

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 Sections 23.1 and 23.2 of Title 10 (Expansion of Minor Consent for HIV Treatment Access and Prevention)

Statutory Authority:

Public Health Law Sections 225(4), 2304, 2305 and 2311

Description of the regulation:

This amendment supports the Governor's plan to end the AIDS epidemic in New York State by 2020, by connecting persons diagnosed with HIV with treatment, including prevention services. After being diagnosed, young people currently face barriers that can prevent or delay access to care, including denial and fear of their HIV infection, misinformation, HIV-related stigma, low self-esteem, lack of insurance, homelessness, substance use, mental health issues, and lack of adequate support systems. Because of these factors, many young people need the ability to consent to HIV treatment, including prevention services. These regulations are necessary to provide appropriate health care rights and protections to minors and remove the barriers that can prevent or delay access to care. The regulation should continue without modification.

Amendment of Section 86-1.47 of Title 10 (Hospital Indigent Care Pool Payment Methodology)

Statutory Authority:

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

Description of the regulation:

Part 86-1.47 of Title 10 NYCRR extends for another two calendar years, 2019 and 2020, the current indigent care distribution methodology which replaced a complex distribution approach that expired December 31, 2012. Public Health Law Section 2807-k (5-d) requires the Department to have such a methodology in place through 2020. This regulation will be extended to accommodate a not greater than seventeen and a half percent for 2019 and a twenty percent for 2020 reduction in payments.

**Addition of Part 350 to Title 10
(All Payer Database)**

Statutory Authority:

Public Health Law Sections 2816 and 206(18-a)(d)

Description of the regulation:

These regulations establish New York State's All Payer Database (APD). The APD provides a robust dataset that supports a variety of comparative analyses. The APD enables evaluation of care delivery and payment models and identifies opportunities to avoid waste, over/under utilization, misuse of treatments, and conflicting plans of care. The regulations should continue without modification.

**Amendment of Part 405 of Title 10
(Federal Conditions of Participation)**

Statutory Authority:

Public Health Law Section 2803

Description of the regulation:

The Centers for Medicare and Medicaid Services (CMS) requires hospitals to meet specified Conditions of Participation (CoPs) in order to participate in the federal Medicare and Medicaid programs. The CoPs outline the basic requirements related to a hospital's structure, operations and delivery of patient care. CMS made numerous changes to the CoPs effective on July 16, 2012. As a result, New York State general hospital regulations were revised to reflect the federal changes. The regulation should continue without modification.

**Amendment of Section 405.21 of Title 10
(Perinatal Services)**

Statutory Authority:

Public Health Law Section 2505-a

Description of the regulation:

Describes hospital requirements for perinatal care. This amendment expanded rights of breastfeeding mothers. Marketing of breast milk substitutes was restricted. Hospitals were required to annually disseminate hospital breastfeeding policies and procedures to staff providing maternity and newborn care, inform the mother of community services, including the Special Supplemental Nutrition Program for Women, Infants and Children (WIC), and to make referrals

to such community services as appropriate. The regulation should continue without modification.

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

Statutory Authority:

Public Health Law Sections 3369-a and 502

Description of the regulation:

These regulations comprehensively govern the medical marijuana program pursuant to Public Health Law §§3360-3369 and set the rules for patients to participate in the program, as well as for practitioners to certify them and for Registered Organizations to manufacture and distribute medical marijuana products in New York State.

Subpart 55-2 describes certification requirements for environmental laboratories that test samples that originate from New York State. Section 55-2.15, which describes requirements for testing for medical marihuana, was updated to correct the name of the Drug Enforcement Administration and to include disposal requirements for medical marihuana.

The regulations should be amended to improve patient access to the medical marijuana program, reduce the costs of medical marijuana products, clarify requirements for research on medical marijuana products, and promote social equity within the medical marijuana industry. Section 55-2.15 was recently amended, effective 08/21/2019, and future amendments may be required with changes in industry standards.

Title 10 NYCRR - Five 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:

The regulation prohibits the manufacture and sale of certain synthetic cannabinoids.

The regulation should be amended to conform to and supplement subsequent amendments to Public Health Law §3306, which added several synthetic cannabinoids to New York State's schedule of controlled substances.

Amendment of Subpart 50-3 of Title 10 (Medical Records Access Review Committees)

Statutory Authority:

Public Health Law Section 18(4)

Description of the regulation:

Effective January 1, 1987, patients and other qualified persons were granted access to health care records by Section 18 of the New York State Public Health Law (PHL), which was enacted in Chapter 497 of the Laws of 1986. The law contains the procedures for making records available, the conditions under which a provider can deny access to records, and a process to resolve situations in which patients or other qualified persons dispute a provider's denial of access to records.

If a patient is denied access to their health care records, the patient or other qualified persons are afforded the right of appeal to Medical Records Access Review Committees (MRARC) designated by the Commissioner of Health pursuant to PHL Section 18 to hear and make determinations on appeals. Subpart 50-3 of Title 10 of the New York State Codes, Rules and Regulations (NYCRR) governs the operations of the MRARCs, comprised of Department of Health professionals.

Subpart 50-3 describes the steps that physicians and non-physician professionals must take in the event of an appeal to the denial of access to patient information and the process to be followed by MRARCs in hearing and issuing determinations on appeals. 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 & 587

Description of the regulation:

Subparts 58-1 (Clinical Laboratories), 58-8 (HIV Testing) and 34-2 (Laboratory Business Practices) had previously included language that prohibited a patient from obtaining their test results directly from a laboratory. These regulations were amended to allow patients to access their test results directly from a laboratory. 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:

This regulation describes requirements for blood banks and requirements for laboratories performing immunohematology testing. Numerous amendments were made to update practice standards, to address changes in nomenclature and technologies used in the field of blood banking and immunohematology testing and added requirements for ambulance services that administers blood components during transport from one hospital to another hospital.

Amendments will be proposed to clarify requirements for reinfusion procedures; modify the requirements for the collection and handling of blood for subsequent transfusion; establish requirements for the issuance of blood, blood components and derivatives during routine and emergency situations; revise donor qualifications, collection and testing requirements for whole blood, apheresis and serial plasmapheresis; update record retention requirements to be consistent with the FDA and industry standards; amend requirements for standard operating procedures; amend the standards for transfusion and immunohematology testing requirements; clarify personnel and supervisory requirements for serial plasmapheresis and apheresis collection of blood components.; clarify requirements for transfusions that occur outside of a hospital setting and during interfacility transport; and revise criteria for exceptions to reflect industry standards.

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

Statutory Authority:

Public Health Law Sections 2164 and 2168

Description of the regulation:

On June 13, 2019, Governor Andrew Cuomo signed legislation removing non-medical exemptions from school vaccinations for children. Therefore, in August 2019, Section 2164(10) of the Public Health Law (PHL), sections 66-1.1, 66-1.2, 66-1.3, 66-1.6, and 66-1.10 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York were amended via emergency regulation changes, to be compatible with the new legislation. At the same time, a notice of proposed rulemaking was submitted for public comment.

