

# REGULATORY AGENDA

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## Department of Health

The following regulatory actions are under consideration for submission as a Notice of Proposed Rulemaking from January through December 2019:

### DESCRIPTION OF THE RULE SUBJECT MATTER Title 10 NYCRR (Health)

2.1 Communicable Diseases - Modify the list of reportable diseases set forth in the New York State Sanitary code (10 NYCRR 2) to add new emerging infections and remove diseases that do not require a public health response. The addition of new or emerging cases to the list of reportable communicable diseases allows public health officials to prevent secondary transmission, identify new emerging infections, identify outbreaks and evaluate the effectiveness of control measures.

2.5 Communicable Diseases - Revise the list of reportable diseases in 10 NYCRR, section 2.5 (list of diseases for which physicians have a duty to submit specimens) to be consistent with those listed in section 2.1.

2.14 Communicable Diseases - Amend the regulations related to rabies to be consistent with changes enacted to the Public Health Law. The regulations will provide definitions and requirements for reporting human exposures, confinement of suspected animals and people exposed to them, quarantine of rabid animals or animals suspected of being rabid, and county responsibility for animal control related to rabies.

4 Protection Against Legionella – Amend Subpart 4-1 to revise and add definitions, provide additional specificity to the content of the maintenance program and plan, revise the sampling and inspection intervals, and amend other provisions. Amend Subpart 4-2 to clarify sampling intervals and revise provisions for reporting data and information collected as part of the environmental assessment form and the sampling and management plan.

5-1 Public Water Systems – Amend the regulation to incorporate maximum contaminant levels (MCLs) for several emerging contaminants that are not specifically regulated under the United States Environmental Protection Agency’s Safe Drinking Water Act or the State Sanitary Code (10 NYCRR Part 5), that have been detected in New York State public water systems, that present a potential public health concern, and that were the subject of an MCL recommendation from the NYS Drinking Water Advisory Council. Additionally, amend the regulation to correct minor grammatical/typographical errors and erroneous citations.

6-1 Swimming Pools – Amend the regulation to update the swimming pool design and operation standards, using the Centers for Disease Control and Prevention’s Model Aquatic Health Code as a guide. This will modernize the design standards, which were last updated in 1988, and provide consistency with national standards that are based on science and best practices.

6-2 Bathing Beaches - Amend the regulation to incorporate the recreational water quality criteria for bacterial pollution and toxins required by the United States Environmental Protection Agency (EPA) to make New York’s regulations consistent with EPA requirements.

14 Food Protection - Amend the regulation to consolidate all current subparts by adopting Chapters one through seven of the United

States Food and Drug Administration (FDA) Model Food Code. Adopting the technical content of the Model Food Code will address the requirements of the Chapter Laws of 2001 and 2007, modernize Part 14 which was last amended in 1997, and provide consistency with national standards. The amendments will also promote uniformity among local health departments, many of which have already established local requirements more consistent with the FDA Model Food Code.

16 Ionizing Radiation - Amend the regulation to conform with Public Health Law Article 35, which creates an exception to the general rule that a license is required to apply ionizing radiation to humans (i.e., operate x-ray machines or related equipment). Article 35 was amended through legislation (Bill No.: A06838, S5337) in October 2018. Under the new exception, county and New York City correctional facility staff do not need a license to operate body imaging scanning equipment. The legislation mandates the Department (and New York City Department of Health and Mental Hygiene) develop regulations governing the equipment and use within 120 days of the legislation, and prior to using x-ray body imaging scanning equipment, the chief administrative officer must ensure that the facility has complied with the Department’s regulations including training requirements for staff who will use such equipment. Safety standards will be incorporated in the radiation safety regulation of 10 NYCRR 16 and an exemption for practice will appear in 10 NYCRR 89.

Additionally, amend the Part 16 regulations to reflect consistency with federal regulations and mandates applicable to industrial use of radioactive material, radiation protection standards, security for high-risk radioactive sources, and license termination/decommissioning standards. The amendments will update the quality assurance requirements for diagnostic x-ray equipment to align with current equipment and imaging modalities to ensure patient safety. The amendments will consolidate current requirements in 12 NYCRR 38 (NYS Department of Labor Ionizing Radiation) into 10 NYCRR 16, consistent with the merger of the NYS Department of Labor Radiological Health unit into the New York State Department of Health’s Center for Environmental Health’s Bureau of Environmental Radiation Protection program. Finally, the amendments will organize 10 NYCRR 16 into subparts and incorporate relevant Title 10 Code of Federal Regulations (CFR) provisions by reference for specific sections.

19 Clinical Laboratory Directors - Revise qualifications for directors of clinical laboratories to recognize professional boards accepted as qualifying under the federal Clinical Laboratory Improvement Amendments (CLIA); codify the definitions of assistant director, earned doctoral degree, training, and experience; codify the ability of the department to issue certificates of qualifications (CQ) with limitations; and revise responsibilities of directors.

