fee for tanning services. Subpart 72-1 must be modified to conform with the amendment to Public Health Law.

Amendment of Sections 80.2, 80.23, 80.67, 80.68, 80.69, 80.71, 80.73, 80.74, 80.132 and 80.134 of Part 80 of Title 10 - Controlled Substances Data Submissions

Statutory Authority:

Public Health Law Section 3308(2), 3333, 3343-a, 3371

Description of the regulation:

These regulations govern and control possession, prescribing, manufacturing, dispensing, distribution and reporting of controlled substances and needles and syringes within New York State. The regulation should continue without modification.

Amendment of Section 86-1.62 of Title 10 - Service Intensity Weights (SIWs) and Average Lengths of Stay

Statutory Authority:

Public Health Law Section 2807-c(3)

Description of the regulation:

Section 86-1.62 was repealed. Section 86-1.18 is still valid. Service intensity weights (SIW) and average lengths of stay (LOS) are integral components of the current DRG based inpatient Medicaid rate-setting methodology. This regulation should therefore be retained.

Amendment of Section 86-4.9 of Subpart 86-4 of Title 10 - Payment for FQHC Psychotherapy and Off-site Services (previously known as Payment for Psychiatric Social Work Services in Article 28 FQHCs)

Statutory Authority:

Public Health Law Section 201.1(v)

Description of the regulation:

Medicaid reimbursement for psychotherapy and off-site services provided by federally qualified health centers (FQHCs) continues to be required under federal Medicaid statutes. Accordingly, this regulation should be retained.

Amendment of Part 89 of Title 10 - Practice of Radiologic Technology

Statutory Authority:

Public Health Law Section 3504

Description of the regulation:

The amendments updated educational, licensing and certification requirements for persons engaged in the practice of radiologic technology as well as standards for educational programs in radiologic technology. The regulation should continue without modification.

Amendment of Section 400.12 of Title 10 - PASRR SCREEN Requirements

Statutory Authority:

Public Health Law Section 2803(2)

Description of the regulation:

This measure updated Pre-Admission Screen and Resident Review (PASRR) provisions. The SCREEN is used to determine a person's potential to be appropriately cared for in a setting other than a Residential Health Care Facility (RHCF). It is also used to assess persons being recommended for RHCF placement for possible mental illness and/or mental retardation or developmental disabilities. The regulation should continue without modification.

Addition of new Part 402 to Title 10 - Criminal History Record Check

Statutory Authority:

Public Health Law Section 2899-a(4) and Executive Law Section 845-b(12)

Description of the regulation:

These regulations are required by Chapter 769 of the Laws of 2005, as amended by Chapters 331 and 673 of the Laws of 2006, as amended by Chapters 60 and 94 of the Laws of 2014, as amended by Chapter 471 of the Laws of 2016 and Chapter 206 of the Laws of 2017, as amended by Chapter 57 of the Laws of 2018. The regulations required prospective unlicensed employees of nursing homes, certified home health agencies, licensed home care services agencies, long term home health care programs, adult care facilities and hospice programs that will provide direct care or supervision to patients, residents or clients of such providers to undergo a criminal history record check. The regulations established standards and procedures for the criminal history record checks required by statute.

The regulations should continue with modification. Update Criminal History Record Check regulations to conform to recently enacted changes to the Public Health Law. The regulations, which currently cover certain prospective employees, as set forth above, will now include definitions and requirements for certain Health Home care managers and children's Home and Community Based Services (HCBS) providers across New York.

The regulation is being modified to include adult care facilities and advanced home health aides as entities requiring CHRC checks, consistent with recent statutory changes.

Amendment of Sections 405.19, 405.22 and Addition of new Section 405.29 of Title 10 - Emergency and Cardiac Services

Statutory Authority:

Public Health Law Sections 2800 and 2803

Description of the regulation:

These provisions created Section 405.29 specific to cardiac services and set forth requirements for the direction, staffing, structure and services, patient selection and minimum workload standards for cardiac surgery, diagnostic cardiac catheterization, percutaneous coronary intervention (PCI), and for cardiac electrophysiology (EP) programs.