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

Statutory Authority:

Public Health Law Section 3309

Description of the regulation:

The Commissioner is authorized to establish standards for approval of any opioid overdose prevention program, and opioid antagonist prescribing, dispensing, distribution, possession and administration pursuant to this section which may include, but not be limited to, standards for program directors, appropriate clinical oversight, training, record keeping and reporting.

The standards, since the inception of New York State's opioid overdose prevention initiative in 2006, have been codified in 10 NYCRR 80.138. These standards, with minor proposed amendments to the regulation, must remain to ensure the orderly continuance of the state's opioid overdose prevention initiative. Modifications will be proposed to conform to updated program standards.

**Addition of Section 86-1.45 to Title 10
Inpatient Rate for Language Assistance Services**

Statutory Authority:

Public Health Law Section 2807-c(35)

Description of the regulation:

Reimbursement for language assistance services in the hospital inpatient setting. 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:

Rate rationalization reformed the operating component of the rate by introducing methodological rigor into what was previously a negotiated rate. Further, these regulations consolidate the rate-setting functions of Medicaid services previously exercised by the Office for People with Developmental Disabilities (OPWDD) within the Department of Health.

OPWDD was responsible for the reimbursement of the capitol cost component of Residential and Day Habilitation providers and the Department of Health is responsible for reimbursement of the operating cost component. This arrangement has been ratified by the Centers for Medicare and Medicaid Services (CMS), along with the changes to reimbursement for Residential and Day Habilitation services reflected by this regulation.

The regulation should not continue without modification.

Amend regulation to add the following:

- Direct Care Support Professional and Clinical 2% compensation increases
- Cap reimbursement of Agency Administration at 15 percent
- Offset other income surpluses against allowable Medicaid costs.

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

Statutory Authority:

Social Services Law Section 201

Description of the regulation:

Rate rationalization reformed the operating component of the rate by introducing methodological rigor into what was previously a negotiated rate. Further, these regulations consolidate the rate-setting functions of Medicaid services previously exercised by the Office for People with Developmental Disabilities (OPWDD) within the Department of Health.

OPWDD was responsible for the reimbursement of the capitol cost component of ICF/DD services and the Department of Health is responsible for reimbursement of the operating cost component. This arrangement has been ratified by the Centers for Medicare and Medicaid Services (CMS), along with the changes to reimbursement for ICF/DD services reflected by this regulation.

The regulation should not continue without modification.

Amend regulation to add the following:

- Direct Care Support Professional and Clinical 2% compensation increases
- Cap reimbursement of Agency Administration at 15 percent

**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 limits applied to Office for People with Developmental Disabilities licensed clinics. The regulation should continue without modification.

**Amendment of Part 94 of Title 10
(Physician Assistants and Specialist Assistants)**

Statutory Authority:

Public Health Law Sections 3308, 3701 and 3703

Description of the regulation:

Part 94 of Title 10 sets forth the supervision and scope of duties of a licensed physician assistant or a registered specialist assistant performing medical services only under the supervision of a physician. This includes the number of assistants that can be supervised by a physician, the prescribing authority of an assistant, and the types of specialist assistants. The regulation should continue without modification.

**Amendment of Sections 98-1.2 & 98-1.11 of Title 10
(Managed Care Organizations)**

Statutory Authority:

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

Description of the regulation:

Section 98-1.2 includes a definition for the HARP line of business. Section 98.11(e) (1) ii maintains the contingent reserve percentage at 7.25% for the Medicaid Managed Care, HARP and HIV SNP Programs. 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) and 4403(f)(7)

Description of the regulation:

The regulation extends 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 must adhere to the same financial reporting requirements and standards in the filing of audited financial statements. The regulation is closely patterned upon 11 NYCRR 89 (Regulation 118) adopted by the Department of Financial Services and the National Association of Insurance Commissioners model audit rule ("NAIC model") that reflects a consensus of the insurance

regulators of all states and territories of the United States as to scope, detail, needs and benefits. 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 Nursing Care Quality Protection Act (Chapter 422 of the Laws of 2009), added PHL Section 2805-t which requires Article 28 facilities to disclose identified nursing quality indicator information upon request to any member of the public, and to the Commissioner of any State agency responsible for licensing the facility or responsible for overseeing the delivery of services by the facility, or any organization accrediting the facility. PHL Section 2805-t authorizes the Commissioner to promulgate regulations regarding disclosure of nursing quality indicators to such requesters. This regulation establishes standards for the collection and disclosure of data regarding nursing staffing levels and nursing-sensitive patient outcome indicators. 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 regulation relates to standards applicable to programs licensed or certified by the Department of Health, Office of Mental Health or Office of Alcoholism and Substance Abuse Services which desire to add to services provided under the licensure or certification of one or both agencies. The regulation should not continue without modification. In response to the Regulatory Modernization Initiative and to and to make permanent the DSRIP Project 3.a.i. Licensure Threshold, these regulations will be amended by DOH, OMH, and OASAS to facilitate the integration of health care services by any provider licensed by one of those agencies.

**Amendment of Part 405 of Title 10
(Hospital Observation Services)**

Statutory Authority:

Public Health Law Sections 2803, 2805-v & 2805-w

Description of the regulation:

Legislation passed in 2013 added new Sections 2805-v and 2805-w of the Public Health Law. This legislation established new requirements for hospital observation services. Since these requirements differed from those in the existing regulations, amendments were made to bring the regulations into conformance with the provisions of PHL. The regulation should continue without modification.

**Amendments of Section 415.3(h) of Title 10
Nursing Home Transfer and Discharge Rights**

Statutory Authority:

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

Description of the regulation:

Resident rights as it relates to transfer and discharge from nursing home facility. The regulation should continue without modification.

The Division is currently reviewing all of Part 415 of Title 10 and intends to make appropriate updates.

**Amendment of Sections 600.3 and 710.5 of Title 10
(Amendment of Certificate of Need (CON) Applications)**

Statutory Authority:

Public Health Law Sections 2801-a(1) and 2802(1)

Description of the regulation:

The regulation clarified language relating to changes to Certificate of Need applications prior to and after Public Health and Health Planning Council (PHHPC) approval and set forth conditions under which such changes would be referred back to PHHPC for reevaluation and recommendations. The regulation should continue without modification.

**Amendment of Section 710.1 of Title 10
(Certificate of Need Requirements)**

Statutory Authority:

Public Health Law Section 2802

Description of the regulation:

The regulation removed CON review requirements for repair and maintenance projects and equipment replacement projects costing more than \$6 million. The regulation also removed the requirement that non-clinical infrastructure projects exceeding \$15 million be subject to administrative review. In lieu of the submission of administrative or full review CON applications, the amended rule required the submission of only a written notice and, where applicable, specified certifications and a plan for patient safety during project construction.