22.7 Reportable Levels of Heavy Metals in Blood and Urine - Amend the regulation to remove the threshold levels for reporting cadmium, mercury and arsenic. All laboratory tests for cadmium, mercury and arsenic will be submitted to enable case monitoring to assist in assessing interventions and education to reduce elevated exposures.

22 Environmental Diseases - Amend the regulation to define the New York State Birth Defects Registry and program, and to describe

how reports of birth defects diagnosed in NYS are received, maintained, shared, and used by the Department. The Department's New York State Birth Defects Registry is used to conduct epidemiological investigation and surveillance and to inform public health initiatives that seek to reduce the burden of birth defects in NYS. Amend Section 22.2 to correct a grammatical error regarding birth weight.

40-2 Performance Standards and Minimum Requirements for Core Public Health Services - Amend the regulation by adding section 40-2.59 Cooling Towers. The objective of this amendment is to conform to regulatory changes which were adopted into the New York State Sanitary Code, effective July 6, 2016.

40-2.57 Environmental Health Exposure Investigation, Assessment and Response; Performance Standards - Amend the regulation by correcting a wording omission and to clarify technical terminology.

46 Physically Handicapped Children - Amend the regulation to update and clarify coverage of medical and orthodontic services to children under the age of 21 years under the Physically Handicapped Children's Program. The proposed amendments will allow the inclusion of specific orthodontic procedures and criteria in the Department's Medicaid Dental Provider Manual.

52 Tissue Banks and Nontransplant Anatomic Banks – Amend the regulation to update categories of tissues and activities, their definitions and requirements to reflect advances in technology and changes in industry standards and regulations; 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 hospitals and appropriately licensed banks; clarify language for license denial and add language for other enforcement procedures to be consistent with public health law.

55-2 Approval of Laboratories Performing Environmental Analysis - Amend the regulation 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 update the definition of Quality System Standards to reference the most up-to-date standards; clarify that regulated analytes exclude analytes considered process controls by other state regulatory agencies and update qualifications for contract laboratory protocol personnel to establish consistency with Department of Environmental Conservation (DEC).

55-3 Environmental Laboratory Approval Fee – Amend the regulation to revise the timeline for setting fees charged to environmental laboratories to reflect the State budget process.

57 Rabies - Dogs at Large in Rabies Areas - Repeal this regulation as it is outdated since rabies is endemic in wildlife in New York. Important provisions will be included in section 2.14.

58-1 Clinical Laboratories – Amend the regulation to revise laboratory personnel requirements to reflect industry standards and NYS Education Department licensure requirements; revise clinical laboratory supervision requirements; update persons authorized by law to request the examination of specimens; clarify requirements for the issuance of permits, provisional permits and restricted permits; clarify mandatory on-site presence requirements for laboratory directors; clarify enforcement actions for failure to notify the Department of changes in laboratory directorship; consolidate existing requirements for clarity; codify quality systems, performance testing and other requirements as necessary to align with federal CLIA standards; clarify assistant director responsibilities; establish standards for tracking and referral of critical agent and communicable disease specimens; establish standards for demonstrating the technical and clinical validity of test methods; codify the requirements for retention of work product used in diagnostic interpretation; revise cytotechnologist workload standards to comply with federal CLIA standards; require that the address of the patient be captured on the accessioning records and the laboratory report to comply with 10 NYCRR Part 2 for reporting of communicable diseases.

58-2 Blood Banks and Laboratories Performing Immunohematology Testing - Amend the regulation to 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.

58-3 Clinical Laboratory Inspection and Reference Fees – Amend the regulation to clarify the definitions of gross annual receipts and prevailing rate for testing services; clarify reportable gross annual receipts for laboratories located outside New York; and revise the requirements for payment of travel expenses for laboratories located outside New York.

58-5 Hematopoietic Progenitor Cell Banks - Update requirements for donor suitability determination, infectious disease testing, and record keeping related to hematopoietic progenitor cell (HPC) donation and transplantation. Amend the regulations to require the HPC bank medical director to establish a policy regarding testing allogeneic donors for West Nile virus, Trypanosoma cruzi, and hemoglobinopathies.

58-8 Human Immunodeficiency Virus (HIV) Testing - Amend regulations to provide consistency with HIV testing requirements in Public Health Law and supporting regulations in Part 63. Address updated technologies and revise testing algorithms for the management of HIV.

59 Chemical Analysis of Blood, Urine, Breath or Saliva for Alcoholic Content – Amend the regulation to update requirements for blood alcohol testing described in section 59.3; update the list of approved evidential breath measurement devices listed in section 59.4; update section 59.10 to be consistent with current model specifications adopted by the National Highway Traffic Safety Act (NHTSA) as published in the Federal Register on May 8, 2013 (78 Fed. Reg. 26849 – 26867); and add language that allows the delegation of authority by the commissioner to others in the Department.