The regulation should continue without modification. There are plans in the works to modify this particular regulation as a result of the RMI for cardiac surgery held earlier in 2018.

Amendment of Section 709.14 of Title 10 - Cardiac Services Need Methodology

Statutory Authority:

Public Health Law Sections 2800 and 2803

Description of the regulation:

These standards are used to evaluate certificate of need (CON) applications for cardiac catheterization laboratory center services and cardiac surgery center services. The regulation should continue without modification.

Amendment of Section 710.1 of Part 710 of Title 10 - Certificate of Need Process for Cardiac Services

Statutory Authority:

Public Health Law Section 2803(2)

Description of the regulation:

This regulation streamlined approvals of applications by approved

cardiac surgery programs and cardiac catheterization laboratory centers to expand capacity and/or add electrophysiology (EP). It also addressed in regulation for the first time the Certificate of Need (CON) reviews of cardiac EP services. The regulation should continue without modification.

Amendment of Section 710.1 of Part 710 of Title 10 - Initial Purchase of Magnetic Resonance Imagers (MRIs)

Statutory Authority:

Public Health Law Section 2802

Description of the regulation:

Proposals for acquisition of MRIs were eligible for administrative review provided that acquisitions of MRIs by a general hospital may be reviewed under the provisions for proposals requiring a limited review. The regulation should continue without modification.

Amendment of Section 710.1 of Part 710 of Title 10 - Non-clinical Projects

Statutory Authority:

Public Health Law Section 2802

Description of the regulation:

These provisions exempted those non-clinical projects from requiring a Certificate of Need that are subject to the provisions for proposals requiring a limited review. The regulation should continue without modification.

Amendment of Section 710.1 of Part 710 of Title 10 - Relocation of Extension Clinics

Statutory Authority:

Public Health Law Section 2802

Description of the regulation:

This regulation authorized administrative review for the operation or relocation of an extension clinic when such relocation is to a site outside the current services area of the extension clinic and did not entail an increase in scope of services or clinical capacity.

It also authorized for limited review the relocation of an extension clinic within the same service area, defined and (1) one or more postal zip code areas in each of which twenty-five (25) percent or more of the extension clinic's patients reside, or (2) the area within one mile of the current location of such extension clinic, which does not entail an increase in services or clinical capacity. The regulation should continue without modification.

Amendment to Section 901.9 of Title 10 - Notification & Submission Requirements for Continuing Care Retirement Communities

Statutory Authority:

Public Health Law Section 4602(2)(g)

Description of the regulation:

The amendment provided that requests made by Continuing Care Retirement Communities (CCRCs) for certain extensions of construction completion dates can be approved by the Commissioner of Health, in consultation with the Superintendent of the Division of Financial Services, and eliminated the requirement to obtain CCRC Council approval. This provision streamlined the process for such requests and assists CCRCs working within strict financing deadlines. The regulation should continue without modification.

Amendment of Section 1000.1 of Title 10 - Physician Board Certification Entities

Statutory Authority:

Public Health Law Section 2995(1)(b)

Description of the regulation:

Part 1000 of 10 NYCRR set forth the Physician Profiles provisions. Section 1000.1 contained the definitions for Part 1000 including the definition for Board Certification. This definition specified that Board Certification means a specialty or subspecialty in which a physician is certified by the American Board of Medical Specialties (ABMS), American Osteopathic Association (AOA), or Royal College of Physicians and Surgeons of Canada (RCPSC). The regulation should continue without modification.

Title 18 NYCRR - Ten Year Review

Amendment of Section 505.11 of Title 18 - Physical Therapist Assistants and Occupational Therapy Assistants

Statutory Authority:

Social Services Law Section 363-a and Public Health Law Section 201(1)(v)

Description of the regulation:

Section 505.11 pertained to rehabilitation services (physical, occupational and speech therapy).

Section 505.11 of Title 18 is on the current Regulatory Agenda. This regulation is being amended to align it with State Education law, federal guidelines, and current standards of practice for physical, occupational, and speech therapy.