The regulation was amended again effective 9/6/17 to eliminate the requirement that notice be provided for non-clinical infrastructure projects that do not exceed \$6 million and to apply the notice requirement to non-clinical infrastructure projects costing over \$6 million. 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:

Part 757 of Title 10 of the New York Codes Rules and Regulations (NYCRR) outlines the requirements for services provided in New York State chronic renal dialysis centers. These centers must comply with the regulations contained in Title 42 of the Code for Federal Regulations (CFR), Amendments to 42 CFR established new conditions for coverage that chronic renal dialysis centers must meet to be approved by the Centers for Medicare and Medicaid Services. It establishes performance expectations for centers and encourages patients to participate in their plan of care and treatment. It also reflects advances in dialysis technology and standard care practices. This regulation was updated in 2015 to be in compliance with the revised federal requirements. The regulation should continue without modification.

**Amendment of Part 800 of Title 10
(Emergency Medical Services)**

Statutory Authority:

Public Health Law Section 3002

Description of the regulation:

This regulation provides descriptions of all terms used in regulations, outlines the requirements and process in order to become a certified EMS provider in New York State. Further, this regulation outlines the requirements to participate in the NYS Continuing Medical Education recertification program, provides the guidelines that regulate the conduct of EMS providers related to pre-hospital care and provides the guidelines on disciplinary action of EMS providers and agencies.

The regulations will be amended to match current medical practice, educational standards and EMS operations.

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

Statutory Authority:

Public Health Law Section 3369-a

Description of the regulation:

These regulations comprehensively govern the medical marijuana program pursuant to Public Health Law §§3360-3369 and set the rules for patients to participate in the program, as well as for practitioners to certify them and for Registered Organizations to manufacture and distribute medical marijuana products in New York State.

Subpart 55-2 describes certification requirements for environmental laboratories that test samples that originate from New York State. A new section, Section 55-2.15, was added which describes requirements for testing for medical marijuana.

The regulations should be amended to improve patient access to the medical marijuana program, reduce the costs of medical marijuana products, clarify requirements for research on medical marijuana products, and promote social equity within the medical marijuana industry.

Section 55-2.15 was recently amended, effective 08/21/2019, and future amendments may be required with changes in industry standards.

Title 18 NYCRR - Five Year Review

**Amendment of Section 505.2(l) of Title 18
(Transgender Related Care and Services)**

Statutory Authority:

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

Description of the regulation:

Authorizes the provision of transition-related care and services for Medicaid eligible persons diagnosed with gender dysphoria. The regulation should continue without modification.

**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:

Sets forth the requirements for Medicaid payment for home health services provided by personal care agencies.

This regulation is under review for amendment.

Title 10 NYCRR - Ten Year Review

Amendment of Subpart 6-2 of Title 10 (Ocean Surf Bathing Beaches and Automated External Defibrillators (AEDs))

Statutory Authority:

Public Health Law Section 225

Description of the regulation:

The regulation requires automated external defibrillation (AED) equipment and at least one lifeguard trained in the use of an AED at regulated surf beaches during all hours of operation. The regulation further requires all ocean surf beaches operated by a homeowners association to have qualified surf lifeguards on duty, and to comply with Subpart 6-2 of the State Sanitary Code. The regulation should continue without modification.

Addition of Section 23.5 to Part 23 of Title 10 (Expedited Partner Therapy to Treat Chlamydia Trachomatis)

Statutory Authority:

Public Health Law Section 2312

Description of the regulation:

The regulation permits health care providers to provide *Chlamydia trachomatis* patients with antibiotics or a written prescription for antibiotics to deliver to his or her sexual partner(s) without prior clinical assessment of those partners. The regulation furthers an important goal to reduce the incidence of Chlamydia re-infection and augments provider options for managing the care of Chlamydia patients. The regulation is under review for amendment to conform to chapter 298 of the Laws of 2019.

**Amendment of Part 40 of Title 10
(State Aid for Public Health Services: Counties and Cities)**

Statutory Authority:

Public Health Law Section 602(3)(a)

Description of the regulation:

10 NYCRR Part 40 establishes regulations regarding State Aid to local health departments for general public health work. Subpart 40-1 establishes the administrative aspects of the State Aid program.

In 2010, certain Subpart 40-1 regulations relating to State Aid eligibility were amended. Effective December 31, 2014, Subpart 40-1 was repealed and a new Subpart 40-1 was issued. The new Subpart 40-1 clarifies, simplifies and modernizes certain regulations related to the administrative aspects of the State Aid program.

Part 42 establishes regulations for State Aid for public health laboratories. Part 42 was also amended in 2010 to eliminate State Aid for laboratory services that do not support public health programs. The Part 42 regulations should continue without modification.

**Amendment of Sections 40-1 & 40-3 of Title 10
(State Aid for Public Health Services: Counties and Cities - Reimbursement to Municipalities per PHL Article 6 for Home Health Services)**

Statutory Authority:

Public Health Law Section 602(3)(a)

Description of the regulation:

10 NYCRR Part 40 establishes regulations regarding State Aid to local health departments for general public health work. Subpart 40-1 establishes the administrative aspects of the State Aid program. In 2010, certain regulations relating to State Aid for home health services provided by the local health department were amended.

Effective December 31, 2014, Subpart 40-1 was repealed and a new Subpart 40-1 was issued. The new Subpart 40-1 clarifies, simplifies and modernizes the regulations related to the administrative aspects of the State Aid program, including those for home health services provided by the local health departments.

Subpart 40-3, related to optional programs reimbursable for State Aid, was also repealed effective December 31, 2014. This regulation should continue without modification.

**Amendment of Subpart 43-2 of Title 10
(HIV Uninsured Care Programs)**

Statutory Authority:

Public Health Law Sections 2776(1)(e), 201(1)(h) & (p) & 206(3)

Description of the regulation:

The regulation supports access to medications, primary care and insurance premium assistance for uninsured and underinsured New Yorkers. Additional amendments to the regulation were promulgated in April 24, 2019. The regulation should continue without modification.

**Addition of New Part 48 to Title 10
(Palliative Care Certified Medical Schools and Residency Programs)**

Statutory Authority:

Public Health Law Sections 2807-n

Description of the regulation:

Section 48.10 establishes the criteria for New York Medical Schools and Residency programs to become certified. The regulation provides that in order to become NYS certified the school must be accredited by the Liaison Committee on Medical Education or the American Osteopathic Association.

Section 48.20 provides for the Commissioner or his/her designee to award designation upon receipt of an application from a NYS Medical School or residency program which meets the criteria in 48.10

The regulations should continue without modification.

**Amendment of Subpart 55-2 of Title 10
(Environmental Testing for Critical Agents Using Autonomous Detection Systems (ADS))**

Statutory Authority:

Public Health Law Section 502

Description of the regulation:

Subpart 55-2 describes certification requirements for environmental laboratories that test samples that originate in New York State. The amendment revised Sections 55-2.10 and 55-2.13, as well as added a new Section 55-2.14, established standards for the certification and

operation of environmental laboratories that seek approval to engage in critical agent testing by means of new technologies, including polymerase chain reaction (PCR)-based methods and immune-based bioassays employed at a fixed-base facility, or by use of an autonomous detection system (ADS) deployed in the field. An ADS is, generally speaking, an automated, real-time, self-contained sampling and analytical system for detection of critical agents situated outside a fixed-base laboratory. This regulation should continue without modification.