60-1 WIC Program - Amend regulations to clarify or add definitions and update terminology as needed to accurately describe eWIC transactions in this section and throughout subpart 60-1. Amend to eliminate participant and vendor violations made obsolete by eWIC; and add provisions pertinent to eWIC. Further amend section 60-1.7 to establish two new participant program violations. Further amend section 60-1.8 to remove fixed limits on monetary penalties and periods of disqualification for vendors. Amend such that 60-1.11 exclusively addresses hearings concerned with disciplinary actions (i.e., disqualification or imposition of a civil money penalty or fine), and section 60-1.12 exclusively addresses hearings concerned with actions that affect contract status (i.e., denial of an application or termination of a contract). Amend section 60-1.13 to incorporate all federal vendor enrollment criteria by reference; strengthen business integrity provisions such that a history of multiple civil money penalties (CMPs) is grounds for application denial; and grant the Commissioner of Health or his/her designee authority to define participant access criteria and vendor limiting criteria in program policy.

60-1.13 Vendor Applicant Enrollment Criteria - Amend regulations to conform to USDA program requirements regarding vendor authorization and management including vendor participant ratio, geographic proximity and transaction volume of nearby vendors.

63.4 Filing of Reports – Amend current regulations that require the reporting of persons with HIV infection and AIDS to NYSDOH from 14 days to 24 hours.

66-1.1 Immunization - Amend Subpart 66-1 (School Immunization Requirements) to update the version of the Advisory Committee on Immunization Practices (ACIP) recommended immunization schedule, incorporated by reference into the regulation, to the most recently published version. The ACIP recommended immunization schedule is updated annually and the school immunization requirements should reflect the most current schedule to ensure that New York State requirements are consistent with national standards.

66-2.1 through 66-2.9 Immunization - Amend regulations to be consistent with current Advisory Committee on Immunization Practices

and Centers for Disease Control and Prevention vaccine recommendations. The regulation will be amended to require two doses of mumps-containing vaccine for attendance at a post-secondary institution. Language regarding certificates of immunization will be amended to remove physician diagnosis of mumps and/or measles disease and add laboratory confirmation of mumps, measles and rubella disease. In addition, language regarding attendance requirements, non-compliance, exclusion criteria, and exemptions will be clarified and expanded.

67-4 Lead Testing in School Drinking Water – Establish regulations for all school districts and boards of cooperative educational services (BOCES), including those already classified as a public water system under Subpart 5-1, to test potable water for lead contamination and to develop and implement a lead remediation plan, where applicable.

69-2 Umbilical Cord Blood Testing - Amend regulations to reflect recent changes in laboratory practices for the diagnosis of syphilis.

69-4 Early Intervention Program - Amend the regulations, as needed, to comply with 34 CFR Parts 300 and 303. Contingent on approval by the Centers for Medicare and Medicaid Services of an amendment to the Medicaid State Plan, revise 10 NYCRR 69-4.30 to authorize the commissioner to establish a fixed payment methodology for service coordination services. Amendments also may be needed to ensure quality and consistency of EI service delivery.

69-8 Newborn Hearing Screening - Amend the regulation to align with 2010 changes to Public Health Law section 2500-g regarding reporting of infant hearing screening by licensed health care professionals, and collection and use of such data by the Department.

70 Regulated Medical Waste - Revise the requirements for the labeling of regulated medical that will be transported off-site for treatment to be consistent with requirements of the United States Department of Transportation (USDOT) and New York State Department of Environmental Conservation (NYSDEC). Part 70 currently requires the labeling of primary container with the name and address of the generator if the waste is transported off-site for treatment. USDOT and NYSDEC regulations do not require this label if the primary container will be placed in a secondary container that is a bulk container used by a single generator.

71 Requirements for Vent-Free Gas Space Heating Appliances - Amend the regulation to modify language requirements for an appliance shipping carton label as defined by Section 71.3(a). Notable changes include updates to the language on the shipping carton label to reflect requirements mandating installation of a carbon monoxide detector with the use of fuel burning appliances in residential and commercial settings (Executive Law Section 378 Standards for New York State Uniform Fire Prevention and Building Code (Uniform Code) 5-a and 5-d) and enhancement of consumer education about proper use and maintenance.

72-1 Tanning Facilities - Amend the regulations to improve clarity and to conform with a 2018 amendment to Public Health Law Article 35-A, prohibiting the use of commercial ultraviolet indoor tanning devices by minors, and modifying the definition of Tanning Facility to include establishments that do not charge a direct or indirect fee for tanning services.

72-2 Body Art - Establish regulations to be consistent with Public Health Law Article 4-A, Regulation of Body Piercing and Tattooing. The regulations will provide definitions and requirements for permit, inspection, ink handling procedures (as approved by the Department), operation of tattooing facilities, and the licensing of tattoo artists.

73 Asbestos Safety Training Program Requirements - Amend the regulations to incorporate changes made by the New York State Department of Labor to 12 NYCRR Part 56 as well as changes that have occurred in the industry that should be reflected in the training programs.

74 Approval of Realty Subdivisions - Amend the regulation to update and clarify requirements for plan submittals and approvals of realty subdivisions.