Title 10 NYCRR - Fifteen Year Review

Amendment of Sections 2.1 and 2.5 of Title 10 (Communicable Disease Reporting-Severe Acute Respiratory Syndrome (SARS))

Statutory Authority:

Public Health Law (PHL) § 206(1)

Description of the regulation:

Severe Acute Respiratory Syndrome (SARS) is a viral respiratory illness that was recognized as a global threat in March 2003, after first appearing in Southern China in November 2002. In 10 percent to 20 percent of cases, patients require mechanical ventilation. Most patients develop pneumonia. The primary way that SARS appears to spread is by close person-to-person contact. In 2003, SARS was added to the communicable disease list in 10 NYCRR.

Although there have been no SARS cases reported since July 2003, it remains critical to keep SARS as a reportable condition to ensure the immediate identification, reporting, and investigation of any possible new cases. If cases go unidentified, spread in the population could have significant public health consequences. The regulation should be continued without modification.

Amendment of Sections 2.1 and 2.5 of Title 10 (Communicable Diseases - Monkeypox)

Statutory Authority:

PHL §§ 225(4), 225(5)(a), (g), (h) and (i), and 206(1)

Description of the regulation:

Monkeypox is a viral disease from Africa that resembles smallpox in humans and can be spread from animal to person or person to person through direct contact or respiratory droplets. Although human cases in the U.S. have not been seen since 2003 when this regulation was enacted, there is the possibility of cases occurring again in the future. Continuance of this regulation is warranted in order to improve reporting (Section 2.1) and laboratory testing (Section 2.5) of cases. The regulation should be continued without modification.

Amendments to Section 2.1(a) and addition of new Section 2.2(h) to Title 10 (Communicable Diseases - Arboviral Infection Reporting)

Statutory Authority:

PHL §§ 206(1) and 602.3

Description of the regulation:

This regulation simplified the requirements for reporting all arthropod-borne viral (arboviral) diseases rather than listing individual diseases with separate responses. This regulation grouped all of these, primarily mosquito-borne and potentially fatal diseases, into one inclusive term. As such, any potential confusion regarding responses to individual disease pathogens is minimized. The regulation should be continued without modification.

Amendment to various Sections in Part 5 of Title 10 (Public Notification, ByProducts and Interim Enhanced Surface Water Treatment Rule (SWTR) - Drinking Water)

Statutory Authority:

PHL § 225

Description of the regulation:

The amendment to various sections of Subpart 5-1 incorporated the requirements of the United States Environmental Protection Agency's Interim Enhanced Surface Water Treatment Rule (IESWTR), the Stage 1 Disinfectants and Disinfection Byproducts Rule (DBP Rule), and

the Public Notification Rule (PNR). These rules are requirements of 40 CFR Part 141. As a condition of the New York State Department of Health's primacy, the state's rules or other authority must be, at minimum, as stringent as 40 CFR Part 141. Additional amendments were incorporated in Subpart 5-1 in 2018 to conform with revisions to the United States Environmental Protection Agency's Interim Enhanced Surface Water Treatment Rule (IESWTR) and the Disinfectants and Disinfection Byproducts Rule.

The amendment should continue without modification.

Amendment of Subpart 6-2 of Title 10 (Bathing Beaches)

Statutory Authority:

PHL § 225

Description of the regulation:

The amendments clarified the definition of "bathing" so that activities such as fishing, scuba diving and surf boarding are no longer prohibited at areas outside of regulated bathing beaches or at regulated bathing beaches when not open to bathing. The amendment also added enterococcus and E. coli as acceptable bacteriological indicator organisms to assess water quality at bathing beaches and clarified factors to be considered when determining if water quality creates a potential health hazard requiring closure of a beach.

The regulation will be amended to incorporate and maintain consistency with the United States Environmental Protection Agency's current recreational water quality criteria for bacterial pollution and toxins.

Amendment of Subpart 7-2 of Part 7 of Title 10 (Children's Camps)

Statutory Authority:

PHL §§ 225 and 1394

Description of the regulation:

The September 29, 2004 amendments to Subpart 7-2 added standards for children's camp trips, swimming, incidental water immersion, on-site activities and bunk bed guardrails; clarified and added potable water standards; and updated and clarified obsolete wording and standards. On July 6, 2011, minor revisions pertaining to swimming were incorporated into the regulation.