**Amendment of Section 60-1.13 of Title 10
(WIC Vendor Minimum Stocking Requirements)**

Statutory Authority:

Public Health Law Section 2500

Description of the regulation:

10 NYCRR 60.1.13 sets forth the criteria that a retail vendor must meet in order to become an approved vendor for the New York State Women, Infant and Children's (WIC) supplemental food program.

The regulations, as they pertain to minimum stocking requirements, should continue without modification. However, the Department intends to propose amendments to other provisions of the existing regulation to conform to U.S. Department of Agriculture (USDA) program requirements regarding vendor authorization and management including vendor participant ratio, geographic proximity and transaction volume of nearby vendors.

**Amendment of Subpart 69-4 of Title 10
(Early Intervention Program)**

Statutory Authority:

Public Health Law Sections 2540 - 2559-b

Description of the regulation:

These regulations set forth State requirements, in conformance with federal requirements, for New York's Early Intervention Program for infants and toddlers ages birth to three years and their families. The regulations include definitions, child find to identify potentially eligible children, provider qualifications and standards, multidisciplinary evaluations, initial and ongoing eligibility criteria, individualized family service plans, service delivery options and standards, monitoring of providers, procedural safeguards, transition, content and retention of records, and computation of reimbursement rates for program services. These regulations must be revised to conform to revised federal regulations and amendments to state statute.

Amendment of Appendix 75-A of Part 75 of Title 10 - Wastewater Standard-Residential Onsite Systems

Statutory Authority:

Public Health Law Section 201(1)(l)

Description of the regulation:

The regulation sets forth design standards to be met in the construction of residential onsite wastewater treatment systems. These design standards provide for the safe, sanitary means of treating and dispersing wastewater. The Department intends to propose amendments to the regulations to delete reference to obsolete standards. This regulation should continue until the proposed amendments are adopted.

Amendment of Subpart 86-8 of Title 10 (Ambulatory Patient Groups (APGs) Methodology)

Statutory Authority:

Public Health Law Section 2807(2-a)

Description of the regulation:

Modifies existing APG transition provisions for new providers and the listing of APG reimbursable and non-reimbursable services. The regulation is under review for amendment.

Amendment of Subpart 86-8 of Title 10 (Ambulatory Patient Groups (APGs) Outpatient Rate Setting Methodology)

Statutory Authority:

Public Health Law Section 2807(2-a)(e)

Description of the regulation:

To refine APG payment methodology regarding new APG weights, new procedure-based weights & minor changes in APG payment rules. The regulation is under review for amendment.

**Amendment of Parts 405, 410, 420, 600, 703, 705, 709 and 710 of Title 10
(Revisions to Certificate of Need (CON) Process for Threshold Levels)**

Statutory Authority:

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

Description of the regulation:

The regulations set forth the dollar cost thresholds that determine the various levels of CON review—limited, administrative or full review—for construction projects by health care facilities subject to Article 28 of the Public Health Law. The regulations should continue as modified in 2017 to raise dollar cost thresholds for general hospital projects.

**Amendment of Sections 405.3, 405.9, 405.10, 415.26, 751.6, 763.13, 766.11, and 793.5 of Title 10
(Personnel Health Amendments and Medicare Conditions of Participation)**

Statutory Authority:

Public Health Law Sections 2800, 2803, 3612 and 4010

Description of the regulation:

The regulations were amended to permit the use of the FDA-approved blood assays for the detection of latent TB infection, as an alternative to the skin test as a condition of employment or affiliation in general hospitals, diagnostic and treatment centers, nursing homes, certified home health agencies, long term home health care programs or AIDS home care programs, licensed home care service agencies, and hospices. In addition, the amendments were made to update the regulations to be consistent with federal requirements (Medicare Conditions of Participation) regarding the timeframe for completion of the hospital admission history and physical examinations, and for authentication of verbal orders and persons who may authenticate verbal orders in hospitals. The regulations should continue without modification.

**Amendment of Sections 405.6, 405.7, 405.19, 708.5 of Title 10
(Hospital Minimum Standards and Appropriateness Review)**

Statutory Authority:

Public Health Law Section 2803

Description of the regulation:

The regulations were amended to allow hospitals a five year “look back” period of a person’s employment instead of ten years when granting privileges to physicians, podiatrists and dentists. The existing regulation concerning patient’s rights prohibited hospitals from

discriminating against patients on the basis of race, color, religion, sex, national origin, disability, sexual orientation, or source of payment. This amendment added a prohibition against discrimination based on age. In addition, hospital emergency department requirements were amended to allow hospitals with less than 15,000 emergency department visits a year to staff their emergency departments with a supervising or attending physician who is not present, but is available within 30 minutes, instead of the previous requirement of 20 minutes, provided that a nurse practitioner or physician assistant is on site. The regulations should continue without modification.

**Amendment of Section 405.12 of Title 10
(Circulating Nursing Required)**

Statutory Authority:

Public Health Law Sections 2800, 2803(2) and 2805-s

Description of the regulation:

The regulation was amended to implement Chapter 158 of the Laws of 2008. This chapter law requires general hospitals to employ a registered nurse, qualified by training and experience, to be present as a circulating nurse, in any and each separate operating room where surgery is performed for the duration of the operative procedure. The regulation should continue without modification.

**Amendment of Section 709.3 of Part 709 of Title 10
(Residential Health Care Facility (RHCF) Bed Need Methodology)**

Statutory Authority:

Public Health Law Section 2803(2)

Description of the regulation:

The regulation lists the factors and formulas used in the calculation of the public need for residential health care facility beds as reviewed in the Certificate of Need (CON) process under Article 28 of the Public Health Law. The regulation should be amended to project bed need out to 2025.

**Amendment of Parts 711, 712, 713, 714, 715 & 716 of Title 10
(Standards of Construction for Health Care Facilities)**

Statutory Authority:

Public Health Law Section 2803(2)

Description of the regulation:

These regulations establish architectural, engineering and construction standards for hospitals, nursing homes, diagnostic and treatment centers and other facilities subject to Article 28 of the Public Health Law. The regulation should be amended to require that future health care facility construction projects conform to the 2014 edition of Guidelines for Design and Construction of Health Care Facilities.

**Amendment of Section 755.6 of Part 755 of Title 10
(Post Anesthesia Evaluations at Freestanding and Hospital Off-Site Ambulatory Surgery Centers (ASCs))**

Statutory Authority:

Public Health Law Section 2803

Description of the regulation:

This amendment was made to conform the regulation with a federal regulatory change (42 CFR 416.42), which specifies that in the ambulatory surgery center (ASC) setting the post anesthesia assessment must be completed and documented by a physician, anesthetist, or certified registered nurse anesthetist (CRNA). Previously, the regulation only authorized a physician to evaluate each patient for proper anesthesia recovery in ASCs. The regulation now permits CRNAs and dentists (the federal definition of physicians includes dentists) to conduct the post-anesthesia evaluation. The regulation should continue without modification.

