

REGULATORY AGENDA

Department of Health

The following regulatory actions are under consideration for submission as a Notice of Proposed Rulemaking from January through June 2016:

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 – Establish regulations and requirements for cooling towers relating to registration, reporting and recordkeeping; testing; cleaning and disinfection; maintenance; inspection; and certification of compliance. Additionally, the regulations will require general hospitals and nursing homes to implement a Legionella sampling plan and take necessary responsive actions.

5-1 Public Water Systems - Amend the regulation to incorporate mandatory federal regulations pertaining to control of lead and copper in public water supply systems, under the Lead and Copper Rule (LCR) for both the minor revisions (LCRMR) and short-term revisions (LCRSTR) regulations; incorporate mandatory federal regulations to improve control of microbial pathogens as prescribed by the Long Term 2 Enhanced Surface Water Treatment Rule (LT2SWTR), while limiting risks associated with the formation of and exposure to disinfection byproducts required under the Stage 2 Disinfectant/Disinfection Byproducts Rule (Stage 2 D/DBPR); incorporate mandatory federal regulations applicable to variances and exemptions (V&E); incorporate provisions of previously enacted changes to Public Health Law (PHL) § 1125 pertaining to water supply emergency plans and PHL § 225 pertaining to backflow device tester certification requirements; as well as incorporate several minor changes to update and clarify specific code references, correct typographical errors, and restructure Appendix C to update and simplify listings of approved analytical methods for drinking water. The revisions are necessary to make the regulations consistent with federal regulation and do not add or change any of the requirements for State public drinking water systems, as the affected public water systems already must comply with the federal regulations. Similarly, since the Public Health Law (PHL) changes have already been implemented for over one year,

there will be no additional requirements or costs for the regulated community based on the incorporation of the PHL revisions into 5-1.

5-1 Public Water Systems – Amend the regulation to incorporate the Revised Total Coliform Rule (RTCR) that was promulgated by the United States Environmental Protection Agency (EPA) and will take effect on April 1, 2016, to make New York’s regulations consistent with EPA requirements.

6-1 Swimming Pools – Amend the regulation to update the swimming pool design 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 required by the United States Environmental Protection Agency (EPA) to make New York’s regulations consistent with EPA requirements.

7-2 Children’s Camps - Amend the regulation to conform to Chapter 501 of the Laws of 2012, which established the New York State Justice Center for the Protection of People with Special Needs (Justice Center) to strengthen and standardize the safety of care received by vulnerable people from New York’s Human Services Agencies and Programs. The legislation includes children’s camps for children with developmental disabilities as a type of facility within the oversight of the Justice Center and requires the Department to promulgate regulations pertaining to staff hiring and training and incident management at these camps. Additionally, some health and safety protections will be extended to all camps enrolling a child with a developmental or other disability and not just to children’s camps for children with developmental disabilities.

9.1 Synthetic Phenethylamines and Synthetic Cannabinoids - Amend the regulations to expand the list of prohibited synthetic cannabinoids.

14 Food Protection - Amend the regulation to consolidate all current subparts by adopting Chapters one through seven of the U.S. Food and Drug Administration (FDA) Model Food Code. Adopting the technical content of the Model Food Code will address requirements of 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 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. Update the quality assurance requirements for diagnostic x-ray equipment to align with current equipment and imaging modalities to ensure patient safety. Consolidate current requirements in 12 NYCRR 38 (NYS DOL Ionizing Radiation) into 10 NYCRR 16, consistent with the merger of the NYS DOL Radiological Health unit into the New York State Department of Health/Center for Environmental Health/Bureau of Environmental Radiation Protection program. Organize 10 NYCRR 16 into subparts and incorporate relevant 10 CFR regulations by reference for certain 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 definition of assistant director; and establish qualifications for directors of forensic identity and other categories not currently specified in the regulation.

22.3 Supplementary Reports of Certain Congenital Anomalies for Epidemiological Surveillance; Filing - Amend the regulation by requiring reporting to the Congenital Malformations Registry of children up to 10 years of age with certain birth defects, as well as fetuses diagnosed with defects prior to birth. Reporting of cytogenetic test results confirming presence of a birth defect will also be required. Changes will support an improved ability to accurately document prevalence rates for certain birth defects and help monitor the impact of environmental factors or preventive measures.

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.

22.11 Environmental Diseases - Amend the regulation to add requirements that health care practitioners and clinical laboratories report any poisonings to a poison control center. This additional mandated reporting of poisonings will assist public health officials with the identification and monitoring of adverse health effects from various harmful substances, including carbon monoxide and drug/toxic agent poisonings, and will guide public health responses, prevention efforts, policies and programs.