The regulation should continue without modification.

Amendments to Section 16.58 of Part 16 of Title 10 (Fluoroscopic X-ray Equipment)

Statutory Authority:

PHL § 225

Description of the regulation:

The amendment to Section 16.58 of Part 16 updated the quality control testing for fluoroscopic x-ray equipment to assure uniformity in testing and compliance with standards for image quality and patient doses. The regulation should continue without modification.

Amendment of Sections 55-2.1 through 55-1.12 of Subpart 55-2 of Title 10 (Environmental Laboratories)

Statutory Authority:

PHL § 502

Description of the regulation:

The rule established minimum standards for the certification and operation of environmental laboratories analyzing New York State samples. These sections describe requirements for approval, on-site assessments, proficiency testing, personnel and quality systems standards for analytical processes and record keeping.

The Department continues to provide oversight of environmental laboratories that perform testing on environmental samples that originate from New York State. The regulation should continue with modification.

Amendments are being considered to accommodate a tiered level of certification pertaining to types of analysis performed, application requirements, requirements for on-site assessment and proficiency testing as well as requisite qualification of technical directors. In addition, amendments will update the definition of Quality System Standards to reference the most up to date standards and clarify that regulated analytes exclude analytes considered process controls by other state regulatory agencies.

Addition of new Sections 55-2.12 and 55-2.13 to Subpart 55-2 of Title 10 (Environmental Laboratory Standards)

Statutory Authority:

PHL § 502

Description of the regulation:

This regulation established requirements for the certification and operation of environmental laboratories. Section 55-2.12 establish qualifications for contract laboratory protocol personnel and Section 55-2.13 established requirements for laboratories engaged in testing for critical agents in environmental samples.

The Department continues to provide oversight of environmental laboratories that perform testing on environmental samples that originate from New York State. The regulation should continue with modification.

Modifications to section 55-2.12 are being considered to establish consistency with Department of Environmental Conservation requirements. Section 55-2.13 should be continued without modification.

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

Statutory Authority:

PHL § 3121(5)

Description of the regulation:

Subpart 58-2 established minimum standards for the proper collection, processing, fractionation, storage, distribution and supply of human blood or blood products for use in transfusion.

The Department continues to provide oversight of blood banks that collect, process, fractionate, store and distribute human blood and blood products. The regulation should continue with modification.

Amendments to Subpart 58-2 are being drafted that will clarify requirements for reinfusion procedures; establish requirements for the collection and handling of blood for subsequent reinfusion; establish requirements for the issuance of blood, blood components and derivatives during routine and emergency situations; revise requirements for blood donor qualifications, collection and testing; amend record retention requirements to be consistent with the FDA and industry standards; clarify personnel and supervisory requirements for plasma and apheresis collection; clarify requirements for transfusions that occur outside of a hospital setting; and revise criteria for exceptions to reflect industry standards.

Amendment of Subpart 58-5 of Title 10 (Hematopoietic Progenitor Cell Banks)

Statutory Authority:

PHL §§ 3121(5) and 4365(7)

Description of the regulation:

Subpart 58-5 established minimum standards for the banking of hematopoietic progenitor cells (HPCs), which are immature blood cells. These requirements have helped ensure that HPCs collected, processed, and used in New York State are obtained from fully screened and tested donors with documented informed consent. HPC banks operating in New York are subject to tissue bank licensure under Part 52 pursuant to PHL 4364.

The Department continues to oversee tissue banks that bank HPCs. The regulation should continue with modification.

The regulations must be amended from time to time, in order to keep pace with advances in technology and practice standards. Amendment under consideration include an update in requirements for donor suitability determination, infectious disease testing, and record keeping related to hematopoietic progenitor cell (HPC) donation and transplantation. Continuance of these regulations is warranted.