Title 18 NYCRR - Ten Year Review

**Amendment of Section 505.23 of Title 18
(Certified Home Health Agency Program)**

Statutory Authority:

Social Services Law Sections 363-a(2), SSL 365-a(2)(d)

Description of the regulation:

Sets forth the requirements for Medicaid payment for home health services provided by a certified home health agency. The regulation should continue without modification.

Title 10 NYCRR - Fifteen Year Review

Amendment of Section 2.1(a) of Title 10 (Communicable Diseases-Addition of Laboratory Confirmed Influenza)

Statutory Authority:

Public Health Law (PHL) §§ 225(4) and (5)(a), (g) and (h)

Description of the regulation:

This amendment to the regulation added laboratory confirmed influenza to the NYS list of reportable communicable diseases. This initiative protected the public health by permitting closer monitoring of communicable diseases. This addition was the basis for the Department's enhanced monitoring of influenza and has been instrumental in the prompt identification and surveillance of unusual strains of influenza circulating in NYS such as the novel A influenza H1N1virus. Requiring laboratories to electronically submit confirmed influenza laboratory data via the NYSDOH electronic clinical laboratory reporting system (ECLRS) permitted adequate disease monitoring without unnecessarily burdening the disease reporting system. During the 2008-2009 influenza season there were 30,144 laboratory reports of confirmed influenza received via ECLRS which has more than doubled the number of cases previously reported. This data allowed the department to characterize the outbreak, watch for changes in transmission, monitor for antiviral resistance, determine geographic and temporal changes and mount an appropriate public health response. For these reasons, amending the list of reportable communicable diseases to add laboratory confirmed influenza, should be retained. The Department intends to further amend the list of reportable diseases set forth in the regulation in the future.

Revisions to Subparts 5-1, 5-2, Repeal existing Appendix 5-B and add a new Appendix 5-B, and addition of a new Appendix 5-D to Part 5 of Title 10 (Water Well Construction)

Statutory Authority:

PHL §§ 201, 206(18), 225 and 1120

Description of the regulation:

Section 206 of Public Health Law was amended in 1999 to require the Department to promulgate standards for water wells, including drilling, construction, abandonment, repair, maintenance, water flow and pumps. Extensive outreach to water well drillers, other interested parties and also to other states with long-standing water well programs was conducted to assure that all directives of the law were implemented. Appendix 5-B was promulgated, containing standards for all water supply wells, including both residential and public water supply wells. Appendix 5-D was promulgated to include supplementary and complementary requirements for

public water supply wells. Subparts 5-1 and 5-2 were revised to accommodate 5-B and 5-D as reference standards. These regulations should continue without modification.

Amendment of Section 5-1.52 and 5-1.91 of Subpart 5-1 of Title 10 (Treatment, Monitoring and Reporting for Radionuclides)

Statutory Authority:

PHL § 225

Description of the regulation:

Sections 5-1.52 and 5-1.91 of Subpart 5-1 were amended to incorporate and reflect federal regulations promulgated by the U.S. Environmental Protection Agency. New maximum containment levels, monitoring frequencies, notification and compliance requirements for various radionuclide contaminants were established, as were provisions for variances from specified treatment techniques. The U.S. Environmental Protection Agency has further revised federal regulations. For the Department to obtain primacy for the implementation and enforcement of federal drinking water regulations, these regulations should be amended.

Amendment of Sections 69-1.1, 69-1.2 and 69-1.3 of Subpart 69-1 of Title 10 (Newborn Screening Panel)

Statutory Authority:

PHL § 2500-a

Description of the regulation:

Subpart 69-1 designates diseases or conditions which must be included in the state's newborn screening panel and enumerates the responsibilities of the hospital CEO with regard to such screening, in accordance with the Department's mandate to prevent infant and child mortality, morbidity and diseases and disorders of childhood. The rule implemented the public health aims of early identification and timely medical intervention for all the State's youngest citizens. The Department's Newborn Screening Program continues to perform testing on newborns and continually updates the panel of tests that are performed.

The regulation should continue with modification. Subpart 69-1 was recently amended, effective on 2/13/19, that 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. Section 69-1.2 was amended such that the diseases to be screened will no longer be listed and will instead be listed on the Department's web page.

Addition of new Subpart 69-9 to Title 10 (Standardized Autopsy Protocols for Unanticipated Infant Deaths)

Statutory Authority:

PHL § 4210, as amended by Chapter 58 of the Laws of 2002

Description of the regulation:

The regulation was established to provide standardized autopsy protocols. The Infant Autopsy Protocol is intended to:

- Ensure comprehensive postmortem examinations of infants who die suddenly and unexpectedly.
- Provide findings to correlate with the decedent's medical history.
- Provide findings to correlate with the death scene investigation.
- Develop documentation that justifies the autopsy diagnoses.
- Establish accurate causes of death.
- Develop accurate vital statistics, information and records.
- Assist in prioritizing the allocation of health care resources.
- Fulfill criteria to make a diagnosis of Sudden Infant Death Syndrome (SIDS)
- Allow comparison of SIDS and sudden, unexpected death cases in different locales.

The regulation should continue without modification.

Amendment of 86-1.89 of Part 86 of Title 10 (Supplemental Distributions of Regional Professional Education Pools)

Statutory Authority:

PHL § 2807-m(5)

Description of the regulation:

This regulation defined “reform goals” for the Supplemental Distribution of Regional Education Pools and specified the method of distributing funds to the pools. This rule was repealed in 2011 as part of the 2009/2010 Executive Budget implementation.

Addition of Subpart 86-8 of Part 86 of Title 10 (Rates of Payment for Limited Home Care Agencies)

Statutory Authority:

Laws of 1995, Chapter 81, section 105-d as amended by Laws of 1997, Chapter 433, section 69

Description of the regulation:

The regulation establishes a rate of payment for limited home care services agencies to reduce Medicaid expenditures for certain personal care services furnished to eligible residents of an adult home or enriched housing program. It provides reimbursement directly to the limited home care services agency rather than an outside personal care provider or certified home health agency. The regulation should continue without modification.

Amendment of Subpart 98-1 of Title 10 (Managed Care Organizations)

Statutory Authority:

PHL Article 44

Description of the regulation:

Article 44 was amended by Chapter 649 and 705 of the Laws of 1996, Chapter 433 of the Laws of 1997 and Chapter 659 of the Laws of 1997 in relation to Medicaid managed care, managed care consumer rights and managed long term care programs. The amendments changed the title and clarified the department's authority over specified forms of managed care organizations, including primary care partial capitation providers, HIV special needs plans and managed long term care plans. The regulations removed obsolete provisions and provided clearer guidance to the health care industry concerning certification and operational requirements for managed care organizations. This regulation should continue without modification because it is necessary for the operation of managed care programs in NYS.