23.2 Sexually Transmitted Diseases Treatment Facilities - Amend the regulation to modernize language and reflect best clinical practice; update the billing requirement related to local health departments providing STD services; make other technical modifications. The proposed modifications to these regulations are required to conform to amendments to Public Health Law made by Chapter 56 of the Laws of 2013.

34-2 Laboratory Business Practices - Regulations relating to recall letters and reporting of test results in Section 34-2.11 will be amended to reflect preferred laboratory director practices.

40-2.1 General Provisions Concerning State Aid Eligibility - Amend the regulation to add a new subdivision (c) to clarify that rent, and maintenance of space in lieu of rent (MILOR) will remain eligible for State Aid. This section was inadvertently omitted when the Department repealed Subpart 40-2 and issued completely revised State Aid regulations, effective December 31, 2014. Several local health departments have requested reinstatement of the former provisions and the Department does not anticipate an objection to this clarifying amendment.

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 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. The regulation will also be amended to update technical requirements to reflect advances in technology and changes in industry standards and enhance monitoring and enforcement of restrictions on the sale of human tissue for transplant.

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, and to clarify that regulated analytes exclude analytes considered process controls by the NYS 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 are being included in section 2.14.

58-1 Clinical Laboratories - Revise laboratory personnel requirements to reflect industry standards and NYS Education Department licensure requirements; 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; and amend the regulation to be consistent with the recently published federal rules that will permit HIPAA-covered laboratories to provide, upon the request of a patient, or the patient's personal representative, copies of completed test reports.

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 the list of approved evidential breath measurement devices listed in Section 59.4 and 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).

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.

63.3 HIV-related testing - Amend regulations related to consent for HIV testing. This amendment makes NYS law consistent with Centers for Disease Control and Prevention (CDC) recommendations for routine HIV screening in healthcare settings. Expanded testing is needed to identify as many individuals as possible and link them to care and treatment. Removing the requirement for written consent, including in correctional facilities, eliminates a barrier to expanded testing. The proposed modification to these regulations is required to conform to amendments contained in the 2014-15 and 2015-16 enacted State budgets.

63.4 Filing of reports - Amend the regulation to set forth exceptions that allow for sharing of identifying information with providers. Broader sharing of data will enable health departments and health care providers to work together to determine which patients are not currently receiving care and what kind of assistance is needed for them to

return to receiving care. This amendment would allow local and state health departments to share HIV surveillance information with health care providers for purposes of patient linkage and retention in care. The proposed amendment is required to conform to statutory amendments to PHL section 2135, and to amendments contained in the 2014-15 enacted State budget.

63.8 Contact Notification - Amend the regulation relating to contact notification to conform to recent changes to Public Health Law and to align the practices of HIV and STD partner services programming. Adding previously diagnosed persons to those served by state and county field services staff enables the use of HIV surveillance data to help link and reengage HIV positive persons to care. Removing the requirement that data on the partners of HIV cases be destroyed after three years will align HIV partner services programming with STD partner services programming. The amendment will also clarify regulations relating to when providers diagnosing new cases of HIV infection should report information about these cases to the State Health Department.

66-1.1 Immunization - Amend Subpart 66-1 (School Immunization Requirements) to incorporate recent amendments to Public Health Law which will require meningococcal vaccine for students entering seventh and twelfth grades effective September 1, 2015. The regulations will also 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 in order to ensure that New York State requirements are consistent with national standards.

66-1.2 Immunization - Amend the statewide immunization information system regulations to conform to changes enacted to the Public Health Law. The amendments will clarify recent changes to reporting requirements for immunization administered to persons nineteen years of age or older.

66-2.1 through 66-2.9 Immunization - Amend regulations to be consistent with current ACIP 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.

69-1 Testing for Phenylketonuria and Other Diseases and Conditions - Amend 69-1.2(b) of the regulation to include Adrenoleukodystrophy (XALD) and Pompe disease to the list of diseases or conditions for newborn testing. Provide definitions governing retention of residual dried blood spot specimens and their subsequent use for quality control, quality assurance, the development and validation of new assays and public health research in the newborn screening program.

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. 10 NYCRR 69-4.30 will be amended 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 specify follow-up where conditions of the screening are considered to contribute to invalid results; require reporting of individualized, identifiable data to the department; require staff involved in newborn hearing screenings to complete training; require that infants who fail an initial screening receive at least one additional screening prior to discharge; require that a re-screening post discharge from a facility occur within 8 weeks of discharge; require that an infant be referred to the early intervention program as an at-risk child, unless the parent objects, if the results of a follow-up outpatient screening are not returned to the facility within 45 days post discharge; and require reporting to an electronic data system.