Amendment of Section 69-1.3(1)(2) of Part 69 of Title 10 (Expedited HIV Testing of Women and Newborns)

Statutory Authority:

PHL §§ 576, 2500-a, and 2522

Description of the regulation:

Subpart 96-1.3(1)(2) promoted the public health and welfare by ensuring that the HIV exposure status is available for all newborns for

mothers who have not been tested for HIV during the current pregnancy or for whom HIV test results are not available at delivery. This allows providers and patients information that is critical for the timely and efficacious administration of antiretroviral medications to prevent mother-to-child HIV transmission should the mother be HIV-infected. This amendment should be continued without modification.

Amendment of Section 80.86 and addition of a new Section 80.84 of Title 10 (Treatment of Opiate Dependence in the Outpatient Setting)

Statutory Authority:

PHL §§ 3308(2), 3351 and 3352

Description of the regulation:

This regulation allowed the treatment of narcotic addiction in the outpatient setting, pursuant to the provisions of the federal Drug Addiction Treatment Act of 2000. Under the regulation, a qualified physician may treat narcotic addiction by issuing a prescription for buprenorphine, a controlled substance approved by the U.S. Food and Drug Administration and the New York State Department of Health for such treatment. The prescription may be dispensed to the patient by a pharmacist. Prior to the regulation, narcotic addiction could only be treated by enrollment in a Methadone Maintenance Treatment Program (MMTP). The regulation ensures effective addiction treatment in the confidentiality of an office setting for persons who may be unable or unwilling to seek treatment in a MMTP venue. The regulation protects the public health by resulting in more persons entering treatment. The regulation should continue without modification.

Amendment to Section 85.21 of Title 10 and Section 505.3 of Title 18 (Smoking Cessation Products)

Statutory Authority:

Social Services Law (SSL) § 365-a(4)

Description of the regulation:

This regulation provided for inclusion of non-prescription smoking cessation drugs on the list of reimbursable drugs under the NYS medical assistance program. This regulation supports the DOH's commitment to curtail tobacco use and to encourage smoking cessation. There have been no changes that would necessitate further amendment or repeal of this section. Continuance of the regulation is warranted.

Amendments to Sections 86-1.62 and 86-1.63 of Title 10 (DRGs, SIWs, Trimpoints and Arithmetic Mean LOS)

Statutory Authority:

PHL §§ 2803(2), 2807(3), and 2807-c(3) and (4)

Description of the regulation:

Sections 86-1.62 and 86-1.63 were repealed. Section 86-1.18 is still valid. Service intensity weights (SIW) and average lengths of stay (LOS) are integral components of the current DRG based inpatient Medicaid rate-setting methodology. This regulation should therefore be retained.

Amendment of Sections 88-2.1 and 88-2.2 of Part 88 of Title 10 (New York State Veterans' Home)

Statutory Authority:

PHL Article 4, Title 1 and PHL Article 26-A.

Description of the regulation:

The amendments to these sections were technical in nature by incorporating all the veterans' homes owned and operated by the NYS Department of Health. The Department currently owns and operates the Veterans' Homes at Batavia (Genesee County), Montrose (Westchester County), Oxford (Chenango County) and St. Albans (Queens County).

There have been no other technical or procedural changes that would necessitate further amendments or repeal of these sections. The benefits of this technical change to include all four veterans' homes as covered by this regulation continue to be realized. Continuance of the regulation is warranted.

Repeal of Section 131.1 of Part 131 and addition of new Section 131.1 of Title 10 (City of Syracuse Watershed Rules and Regulations)

Statutory Authority:

PHL § 1100

Description of the regulation:

The new Section provided extensive regulations intended to protect Syracuse's Skaneateles Lake Watershed by providing various limitations on activities and construction. The regulation provides protection of Syracuse's Skaneateles Lake Watershed and allows the City of Syracuse to maintain filtration avoidance for this surface water source. The regulation should continue without modification.

Amendment of Section 405.22 of Title 10 (Live Adult Liver Donation and Transplantation)

Statutory Authority:

PHL § 2803(2)

Description of the regulation:

Regulations formerly found in 405.22 Critical care, were repealed and 405.30 and 405.31 have been created to contain provision related to Organ and Vascularized Composite Allograft Transplant Services/Programs and the Living Donor Transplantation Services respectively.