Amendment of Sections 128-1.6 and 128-3.8 of Title 10 (New York City Watershed Rules and Regulations)

Statutory Authority:

PHL §§ 1100-1103

Description of the regulation:

The Department adopted amendments to NYC's Watershed Rules and Regulations at New York City's request for the purpose of protecting the water quality of NYC reservoir sources. These amendments were also necessary for NYC to maintain the "filtration avoidance" issued by U.S.

Environmental Protection Administration and NYSDOH for the City's Catskill/Delaware sources. Due to recent federal and state regulatory changes and in order to implement new “filtration avoidance” mandates, these regulations should be amended. The Department plans to propose amendments to this regulation that will continue to protect NYC’s watersheds and preserve NYC’s Filtration Avoidance Determination (FAD). This regulation should continue until the proposed amendments are adopted.

Amendment of Section 131.1 of Title 10 (City of Syracuse-Watershed Rules and Regulations)

Statutory Authority:

PHL § 1100

Description of the regulation:

The Department adopted amendments to the City of Syracuse's Watershed Rules and Regulations at Syracuse's request for the purpose of protecting the water quality of Syracuse's Skaneateles Lake source. These amendments were also necessary for the City of Syracuse to maintain “filtration avoidance,” previously issued by the Department for this source. These regulations should continue without modification.

Addition of new Section 400.10 to Part 400; Addition of new subdivision (f) to 763.11, new subdivision (o) to 766.9 and new subdivision (n) to 793.1 of Title 10 (Health Provider Network (HPN) Access and Reporting Requirements)

Statutory Authority:

PHL §§ 2800, 2803, 3612 and 4010

Description of the regulation:

This regulation required Article 28 facilities, home care facilities and hospices to establish and maintain health commerce system (HCS) accounts with the Department of Health for the purpose of exchanging information with the Department in a rapid and efficient manner in times of emergency or urgent matters. The HCS is a secure web-based application that can be utilized by facilities to receive current and up-to-date information as well as submit data to specialized programs for reporting or surveillance purposes. In times of emergencies or urgent matters, such as disease outbreaks, it is imperative that facilities receive from and submit to the Department information in a rapid, efficient manner. The HCS, a free service, is the best means to ensure this exchange of information. This regulation should continue with the above noted technical modification to the System’s correct name.

Amendment of Section 400.18, Appendix C-4 & C-5 of 400.18 and Section 405.27 (Emergency Department Data Collection by SPARCS)

Statutory Authority:

PHL § 2816

Description of the regulation:

Section 400.18 regulates the operation of the Statewide Planning and Research Cooperative System (SPARCS). The Department intends to repeal the current Section 400.18 and a new Section 400.18 will be promulgated. The reasons for the complete revision are to delete obsolete language and to update the regulation. The new Section 400.18 will authorize SPARCS to collect additional outpatient data not currently being collected by SPARCS from general hospitals and diagnostic and treatment centers licensed under Article 28 of the Public Health Law. This regulation should continue until it is amended.

Amendment of Sections 405.21, 407.14, 708.2, 708.5, 711.4 and Addition of new Part 721 of Title 10 (Perinatal Regionalization)

Statutory Authority:

PHL §§ 2500, 2800, 2803(2) and 2803-j

Description of the regulation:

These regulatory changes updated previous requirements for maternal and newborn care, and formalized perinatal regionalization and designation requirements. The new Part 721 was added to collect in one section all the regulations governing the perinatal regionalization system, which had been divided among several sections of the New York State Hospital Code. The regulatory changes also described the kinds of resources that should be available for different levels of hospitals, and deleted outdated appropriateness-review standards used in the 1985 designation of hospitals at different levels of high-risk neonatal care.

These regulations govern the perinatal regionalization system, in which Regional Perinatal Centers (RPCs) coordinate the perinatal delivery system within their region; provide critical care and transport of pregnant women and infants; provide specialty care, including pediatric open heart surgery; and oversight of quality improvement activities within affiliate hospitals. Perinatal regionalization plays a critical role in reducing maternal and newborn morbidity and mortality.

Section 405.21 for hospital-based perinatal services was amended to support perinatal regionalization efforts, and to clarify and simplify some other existing regulatory requirements.

Sections 407.14, 711.4(d)(21) and (e)(10) were amended to reflect the change in terminology in section 405.21 in which hospital-based "maternity and newborn" services began to be referred to as "perinatal" services.

Section 708.2(b)(6) and Section 708.5(f) were repealed since new Part 721 integrated the requirements for perinatal re-designation and regionalization in one section.

Part 721 defines the perinatal regionalization system including requirements for affiliation agreements between Levels I, II and III hospitals and regional perinatal centers (RPCs), staffing requirements and quality improvement activities. The regulations formalize the designation process, update the Department of Health expectations for resources to be available at each level of care, and clarify the relationship between Levels I, II, and III programs and RPCs.

Amendments to these regulations have been proposed. In particular:

405.21 Perinatal Services - Perinatal hospital standards to be reviewed and updated to be consistent with national authorities based on a literature review and input from an expert workgroup of clinicians and key stakeholders. The regulations will address the professional qualifications of the obstetric and pediatric staff, the requirements for consultation with a qualified specialist when required by specific medical conditions, protocols and resources available to stabilize and assess newborns for their need of neonatal intensive care, and the daily care of maternity patients and infants in the perinatal service.

721.4 Statewide Perinatal Regionalization System - Perinatal hospital standards to be reviewed and updated to be consistent with national authorities based on a literature review and input from an expert workgroup of clinicians and key stakeholders. The regulations will provide definitions and requirements for level of care designations as well as patient care and patient transfers, qualifications and responsibilities of staff and ancillary personnel, quality improvement activities, and affiliation and transfer agreements.

Amendment of Sections 703.6 and 710.1 of Title 10 (Part-Time Clinics)

Statutory Authority:

PHL § 2803(2)

Description of the regulation:

Since its issuance in 2005, the current regulation has proven adequate to help ensure that services provided in part-time clinics are appropriate to those settings, and that the existing number of part-time clinics is sufficient to promote access to needed care. The regulation has also guarded against the operation of an excess number of part-time clinics, which occurred in some parts of the State prior to the amendment of the rule. The regulations should continue without modification.

Amendment of Sections 708.2, 708.5 and 709.16 of Title 10 (Review Criteria for Therapeutic Radiology)

Statutory Authority:

PHL § 2803(2)

Description of the regulation:

The regulations establish a methodology to be used to evaluate public need for therapeutic radiology devices as affected by prevailing medical practice in the use of these devices for curative and palliative care.

The Department intends to repeal this regulation as technological advances in the last 15 years have made it no longer necessary.