80 Controlled Substances - Amend the regulations related to the Prescription Monitoring Program (PMP) Registry for collecting, monitoring and reporting data concerning the prescribing and dispensing

of controlled substances. Amended regulations also will supplement recently adopted regulations that reflect statutory changes requiring the use of electronic prescribing for all prescriptions with limited exceptions; will relate to the treatment of narcotic addiction and associated requirements to allow for the ability to treat a greater number of patients by authorized physicians in conformance with federal regulations; will update reporting requirements for Methadone Maintenance Treatment Programs to conform to changes made to Public Health Law section 3352; will relate to the storage, surrender and disposal of controlled substances; will outline the training requirements associated with certification of Euthanasia technicians (for animals) as required by section 374(3)(b) of the Agriculture and Markets Law; will allow for interstate sharing of PMP information; will amend regulations related to the disposal of medications and will update exceptions, reclassification and exemptions of scheduled controlled substances.

83-2 Certificate of Public Advantage – Amend the regulations to revise provisions related to issuance of a Certificate of Public Advantage.

85.13 Physically Handicapped Children - Repeal the regulation thereby allowing providers outside of the Physically Handicapped Children's Program to provide hearing assessments and order hearing aids for Medicaid eligible children.

86-1 Rebase Hospital Inpatient Rates – Amend the regulation to implement an updated cost base year in the acute hospital inpatient rates for non-comparable costs and to provide reimbursement to hospitals for residents that are displaced due to a teaching hospital closure.

86-1.13 Certified home health agency rates – Amend the regulation to allow for minimum wage costs.

86-1.15 Definitions – Amend the regulation to allow for additional costs to be included in the acute rate method due to the increase in the minimum wage.

86-1.20 Add-ons to the case payment rate per discharge – Amend the regulation to allow for additional costs to be included in the acute rate method due to the increase in the minimum wage.

86-1.21 Outlier and transfer cases rates of payment – Amend the regulation to clarify the temporary rate change policy.

86-1.23 Exempt Units and Hospitals – Amend the regulation to allow for (1) additional costs to be included in the Critical Access Hospital and Medical Rehabilitation Exempt Unit rates method due to the increase in the minimum wage, (2) pediatric ventilator services in the Medical Rehabilitation Exempt Unit rate and (3) specialized services within the Psychiatric Unit rate.

86-1.23 Exempt Units and Hospitals - Amend the regulation for an adjustment to the physical medical rehabilitation rate calculation for pediatric ventilator services.

86-1.31 Mergers, acquisitions and consolidations – Amend the regulation to clarify the temporary rate change policy.

86-1.46 Empire Clinical Research Investigator Program (ECRIP) – Amend the regulation to update the qualifications of researchers as project directors in teaching hospitals for ECRIP and remove the language that prohibits teaching hospitals from funding clinical research positions that were previously funded by such teaching hospital.

86-1.47 Hospital Indigent Care Pool Payments - Amend the regulation to extend the Indigent Care Pool Methodology from January 1, 2019 through December 31, 2019.

86-1.48 Hospital Quality Pool – Add regulations to establish the hospital quality pool to be consistent with the recently enacted changes to the Public Health Law. The regulation will provide the methodology for distribution and the requirements for maintaining payments from the pool.

86-1.49 Sole Community Hospital Enhanced Payments – Add regulations to establish the sole community hospital enhanced payments to be consistent with the recently enacted changes to the Public Health Law. The regulation will define what hospitals are eligible and provide the methodology for distribution.

86-2 Nursing Home Quality Incentive - Amend the regulation to

provide an incentive for nursing homes to improve quality by linking payments to quality.

86-2 Young Adult Special Populations Programs: Add regulations to provide for up to three young adult special populations demonstration programs to provide cost effective, necessary services and enhanced quality of care for targeted populations. The targeted population shall be those persons age twenty one to thirty five; are aging out of a pediatric acute care hospitals, pediatric nursing homes or children's residential homes; and have been diagnosed with severe and chronic medical or health problems which may be combined with developmental disabilities.

86-2.9 Adult Day Health Care Real Property Lease Reimbursement - Amend the regulation to allow for reimbursement for Adult Day Health Care real property leases under limited circumstances.

86-2.10 Computation of Basic Rate - Amend the regulation to remove transportation expense as an allowable cost in the base. Additionally, the regulation will be amended to recognize the addition of a new Neurodegenerative specialty to care for residents with Huntington's disease (HD) and Amyotrophic Lateral Sclerosis (ALS).

86-2.40 Statewide Prices for Non-Capital Reimbursement - Amend the regulation to update the nursing home reimbursement prices to reflect the removal of transportation as an allowable cost and to revise the prices sufficient to restore into the base half of the ATB rate cut. Shall also include a provision to recognize minimum wage increases.

86-2.40(a) Include Specialty Units in Nursing Home Reserve Bed Day - Amend the regulation to include specialty units when specifying that reserve bed days will be used in nursing home calculations that include total bed days.