Amendment of Sections 405.24(h) and 415.29(l) of Title 10 (Standards for Animals in Health Care Facilities)

Statutory Authority:

PHL §§ 2803(2) and 2803-h

Description of the regulation:

This regulation was amended to be consistent with the federal Americans with Disabilities Act (ADA) and PHL § 2803-h which gives hospitals and nursing homes the option to board animals. Service animals, not limited to guide dogs, for a disabled person are allowed, as long as they do not pose a significant risk to the health or safety of others that cannot be eliminated by reasonable accommodation and are not medically contraindicated. The regulation should continue without modification.

Repeal Parts 425-427 and addition of new Part 425 and amendment to Parts 711 and 713 of Title 10 (Adult Day Health Care)

Statutory Authority:

PHL § 2803(2)

Description of the regulation:

Effective 3/17/2004, PHL § 2803(2) defined "adult day health care" as the health care services and activities provided to a group of registrants with functional impairments to maintain their health status and enable them to remain in the community. This program serves registrants, defined as a person (1) who is not a resident of a residential health care facility, is functionally impaired and not homebound, and requires supervision, monitoring, preventive, diagnostic, therapeutic, rehabilitative or palliative care or services but does not require continuous 24-hour-a-day inpatient care and services, except that where reference is made to the requirements of Part 415 of this Subchapter, the term resident as used in Part 415 shall mean registrant; (2) whose assessed social and health care needs can satisfactorily be met in whole or in part by the delivery of appropriate services in the community setting; and (3) who has been admitted to an adult day health care program based on an authorized practitioner's order and the adult day health care program's interdisciplinary comprehensive assessment. The program is defined as an approved adult day health care program located at a licensed residential health care facility or an approved extension site.

Amendments to these regulations are proposed that would enable adult day health care programs in nursing homes to contract and work effectively with managed long term care Plans (MLTC) and coordinated care models (CCM) as more Medicaid recipients are required to enroll in MLTC and CCM.

Amendment of Section 700.2(b)(32) and (44) of Part 700 of Title 10 (Certification Requirements for Physical Therapist Assistants and Limited Permits for Physical Therapists)

Statutory Authority:

PHL § 2803(2) and Chapter 404 of the Laws of 2002

Description of the regulation:

This regulation amended the definitions in the State Hospital Code for "physical therapy assistants" and "physical therapists" to conform to definitions consistent with Chapter 404 of the Laws of 2002.

The law shortened the duration of a limited permit to practice physical therapy from 1 year to 6 months. The previous regulation was silent on the issue of limited permits. New language was also added to the definition for those individuals who are not yet licensed and registered with the Education Department that specifies that they be issued a valid limited permit by the Education Department. The law also added an examination for certification as a physical therapy assistant and provides for limited permits for physical therapy assistants prior to certification. The physical therapy assistant definition added language specifying that they are licensed and currently registered with the New York State Education Department, or have been issued a valid limited permit by that Department. The regulation should continue without modification.

Amendment of Section 709.3 of Title 10 (Need Methodology for Residential Health Care Facility (RHCF) Beds)

Statutory Authority:

PHL § 2802

Description of the regulation:

This regulation was updated in 2010 to reflect changes in demographics and in long-term care services that affect the public need for RHCF (nursing home) beds. The regulation projected RHCF bed need through 2016.

The regulation should be updated again to reflect changes in demographics, service use and service delivery that impact the need for nursing home beds and to project bed need through 2025.

Amendment of Section 800.26 of Part 800 of Title 10 (Emergency Ambulance Service Vehicle Equipment Requirements)

Statutory Authority:

PHL §§ 3011(4) and 3016

Description of the regulation:

This regulation described an emergency ambulance service vehicle (EASV). These vehicles are either owned or operated by an ambulance service and designated for the purposes of responding to medical emergencies with personnel and/or equipment and supplies. The EASV is not to be used to transport patients. This amendment was intended to give ambulance agencies greater flexibility in deploying their equipment and personnel to the scene of a medical or traumatic emergency. The regulation should continue without modification.