Amendment of Sections 709.16 and 709.17 of Title 10 (Need Methodology for Long-Term Ventilator Beds in Nursing Homes)

Statutory Authority:

PHL § 2803(2)

Description of the regulation:

The current regulation provides a methodology to be used in the evaluation of certificate of need applications for certification of long term ventilator beds. Since its issuance in 2005, the regulation has ensured that long-term ventilator beds are distributed throughout the State in a manner that both provided sufficient access to care and guarded against the costs associated with the operation and maintenance of beds in excess of those needed.

The regulation should continue with modification. The Department intends to amend this regulation in keeping with medical and technological advances that have occurred over the last 15 years.

Amendment of Section 763.13, Section 766.11 and addition of new Section 400.32 to Title 10 and amendment of Section 505.14 of Title 18 (Criminal History Record Check)

Statutory Authority:

PHL §§ 201, 2803 and 3612 and Social Services Law (SSL) § 363-a

Description of the regulation:

Section 400.23 related to the criminal history record check program and was repealed on December 19, 2007. It was replaced by Section 402 which implemented the statutory criminal

history record check program defined in PHL Article 28-E. Sections 763.13, 766.11 of Title 10, and the amendment of Section 505.14 of Title 18 added a criminal background check requirement under Section 402. Although the CHRC program had been covered by emergency regulations since August 2006, permanent regulations became effective on December 2, 2009. The regulation should continue without modification.

Title 18 NYCRR - Fifteen Year Review

Amendment of 360-4.10(a)(9) of Title 18 (Spousal Impoverishment Budgeting)

Statutory Authority:

SSL § 366-c (2)(d)

Description of the regulation:

This regulation clarified that the community spouse's pension/retirement funds are resources of the community spouse which are to be included for purposes of determining the community spouse resource allowance and determining the institutionalized spouse's Medicaid eligibility. These funds are considered otherwise available to the community spouse under spousal impoverishment budgeting rules. This regulation should continue without modification.

Amendment of Section 486.2 and 486.5 of Part 486 of Title 18 (Adult Care Facility Inspection Reports)

Statutory Authority:

SSL §§ 460 and 461

Description of the regulation:

These amendments changed the requirement that an adult care facility inspection report include areas where the facility met or exceeded compliance with regulation and also steps for rectification of violations. The amendment provides that a report need only include a statement attesting that areas reviewed are deemed to be in compliance with applicable requirements if no violation is noted. The report may also include directions as may be appropriate as to the manner and time in which compliance with applicable requirements of law and regulation of the Department shall be effected. The regulations should continue without modification.

Addition of new subdivision (k) to Section 487.12, new subdivision (m) to Section 488.12 and new subdivision (k) to Section 490.12 of Title 18 (Health Provider Network (HPN) Access and Reporting Requirements – Adult Facilities)

Statutory Authority:

SSL §§ 460 and 461

Description of the regulation:

This regulation required adult homes, enriched housing programs and residences for adults to establish and maintain Health Commerce System (HCS) accounts with the Department

of Health for the purpose of exchanging information with the Department in a rapid and efficient manner in times of emergency or urgent matters. The HCS is a secure web-based application that can be utilized by facilities to receive current and up-to-date information as well as submit data to specialized programs for reporting or surveillance purposes. In times of emergencies or urgent matters, such as disease outbreaks, it is imperative that facilities exchange information with the Department in a rapid, efficient manner. The HCS, a free service, is the best means to ensure this exchange of information. This regulation should continue with the above noted technical modification to the system's correct name.

Amendment of Section 505.5 of Part 505 of Title 18 (Medicaid Enteral Nutrition Reimbursement Methodology)

Statutory Authority:

PHL § 230(1)(a)

Description of the regulation:

This methodology remains appropriate and consistent with the payment policy of other medical care insurers on this subject. This regulation should continue without modification.

Title 10 NYCRR – Twenty Year Review

Amendment of Parts 2 and 23 of Title 10 (Communicable Diseases)

Statutory Authority:

PHL §§ 225(4) and (5)(a), (g) and (h)

Description of the regulation:

This regulation protected the public health by permitting closer monitoring of communicable diseases. Diseases and infections of substantial public health importance were added to the list of communicable diseases that must be reported to public health authorities and/or require specimen submission for laboratory testing. These changes facilitated the diagnosis and treatment of disease and implementation of preventive measures to stop the spread of disease. In addition, the regulation eliminated from both the reporting list and the list of diseases requiring specimen submission diseases that were no longer of significance. In addition to rabies, clarification of reporting, prevention and control measures and treatment procedures were also made for emerging infections such as West Nile virus, and Severe Acute Respiratory Syndrome (SARS). The regulation was amended in 2005 to add confirmed influenza to the list of reportable communicable disease. These regulations should be retained without modification. The Department intends to amend the list of reportable communicable diseases in Part 2 in the future.

Amendment of Subparts 6-1 and 6-2 of Title 10 (Swimming Pools and Bathing Beaches)

Statutory Authority:

PHL §§ 225(4) and 225(5)

Description of the regulation:

Prior to the amendments, the regulation stated that temporary residence/campground bathing facilities were not required to provide lifeguards for their bathing facilities in 1991 or 1992 and may provide supervision through patron use rules and signage or a responsible person, depending on the level of supervision required at that time. The amendments allowed all temporary residence and campground operators, except those with ocean surf beaches, to select the level of supervision at swimming pools and bathing beaches operated as part of their temporary residence or campground, regardless of the supervision level provided in 1991 or 1992. The amendments provided a uniform standard allowing the same opportunity for selection of bathing facility supervision at all regulated temporary residences and campgrounds in the state, eliminating the differential standards that existed in the State. Also, the amendments clarified the intent, by specifying that parents, guardians, or similar adults must accompany

children less than 16 years of age to a Supervision Level IV bathing facility. The regulation should continue without modification.

Amendment of Sections 12.2, 12.3, 12.13 and 23 of Title 10 (Regulation Affecting Nurse Practitioners, Licensed Nurses and Midwives)

Statutory Authority:

PHL § 225

Description of the regulation:

Amendments to these regulations were adopted to bring these provisions into conformance with amendments to Articles 139 (Nursing) and 140 of the Education Law (Midwife Practice Act). Article 140 of the Education Law, enacted in 1992, defined and established licensure and practice standards for the practice of midwifery. Those amendments rendered several provisions of the Department's regulations either obsolete or inconsistent with the new law. The regulations should continue without modification.

Repeal of Subpart 24-1 of Title 10 (AIDS Reporting)

Statutory Authority:

PHL §§ 225(4) and 225 (5)(a)

Description of the regulation:

This regulation deleted provisions to conform to Part 63 amendments requiring HIV and AIDS case reporting. The deletions continue to be necessary. The regulation should continue without modification.

Amendment of Parts 36, 58, 66, 69, 82, 85 and 766 of Title 10 (Nurse Midwives)

Statutory Authority:

PHL §§ 576, 2164, 2500-a, 2522(6) and 4175; SSL §§ 364(2) and 365-a

Description of the regulation:

Amendments to these regulations were adopted to bring these regulations into conformance with the amendments to Articles 139 (Nursing) and 140 of the Education Law (Midwife Practice Act). Article 140 of the Education Law, enacted in 1992 defined and established licensure and practice standards for the practice of midwifery. Those amendments rendered several provisions of the Department's regulations either obsolete or inconsistent with the new law. This regulation should continue without modification.