69-10 New York State Medical Indemnity Fund – Amend the regulations to provide clearer standards for enrollment, coverage, prior approval processes, and payment rates.

72-2 Body Piercing and Tattooing - Amend the regulations to conform with Public Health Law Article 4-A - Regulation of Body Piercing and Tattooing. The regulations will provide definitions and requirements for permit, inspection, and operation of tattooing and body piercing studios and the permitting of body piercing specialists and tattooists.

73 Asbestos Safety Training Program Requirements - Amend the regulations to conform to 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.

75 Standards for Individual Water Supplies and Individual Sewage Treatment Systems and Appendix 75C - Individual Water Well Quality Standards - Amend the individual water supplies and sewage treatment system regulations to clarify design submittal and approval procedures; and add new regulations for individual water wells in order to establish water quality reference standards for individual wells.

77 Funeral Establishments, Registrations, Funeral Directing, and Misconduct - Amend the regulations to prohibit the recovery of tissue within a funeral establishment, prohibit non-transplant anatomical banks from operating within such establishments, and prohibit a funeral director, or employees of a funeral firm, from soliciting customers by requesting an anatomical donation.

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; and will update exceptions, reclassification and exemptions of scheduled controlled substances.

80.137 Sale and Possession of Hypodermic Syringes and Hypodermic Needles Without a Prescription Under the Expanded Syringe Access Demonstration Project (ESAP) - Amend section 80.137 by removing “Demonstration” from the title of the program and formally adopt “Expanded Syringe Access Program” as the name of the program since the program has become permanent.

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.

86-1.46 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.

86-1.48 - 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 in Residential Health Care Facilities – Amend the regulations describing reimbursement for adult day health care (ADHC) programs based in residential health care facilities (RHCFs) to conform the regulation to proposed changes to Part 759, and to add program guidelines.

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.

86-4.41 Computation of basic rates for day health care services provided to patients with acquired immune deficiency syndrome (AIDS) and other human immunodeficiency virus (HIV) related illnesses by freestanding ambulatory care facilities – Amend the regulations to describe reimbursement for AIDS adult day health care (ADHC) programs based in freestanding ambulatory care programs to conform the regulation to proposed changes to Part 759, and add program guidelines.

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

86-4.9, 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.

89 Practice of Radiologic Technology – Amend the regulations to clarify several scope of practice issues and continuing education requirements, add a provisional status for applicants who are missing continuing education credits, and as requested by the Governor's Council on Community Re-Entry and Reintegration, modify the review of applications from individuals with felony convictions.

92 Pathologists Assistants - Amend regulations to establish a defined mechanism for licensure of pathologist assistants by creating a new category of registered specialist assistants.

98-1 Various Technical Amendments - Revise the 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 Watershed Rules and Regulations for the Town of Schroon Lake Water and Its Sources - Repeal the regulation designed to protect Horseshoe Pond which was previously used as a source of drinking water for the Town of Schroon Lake in Essex County (Town). In 2001, the Town developed and began using groundwater wells for their drinking water supply. The existing Watershed Rules and Regulations (WRR) for Horseshoe Pond are no longer serving their intended purpose.

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

300 Statewide Health Information Network for New York (SHIN-NY) - Promulgate regulations as required under Public Health Law section 206(18-a).

402 Criminal History Record Check Program – Criminal History Record Check regulation will be updated 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 across New York.

405 Federal Conditions of Participation - Amend the regulation to include recent federal conditions of participation.

405.9 Admission/Discharge - Amend the regulation to clarify that

all donor and procurement responsibilities must be carried out before a dead body is removed from a hospital.

405.11 Infection Control - Amend the regulations to conform to PHL section 2819(2). The proposed regulation would define requirements for hospitals to report certain hospital acquired infections using methods, definitions and protocols defined by the Department, ensures patient privacy in collection and release of data, and create standards for publication and release of the data reported.

405.21 Perinatal Services- Amend existing regulations to conform with recommended standards of care. Specifically, restrict the marketing of breast milk substitutes through the provision of gift packs that include breast milk substitutes or coupons and the use of educational materials which refer to proprietary product(s) or bear product logo(s). Pacifiers or artificial nipples may be supplied by the hospital to breastfeeding infants upon specific order by an attending physician. Hospitals will be required to disseminate annually hospital breastfeeding policies and procedures to staff providing maternity and newborn care. When discussing breast milk, the disadvantages of breast milk substitutes shall be included. Add a new section to 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.

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 Chapter 348 of the Laws of 2009.

405.33 Trauma Centers - Add a new section to the Hospital (General) Minimum Standards providing standards for trauma centers.

407 Federal Conditions of Participation - Amend the regulation to incorporate federal conditions of participation for Critical Access Hospitals (CAHs).