Addition of a new Part 801 to Title 10 (Resuscitation Equipment in Public Places)

Statutory Authority:

PHL § 3000-D

Description of the regulation:

This regulation required the owner or operator of a public place, as described in law and the regulation, to make available certain items of resuscitation equipment and make them readily accessible for use by either trained staff or the public during a medical emergency. It required that the equipment be located in such place that it may be brought to a patron's side within three minutes of the onset of an event. Further, the regulations included requirements for appropriate signage indicating the availability of resuscitation equipment for emergency use and providing information on how to obtain cardiopulmonary resuscitation training. The regulation should continue without modification.

Title 18 NYCRR - Fifteen Year Review

Amendment of Section 486.5 of Part 486 of Title 18 (Non-Rectifiable Offenses in Adult Care Facilities)

Statutory Authority:

SSL §§ 460-d and 461

Description of the regulation:

The regulation allowed for the imposition of civil penalties against adult care facilities (except those operated by a social services district) for violation of regulations related to adult care facilities or any order of the Department issued pursuant to Social Services Law § 460-d. Most penalties may be abated if rectified by the facility within 30 days. Subdivision (a)(4) of the regulation provided that penalties imposed because a violation endangered or resulted in harm to a resi-

dent may not be rectified so as to abate the penalty, if the endangerment or harm is the result of one of the following actions or failures to act by the facility:

(i) Total or substantial failure of the facility's fire protection or prevention systems or emergency evacuation procedures;

(ii) Retention of a resident medically requiring placement in a nursing home when the operator has not made and cannot document efforts to secure an appropriate placement;

(iii) Failure of the operator to take appropriate action in the event of a resident's illness, accident, death or attempted suicide;

(iv) Failure of the facility to provide supervision in accordance with the staffing requirements of the regulations;

(v) Failure of systemic practices and procedures;

(vi) Threats of retaliation or taking reprisals against a resident who participates in the investigation of a complaint or who is the subject of an action identified in a complaint.

This regulation enabled the Department's collection of civil penalties from facilities who fail to meet acceptable standards of resident care and supervision in these critical areas and also facilitated enforcement of basic resident protections and the prevention of endangerment and resident harm. The regulation should continue without modification.

Repeal clause (a) of 505.14(h)(7)(iii) and add new clause (a); amendment of 505.14(h)(7)(iii)(b)(1); repeal of subclause (6) of 505.14(h)(7)(i)(a) and add new subclause (6)(i) and (ii) to Title 18 (Personal Care Services Reimbursement (BLTCR))

Statutory Authority:

SSL §§ 363-(a)(2) and 365a(2)(e)

Description of the regulation:

The rule revised Medicaid reimbursement regulations to include a two percent penalty when cost reports are submitted late, and instituted advance notification of January personal care rates. The rule should continue without modification.

Title 10 NYCRR - Twenty Year Review

Amendment of Section 16.58 of Title 10 (Fluoroscopic X-ray Systems)

Statutory Authority:

PHL § 225

Description of the regulation:

The amendment limited the radiation output of fluoroscopic x-ray tubes when a fluoroscopic unit is operating in high-level control mode.

The regulation should continue without modification.

Addition of Subparts 47-3, 47-4, 47-5 and 47-6 to Part 47 of Title 10 (Primary Care Education and Training)

Statutory Authority:

PHL §§ 901, 903 and 904

Description of the regulation:

These regulations effectively served NYS DOH scholarship and loan repayment recipients who fulfilled their service obligations under these programs in the past. Because the benefits of the amendment no longer continue to be realized, continuance of the regulation is not currently warranted.

Amendment to Subpart 58-5 of Title 10 (Hematopoietic Progenitor Cell Banks)

Statutory Authority:

PHL §§ 3121(5) and 4365(7)

Description of the regulation:

Subpart 58-5 established minimum standards for the banking of hematopoietic progenitor cells (HPCs), which are immature blood cells. These requirements have helped ensure that HPCs collected, processed, and used in New York State are obtained from fully screened and tested donors with documented informed consent. HPC banks operating in New York are subject to tissue bank licensure under Part 52 pursuant to PHL 4364.