Amendment of Part 52 of Title 10 (Tissue Banks and Nontransplant Anatomic Banks)

Statutory Authority:

Article 43-B of the PHL

Description of the regulation:

This regulation details administrative and technical requirements pertaining to the collection, processing, storage, and distribution of tissue and nontransplant anatomic parts so as to protect the health of donors and recipients and advance the safety and utility of tissue and nontransplant anatomic parts for transplant, education, and research, as applicable.

The regulations should continue with modification. The regulation had not been amended since 2007 and amendments are proposed to re-organize the regulation to update categories of tissues and activities, their definitions and requirements to reflect advances in technology and changes in industry standards and medical practice; update requirements that need to be met for tissue bank directors; revise requirements for procurement of tissue from deceased donors, including setting restrictions on banks' ownership and business relationships with funeral directors and funeral firms, and limiting recovery of tissue to specific locations; revise requirements for reproductive tissue banking; clarify requirements for activities subject to FDA oversight; revise requirements for compensation of donors; clarify requirements for tissue-derived products; clarify language for license denial and add language for other enforcement procedures, including license revocation, to be consistent with public health law.

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

Statutory Authority:

PHL Article 31

Description of the regulation:

Subpart 58-2 amendments provided technical standards for NYS-permitted blood banks that collect, process, store, distribute and/or transfuse blood and blood components, and laboratories that perform related testing. The Department's efforts to ensure the safety of the blood supply and prevent adverse reactions in donors and transfusion recipients must be maintained through continuation of Subpart 58-2.

The regulation should continue without modification. Amendments will be proposed to clarify requirements for reinfusion procedures; modify the requirements for the collection and handling of blood for subsequent transfusion; establish requirements for the issuance of blood, blood components and derivatives during routine and emergency situations; revise donor qualifications, collection and testing requirements for whole blood, apheresis and serial plasmapheresis; update record retention requirements to be consistent with the FDA and industry standards; amend requirements for standard operating procedures; amend the standards for

transfusion and immunohematology testing requirements; clarify personnel and supervisory requirements for serial plasmapheresis and apheresis collection of blood components.; clarify requirements for transfusions that occur outside of a hospital setting and during interfacility transport; and revise criteria for exceptions to reflect industry standards.

Amendment of Part 63 of Title 10 (HIV/AIDS Testing, Reporting and Confidentiality of HIV Related Information)

Statutory Authority:

PHL §§ 2786 and 2139

Description of the regulation:

This regulation described the protocols and procedures required for HIV/AIDS testing, reporting and confidentiality of HIV related information. Revisions to specific sections of Part 63 are being proposed currently to implement revisions to PHL sections 2781 and 2135. The regulation should continue without modification.

Addition of Section 68.6 of Title 10 (Distributions from the Health Care Initiatives Pool for Poison Control Center Operations)

Statutory Authority:

PHL §§ 2500-d(7) and 2807-1(l)(c)(iv)

Description of the regulation:

This regulation described the methodology for distributing funds from the Health Care Initiatives Pool to regional poison control centers. The regulation should continue without modification.

Amendment of Section 80.132 of Title 10 (Hypodermic Syringes and Needles)

Statutory Authority:

PHL §§ 3308 and 3381

Description of the regulation:

This regulation designates persons or classes of persons who may obtain and possess hypodermic needles and syringes without a prescription for use within the scope of their professions or activities, subject to additional conditions as specified. The regulation implements Public Health Law section 3381(1)(b), which authorizes the Commissioner to designate such persons, and eliminates unnecessary barriers in the provision of care to patients and animals. This regulation should continue without modification. This regulation should continue without modification.

Amendment of Section 86-2.30 of Title 10 (PRI Instructions)

Statutory Authority:

PHL §§ 2803(2), 2807(3) and 2808

Description of the regulation:

This regulation modified the instructions for completing the PRI form to recognize certain medical treatments provided to persons newly admitted as nursing facility residents, and services provided by nurse practitioners and physician assistants.

This regulation should be repealed. The NYSDOH no longer uses from the Patient Review Instrument (RUGS-II) and has adopted the Minimum Data Set (MDS) and RUGS-III for measuring patient acuity, beginning with rates effective April 1, 2009.

Amendment of Sections 401.1 and 710.1 of Title 10 (CON Requirements for Acute Care Beds and Major Medical Equipment)

Statutory Authority:

PHL § 2803(2)

Description of the regulation:

This regulation addressed the removal of certificate of need review of transfers of beds and equipment within established Article 28 hospital networks. This regulation should continue without modification.

Amendment of Section 405.25 of Title 10 (Organ and Tissue Donation Anatomical Gifts)

Statutory Authority:

PHL §§ 2803 and 4351

Description of the regulation:

This regulation sets forth a hospital's responsibilities with regard to organ and tissue donation. Section 405.31 establishes the requirements for performing living donor transplants. Section 405.25 requires the hospital to establish appropriate protocols for contacting the proper organ procurement organizations (OPOs) when a patient is at or near death, and for selecting an OPO and eye and tissue banks, as well as a designated requester, with whom the hospital will work. Medicare Federal Conditions of Participation were considered when these regulations were developed, and the regulations reflect those conditions as well as the requirements of Article 43 of the Public Health Law. The Department intends to amend the regulations to conform to changes made to Article 43. These regulations should continue without modification while the amendments are being developed.

Amendment of Sections 600.3 and 710.5 of Title 10 (Requirements for Amendment of Approved CON Applications)

Statutory Authority:

PHL §§ 280-1-a(10)(a), 2808(2) and 2803(2)(a)

Description of the regulation:

This regulation simplified the certificate of need (CON) process related to the requirements for amendment of approved CON applications. Sections 600.3 and 710.5 have been further amended to reclassify additional changes which currently constitute “amendments” and thus require full review, so that they are instead considered to be “modifications” which are reviewed only by the Commissioner. The regulations should continue without modification.

Amendment of Section 710.1 of Title 10 (CON Requirements for Acquisition of Major Medical Equipment)

Statutory Authority:

PHL §§ 2808(2) and 2803(2)(a)

Description of the regulation:

This regulation amended CON requirements for acquisition of major medical equipment to simplify the purchase of additional equipment and replacement of such equipment by Article 28 facilities. This regulation should continue without modification.

Title 18 NYCRR - Twenty Year Review

Amendment of Section 360-3.2 of Title 18 (Finger Imaging for Medicaid Applicants/Recipients)

Statutory Authority:

Chapter 436 of the Laws of 1997

Description of the regulation:

This regulatory amendment made finger imaging an eligibility requirement for adults who apply for Medicaid and who are subject to the photo identification requirements established by the Department of Health. Chapter 58 of the Laws of 2009 eliminated the finger imaging requirement for Medicaid applicants/recipients. This amendment needs to be repealed.