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.

425.18 Adult Day Health Care (Services for Registrants with Acquired Immune Deficiency Syndrome) - Amend the regulations to create a more flexible model appropriate to the clinical state of the HIV/AIDS epidemic and for inclusion into the Medicaid Managed Care benefit package.

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.

700.2, 717, 793 and 794 Hospices - Amend the regulations to make them consistent with federal conditions of participation; incorporate Medicaid Redesign Team initiatives; and to conform to with Article 40 of the Public Health Law.

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.

708 Appropriateness Review - Repeal the regulations regarding the Trauma Center Designation Standards.

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.

709.17 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 2014 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, 405.21 and current language in Section 721.4(c)(1).

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 includes the standards for approving SAFE hospital programs, approving programs that train individual SAFE examiners, and certifying individual SAFE examiners, and criteria for continuous quality improvement program activities. The SAFE program provides a specialized standard of medical care and evidence collection to victims of sexual assault.

750-759 Treatment Center and Diagnostic Center Operation - Amend to update the regulations.

759 Adult Day Health Care (Services for Registrants with AIDS) - Amend the regulations to create a more flexible model appropriate to the clinical state of the HIV/AIDS epidemic and for inclusion into the Medicaid Managed Care benefit package.

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.

763.7 and 766.4 Home Care Agencies to Obtain Written Medical Orders from Physicians - Amend the regulations regarding certified home health agencies, long term home health care programs and AIDS home care programs to conform with federal conditions of participation/rules; also amend the state regulations for licensed home care services agencies to be consistent with state regulations for certified home health agencies.

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.

1004 Medical Use of Marihuana – Amend Part 1004 to revise requirements related to the medical use of marihuana 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 and consistency to residents, operators and the public with regards to adult care facilities, including role of nurse practitioners and physician assistants, as well as modifications to the assisted living program, including changes to the admission, assessment and medication management processes.

487 and 488 Standards for Adult Homes, Adult Care Facilities and Enriched Housing Programs - Amend the regulations to address the creation of the New York State Justice Center for the Protection of People with Special Needs pursuant to Chapter 501 of the Laws of 2012, and to conform the Department of Health's regulations to requirements added or modified as a result of such law.

505 Medical Assistance – Possible amendment to existing regulations to reference the Community First Choice Option (CFCO) and the services it covers. CFCO is primarily an enhanced personal attendant program that will provide additional federal matching funds for services provided currently through both the State Plan and HCBS waivers to qualified individuals. Individuals are qualified to participate in CFCO if they require an institutional level of care. Individuals must reside in allowable settings for the provision of Medicaid funded home and community based services, and cannot be in two of the special Medicaid eligibility groups that are not Medicaid eligible under the State Plan. Services provided to qualified individuals under CFCO that will generate an additional 6% FMAP include: personal care (including Consumer Directed Personal Care Services), supervision and cueing related to performing ADLs and IADLs, health-related tasks that can legally be performed by an aide under State law, functional skills training related to acquiring, maintaining or enhancing the ability to perform ADLs and IADLs, community transportation, transition expenses, assistive devices and e-mods that are specified in the person centered service plan and increase independence and substitute for human assistance. CMS approved the SPA on October 23, 2015.

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 require-

ments 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).

505.3 Drugs - Amend existing regulations, in conformance with Part C of Chapter 60 of the Laws of 2014, with respect to developing a new methodology for the Medicaid reimbursement of pharmacies.

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.

505.3(b)(1) Drugs – Amend the regulations to allow pharmacies to dispense non-prescription emergency contraceptive drugs in accordance with FDA guidelines.

505.10 Transportation for Medical Care and Services - Amend the regulations to reflect current policy: definitions will be modified, quality standards for transportation will be introduced, 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 Personal Care Services Program - Amend the regulation to 18 NYCRR 505.14(b)(7) to address the expedited Medicaid determination process for Medicaid applicants who purportedly have an immediate need for personal care services, and a new (b)(8) to address districts' expedited authorization process for Medicaid recipients with immediate needs.

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.

505.2(1) – Transgender Related Care and Services – Amend the regulation to (1) establish 18 years of age as the minimum age for coverage of sex reassignment surgery (SRS), including surgeries where sterilization would result; and (2) add psychiatric-mental health nurse practitioners to the list of medical professionals who can provide letters supporting an individual's need for SRS, either as a practitioner who has an established and ongoing relationship with the individual, or as a practitioner who has had an evaluative role with the individual.

505.28 Consumer Directed Personal Assistance Program (CDPAP) - Amend the regulation to address the expedited Medicaid determination process for Medicaid applicants and recipients with an immediate need for CDPAP.

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.

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