86-4.9, 86-8.14, 401.2 Physician Home Visits for Hospitals and Clinic - Amend the regulations to allow primary care services to be provided offsite by all Article 28 outpatient departments of general hospitals and Diagnostic and Treatment Centers (D&TCs) and both to be reimbursed consistent with what is currently allowed for Federally Qualified Health Centers (FQHCs), which is a subset of the D&TCs.

Regulations are in final draft that implement PHL 2803(11), which authorizes provision of primary care in the home by staff from hospital-based outpatient locations and D&TCs. These regulations will modify Sections 405 and 751.

86-4.21 - Allowable Costs - Amend the regulation to allow for additional costs to be included in the Ambulatory Payment Group and Federally Qualified Health Center's rate method due to the increase in the minimum wage.

86-4.33 - Safety Net Payment - Addition of a regulation for the qualifications and distribution method of the Safety Net Payment for freestanding Article 28 and Article 31 clinics.

86-6.2 Hospice Non-Residence Rates - Amend the regulation to include a description of the service intensity add-on for services provided by a registered nurse or social worker during the last 7 days of a beneficiary's life, as required by Federal changes.

86-7 ALPs Billing for Assessment - Add regulations to provide for reimbursement of the cost of preadmission assessments conducted directly by assisted living programs.

86-7.2 Computation of the rate of payment - Amend the regulation to allow for added costs as part of minimum wage.

86-7.3 Adjustments to Rates of Payment - Amend the regulations to allow for rebasing of ALP provider rates.

86-8.4 Capital Cost Reimbursement - Add regulations to revise the capital component reimbursement methodology of Article 28 Free-standing Clinics.

86-8.8 Base rates - Amend the regulation to allow for additional costs to be included in the Ambulatory Payment Group base rates due to the increase in the minimum wage.

86-10 Interim Funding for High Cost Individuals - Amend regulations to reflect availability of interim funding to providers for individuals with high cost staffing needs. Funding would be available until cost for serving the individual is reflected in their cost reporting.

86-10 Rate Rationalization for Community Residences (CRs) / Individualized Residential Alternatives (IRAs) Habilitation and Day Habilitation -

Amend the regulation to allow for minimum wage costs.

86-10 Rates for "Take-Over" of Another Agency - Amend regulations to revise reimbursement methodology when ceasing operations of another agency.

86-10 and 86-13 Rates for Specialized Funding - Amend regulations to authorize the shift of funding for services from BIP to the HCBS waiver due to limited BIP funding. Date may be extended from October 1, 2015 back to April 1, 2014.

86-10 Clinical Rate Change - Amend regulations to revise rates regarding direct hands-on therapies, nutrition, and psychology services.

86-11 Rate Rationalization for Intermediate Care Facilities for Persons with Developmental Disabilities (ICF/DDs) - Amend the regulation to add Children's Residential Program Fees and Active Treatment.

86-11 Specialty Hospital - Add regulations to provide for reimbursement of Specialty Hospital services.

86-13 Rate Rationalization for Prevocational Services (Site-Based and Community-Based), Respite (Hourly), Supported Employment and Residential Habilitation (Family Care) - Amend the regulation to allow for minimum wage costs.

86-13 Respite Rate Caps - Amend regulations to create a new methodology to address caps on respite and enhance access to services.

86-13 Correction to Prevocational Rate - Amend regulations to remove production costs from prevocational rate methodology, effective 7/1/16.

96 License and Registration - Amend the regulations making technical corrections to clarify and update the licensure program. Specifically: amend (1) 96.1 to delete the advisory council language as it is no longer considered necessary; (2) 96.2 to add language that the Board shall have the administrative authority to waive any provision of this subpart if determined appropriate by the board in its sole discretion; (3) 96.5 to include the provision of the applicant's fingerprints and required criminal history information review by the board and add other clarifying language; (4) 96.1 to correct spelling; (5) 96.3 to add language that certificates of registration shall be signed by the commissioner or the commissioner's designee; (6) 96.4, to revise language to change the registration process from the BENHA board's responsibility to the Department's responsibility and update the registration language to current terminology; (7) 96.5, to make technical corrections and change the exam trial period for applicants; (8) 96.8, to add language to define the acceptable course levels; (9) 96.9, to remove the requirement that approved courses will appear on a listing; (10) 96.11, to add language to define the continuing education requirements; (11) 96.12, to add language to broaden the qualifications for out-of-state applicants, add secure electronic delivery language and change the exam trial period for applicants; (12) 96.13, to update notification language with email and primary telephone language.

98-1 Various Technical Amendments - Revise the following regulations, making technical corrections: (1) 98-1.9(b)(3), requiring managed care organizations (MCOs) to provide assurances of continuing compliance with Article 49 of the Public Health Law, in addition to Article 44 and Part 98; (2) 98-1.11(h), restoring language that prohibits health maintenance organizations (HMOs) from discriminating in enrollments and services provisions; (3) 98-1.11(k)(4), clarifying that the MCO is responsible for monitoring contractors' fiscal stability; (4) 98-1.11(q), clarifying that MCOs must comply with Article 49 of the Public Health Law, in addition to Article 44 and Part 98; (5) 98-1.13(c)(iii), correcting a 2005 change which inadvertently limited provider contract assignments to within one year of promulgation of the rule to reflect that the rule applies prospectively; and (6) amending 98-1.5(b)(6)(vii)(e)(2), clarifying that when an MCO delegates management functions to an IPA, that a separate management contract is required between the MCO and IPA, separate from the delivery of service contract.