The Department continues to oversee tissue banks that bank HPCs. The regulation should continue with modification.

The regulations must be amended from time to time, in order to keep pace with advances in technology and practice standards. Amendment under consideration include an update in requirements for donor suitability determination, infectious disease testing, and record keeping related to hematopoietic progenitor cell (HPC) donation and transplantation. Continuance of these regulations is warranted.

Amendment of Subpart 58-8 of Title 10 (HIV Testing of Newborns)

Statutory Authority:

PHL §§ 576(4) and 2786

Description of the regulation:

Subpart 58-8 promoted 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.

The Department continues to oversee clinical laboratories that perform HIV testing. The regulation should continue with modification.

Future amendments will be required to ensure consistency with HIV testing requirements in Part 63 and will address updated technologies and revise testing algorithms for the management of HIV.

Amendment of Sections 80.67, 80.69, 80.73 and 80.74 (Addition of Prescription Information)

Statutory Authority:

PHL §§ 3308(2) and 3338(3)

Description of the regulation:

This regulation allowed pharmacists to complete certain missing or incorrect information on an official New York State prescription, upon receiving oral authorization to do so from the prescribing practitioner. Allowing the pharmacist to add or change such information saved the patient the inconvenience of having to return to the practitioner who issued the prescription. The regulation ensured access to controlled substances for legitimate medical use and saved practice time for the prescriber and the pharmacist resulting from return visits to each. The regulation should continue without modification.

Amendment of Sections 80.67, 80.69, 80.71 and 80.72 (Three-Month Controlled Substance Medication)

Statutory Authority:

PHL § 3308(2)

Description of the regulation:

The regulations provided consistent access to medication for all patients being treated with controlled substances for attention deficit disorder (ADHD). This regulation allowed patients of any age to obtain up to a 3-month supply of a controlled substance for treatment when prescribed by their practitioner since ADHD has been proven to extend into adulthood. Some prescription plans allowed for a single co-pay for a 3-month supply. The amendment has resulted in significant cost savings to the patient. The regulation should continue without modification.

Amendment of Section 86-6.6 (Hospice Supplemental Financial Assistance)

Statutory Authority:

PHL § 4012-a

Description of the regulation:

The regulation permanently extended the Hospice Supplemental Financial Assistance Program until the supporting program legislation expires. The rule should continue without modification.

Amendment of Paragraph 415.14(a)(1) (Qualifications of Nursing Home Director of Food Services)

Statutory Authority:

PHL § 2803(2)

Description of the regulation:

The amendment modified a restrictive personnel qualification standard for the food service director which exceeded the federal requirements set forth at 42 CFR Section 483.35, and did not necessarily contribute to nursing home resident well-being. It also provided nursing home operators greater flexibility in the recruitment of a staff position.

Based upon outcomes identified during nursing home surveillance activities, the amended regulation has not had a negative impact on resident health and safety. The regulation should continue without modification.

Title 18 NYCRR - Twenty Year Review

Amendment of Sections 347.5, 369.1, 369.7, 370.2, 370.7 and 360-3.2 of Title 18 (Child Support-MA)

Statutory Authority:

Chapter 398 of the Laws of 1997

Description of the regulation:

The regulation revision enhanced child support enforcement efforts by requiring Medicaid applicants and recipients to assist in establishing, modifying and enforcing child support orders. Section 360-3.2 was part of a regulatory package submitted by the Office of Temporary and Disability Assistance (OTDA). The revision remains valid in order to implement Chapter 398 of the Laws of 1997. Continuance of this regulation is warranted.

Amendment of Paragraph 505.5(d)(2) of Title 18 (Medicaid DME Pricing Methodology)

Statutory Authority:

Chapter 474 of the Laws of 1996

Description of the regulation:

The regulation established maximum reimbursable prices for standard items of durable medical equipment. This regulatory change was developed with the support and assistance of the State's durable medical equipment providers as a means to simplify billing procedures, to limit cost increases to Medicaid of durable medical equipment, and to minimize audit issues related to the determination of actual invoice cost for pricing. The methodology remains appropriate and consistent with the payment policy of other medical care insurers. This regulation should be retained without modification.