98-1.5 Application for a Certificate of Authority - Amend the regulations to require electronic submission of the managed care organization's provider network, consistent with the filing requirements in 98-1.16(j).

98-1.6 Issuance of the Certificate of Authority - Amend the regulations to add a provision requiring managed care organizations (MCOs) to maintain a complete file on each request for health care services or benefits and associated appeals pursuant to Article 49 of the Public Health Law and federal law and regulations.

98-1.8 Continuance of a Certificate of Authority - Amend the regulations to clarify that managed care organizations must maintain compliance with the requirements of PHL Articles 44 and 49 and 10 NYCRR Part 98, including provisions related to initial application and certification standards, in order to maintain their certificate of authority.

98-1.13 Assurance of Access to Care - Amend the regulations to: (1) require that managed care organizations (MCOs) ensure each member has selected a primary care provider from which the member receives all primary care services; 2) address requirements related to subdivision 5-d to section 4406-c which imposes a “cooling off” period after termination or non-renewal of a contract between an MCO and a hospital; (3) amend regulations to clarify that certain out-of-network service denial notices must include internal MCO and external appeal rights afforded by section 4904(1-a) and (1-b); and (4) promote consistency of initial adverse determination notices issued in accordance with section 4903(5) by clarifying notice content requirements.

98-1.18 MCO Agreements - Amend the regulations to expand the scope of this section to include, as applicable, the relationships between MCOs and licensed pharmacies and laboratories—where the pharmacies and laboratories arrange and/or act as benefit managers for services, equipment, and supplies—and the relationships between these entities and the providers of the services, equipment, and supplies.

114.20 Schroon Lake Water District, Town of Schroon – Repeal the regulation, which describes Horseshoe Pond as the source of public water and provides provisions for source water protection. The Horseshoe Pond reservoir is on state owned land and is no longer used as a public water source. The NYS Department of Environmental Conservation has plans to remove the dam, which will drain the reservoir. The town of Schroon alternatively relies on a drilled well for public water.

128 New York City Watershed Rules and Regulations - Amend the regulations to incorporate requirements intended to protect New York City’s (NYC) Watersheds and preserve NYC’s Filtration Avoidance Determination by providing various limitations on watershed activities and construction.

402 Criminal History Record Check Program – Update Criminal History Record Check regulation to conform to recently enacted changes to the Public Health Law. The regulations, which currently cover certain prospective employees of residential health care facilities, certified home health agencies, licensed home care services agencies, and long term home health care programs, will now include definitions and requirements for adult care facilities and hospice programs serving individuals at home across New York.

404 Integrated Outpatient Services – Amend the regulations to add a pathway for providers with a single license to integrate behavioral health services without applying for additional licensure/certification. Amend regulations that speak to physical plant standards in order make consistent with new physical plant categories.

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.

405.25 Organ and Tissue Donation Anatomical Gifts – Amend the regulation to conform to changes to Article 43 of the Public Health Law made by several statutory amendments including Chapter 248 of the Laws of 2017.

415 Nursing Homes - Amend the regulations to align with new Long-Term Care Facility Requirements of Participation (effective November 28, 2017) and rearranging of regulatory groups.

415.3 Residents’ Rights- Amend the regulations to update the admission, transfer and discharge regulations (10 NYCRR 415.3) to align with new federal health regulation requirement for states and long-term care facilities (CFR 42 Chapter IV Subchapter G part 483)

415.18 Pharmacy Services – Amend the regulation so that it is consistent with the provisions of 8 NYCRR 29.7(a) (special provisions for the profession of pharmacy) regarding re-dispensing medications.

425 Adult Day Health Care - Amend the regulations to align with the Home and Community Based Services Rule.

600.1, 600.3 - 600.7; 610.1 - 610.2; 620.1 - 620.3; 630.1; 640.2 - 640.3; 650.1 - 650.2; 670.1 - 670.6; 680.2; 680.4 - 680.6; 680.8 - 680.10, 705.9 Public Health and Health Planning Council (PHHPC) - Amend the regulations to change references to the Public Health Council to the Public Health and Health Planning Council; and to delete references to the State Hospital Review and Planning Council.

600.2 and 610 Special Requirements for Nonprofit Corporations - Amend the regulation to require review of the members of a nonprofit corporation proposing to operate a hospital, whether or not such members are proposed to exercise powers under section 405.1, except for members proposed to exercise powers set forth in subdivision (d) of section 405.1; add a section to require a previously established nonprofit corporation seeking to add a member that will not exercise powers set forth in section 405.1 to submit a notice to the Department describing the background and qualifications of such member, and the benefits and scope of the proposed member’s relationship to the corporation, as evidenced by organizational document; except for members appointed to exercise powers set forth in subdivision (d) of section 405.1. The amended regulations will provide that if not recommended for disapproval by the Department within 90 days, the proposed addition shall be deemed approved.

705.7, 708.1, 710.1, 710.2, 710.5 Public Health and Health Planning Council (PHHPC) - Amend the regulations to change references to the State Hospital Review and Planning Council to the Public Health and Health Planning Council.

709.3 Residential Health Care Facility Beds – Amend the regulation to update the need methodology used to estimate the need for residential health care facility beds.

709.6 Extracorporeal Shockwave Lithotripters - Repeal this regulation pertaining to the need methodology for extracorporeal shock wave lithotripters. Under amendments filed in 2010, these devices are subject only to limited review, which does not involve consideration of public need. This section is therefore obsolete.

709.14 Determination of Public Need for Cardiac Services - Amend the regulation to update the criteria for approval of new cardiac programs and services as per recommendations from the Governor’s Regulatory Modernization Initiative.

709.17 Long-Term Ventilator Beds - Amend the regulation to update the need methodology used to estimate long-term ventilator beds.

710.7 Approval to Start Construction - Amend the regulation to repeal current provisions and replace with an expedited construction process.

711.3 General Standards of Construction - Site Requirements - Amend the regulation to require health facilities to install flood resistant emergency generators and fuel supplies, readily accessible generators and fuel pumps, external pre-connections in power systems for use in the event of an emergency power system failure and on HVAC systems for temporary boiler and chiller back-up and ensure that the emergency power generation capacity is capable of powering the HVAC system during a power outage. The regulation will also be amended to increase the flood crest level year from 100 to 500.

711, 712, 713, 714, 715 and 716 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 – Amend the regulations to require that future health care facility construction projects conform to the 2018 edition of Guidelines for Design and Construction of Health Care Facilities.

721.4 Patient Care and Patient Transfers - Amend the regulations to allow release to “the sending hospital or other hospital providing a lower level of perinatal services.....” to conform with proposed changes to section 86-1.15, section 405.21 and current language in section 721.4(c)(1).

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.

722 Sexual Assault Forensic Examiner (SAFE) Program - Amend regulations related to the review and approval of licensed Article 28 hospitals as Sexual Assault Forensic Examiner (SAFE) programs. This requires replacing “the Department’s Protocol for the Acute Care of Adult Patient Reporting Sexual Assault” with “A National Protocol for Sexual Assault Medical Forensic Examinations Adults/Adolescents” by the U.S. Department of Justice. In addition, approved SAFE programs are required to meet all generally accepted standards of medical care and State laws for sexual assault patients, including Public Health Law (PHL) section 2805-i and 10 NYCRR subdivision (c) of section 405.9. A recent statutory provision within the New York State Budget revised PHL 2805-i to extend the length of time sexual offense evidence collection kits are preserved from 30 days to 20 years. 405.9 Maintenance of Sexual Offense Evidence must also be revised to meet this new standard of care.

760.5 Certified Home Health Agency (CHHA) Determinations of Public Need - Amend the regulation to update the need methodology used to estimate the need for CHHAs.

765 Approval of Home Care Services Agencies - Add a new section delineating a need methodology for Licensed Home Care Services Agencies (LHCSA’s) pursuant to Section 9-b of Chapter 57 of the laws of 2018.

790.16 Determination of Public Need for Hospice - Amend the regulation to update the need methodology used to estimate the need for hospice care and services.

800 Emergency Medical Services (EMS) - General - Amend the regulations to conform with federal requirements/recommendations, current medical practice and national safety standards. Add regulations related to the use and application by members of the public of automatic external defibrillators; clarify requirements for Advance Life Support First Response Agencies; clarify requirements for Basic Life Support Providers; and update EMS certification and training requirements. The proposed amendments would modernize course sponsors provisions to address the current environment and technology as well as reflecting the current EMS education curricula; strengthen the surveillance portions of these provisions to appropriately address issues of quality, student rights and safety; and establish a new section on the mobilization and/or sharing of resources in the event of a declared disaster. Finally, the regulations would be amended to reflect current ambulance vehicle construction requirements, technology and safety for the patients and EMS providers.

Amend the regulations to reflect current EMS industry standards for ambulance/EMS vehicle construction, safety issues, medical devices and equipment, business and operational practices, quality management, mutual-aid/communication/interoperability, and other areas associated with a modern EMS system.

1001 Assisted Living Residences - Amend the regulation to consolidate and streamline provisions relating to assisted living residences as they exist in adult homes and enriched housing programs to reflect the changing environments of these types of facilities. Amendments will provide clarification and consistency to residents, operators and the public with regards to assisted living residences, including changes to the admission, assessment and medication management processes. Amendments will also include language prohibiting care and service delivery by individuals not employed by the operator or, if not employed by the operator, not qualified to deliver such services.

1004 Medical Use of Marijuana – Amend Part 1004 to revise

requirements related to the medical use of marijuana established by Title 5-A of Article 33 of the Public Health Law.

Title 18 NYCRR (Social Services)

360 Medicaid - Amend the regulations as necessary to conform to statutory changes made by Part D of Chapter 56 of the Laws of 2013 with respect to Medicaid applications and determinations, financial eligibility methodologies, and covered benefits.

485, 486, 487, 488, 490 and 494 Adult Homes, Enriched Housing Programs, Residences for Adults and Assisted Living Programs - Amend the regulations to consolidate and streamline provisions relating to adult homes, enriched housing programs, residences for adults and assisted living programs to reflect the changing environments of these types of facilities. Amendments will provide clarification, consistency and transparency for residents, operators and the public with regards to the care and services available to residents and prospective residents, and provided by adult care facilities and will support quality assurance and performance improvement for better resident outcomes. Amendments will also strengthen enforcement activities and further clarify the imposition of civil penalties for regulatory non-compliance.

505 Children’s Services - Add regulations governing Medicaid coverage of new services for children, including crisis intervention, psychosocial rehabilitation, family peer support services, youth peer support and training, and community psychiatric supports and services. Coverage is dependent on CMS approval of a Medicaid State Plan amendment. Regulations will address requirements for designating providers who are qualified to provide such services.

505 Medical Assistance – Add or amend regulations to set forth the requirements for the Community First Choice Option (CFCO). CFCO is a program that will provide additional federal matching funds for home and community based attendant services and support provided to certain individuals who require an institutional level of care, pursuant to a person-centered plan of care.

Another potential area of new regulation is the Home and Community-Based Settings Final Rule, which requires the State to file a transition plan detailing steps it will take to implement the requirements of the rule. We will have a better sense of whether or not this is necessary after conducting provider surveys and various validation exercises for those programs that were up and running under a 1915(a) or 1115 (B).

505.1 and 505.3 Medical Assistance Services – Amend the regulations regarding prescription and over-the-counter medications and supplies available to eligible members. These regulations specifically exclude medical care, services and supplies furnished solely to promote fertility.

505.3(b)(1) Drugs - Amend the regulations to conform to the provisions of the Affordable Care Act (ACA) requiring prescribers to be enrolled in state Medicaid programs to be eligible to order or refer services reimbursed by the fee-for-service (FFS) Medicaid program.

505.7 Laboratory Services – Amend the regulations to align with current practice standards; clarify who can order laboratory services, testing under a standing order, and clarify the location of materials such as manuals.

505.10 Transportation for Medical Care and Services - Amend the regulations to reflect current policies: definitions will be modified, quality standards for transportation will be introduced including enhanced safety protocols for enrollees, background checks for drivers, and licensing standards; trip documentation requirements will be revised, and existing information regarding the involvement of local county departments of social services in the administration of the transportation benefit will be removed.

505.11 Rehabilitation Services - Amend the regulations to align with State Education law, federal guidelines, and current standards of practice; clarify who can order rehabilitation services, particularly speech-language pathology services provided to Medicaid recipients; clarify supervision requirements for services provided “under the direction of” speech-language pathologists, occupational therapists, and physical therapists.

505.12 Podiatry Services - Amend the regulation to expand podiatry coverage to Medicaid eligible adults with a diagnosis of Diabetes

Mellitus. This will align the regulation with 2012 changes made to state social service laws.

505.14 Appeal Submission – Amend the regulation governing the appeal submission process for Personal Care. Remove language about issuing rates prior to becoming effective and replace with a single appeal process.

505.14 – Personal Care Services - Amend the regulation to allow for added costs due to the increases in minimum wage.

505.14 Rural County Investment – Rural counties experience higher costs due to geographic distance, and this add-on is being developed to mitigate that impact.

The regulation implements a Rural County Investment rate add on for Personal Care, as per 2018-19 State Enacted Budget.

505.15 Psychiatric Care - Amend the regulations to align with federal requirements regarding who may provide school supportive health services.

505.18 Clinical Psychological Services - Amend the regulations to align with federal guidelines and current standards of practice and clarify which practitioners are qualified to provide services in the Preschool/School Supportive Health Services Program to Medicaid recipients.

505.31 Audiology, Hearing Aid Services and Products – Amend the regulations to align with federal and State and current standards of practice and clarify which practitioners are qualified to provide services.

505.31(d)(e)(1) Audiology, Hearing Aid Services and Products - Amend the regulations to align Medicaid regulations with federal guidelines, State Education Law and current standards of practice and clarify who can order audiology services.

505.33 Personal Emergency Response Services (PERS) - Amend the regulations to allow for annual authorizations and to delete the requirement that authorization of PERS be contingent upon a reduction/elimination of personal care aide/home health aide hours.

522 Medicaid Billing for Pre-School Services – Amend the regulation to align with SPA #09-61. Revisions are needed as there is only one Article 28 facility left who bills Medicaid directly for IEP services.

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