

REGULATORY AGENDA

Department of Health

The following regulatory actions are under consideration for submission as a Notice of Proposed Rulemaking from January through June 2015:

DESCRIPTION OF THE RULE SUBJECT MATTER

Title 10 NYCRR (Health)

2.1 Communicable Diseases - Modify the list of reportable diseases defined in the New York State Sanitary code (10 NYCRR 2) in response to new emerging infections and changing priorities for disease surveillance. 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. The list may also be updated to remove diseases that do not require a public health response.

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 - Update the rabies regulations to be consistent with changes enacted to the Public Health Law. The regulations will provide definitions and requirements for reporting human exposures, confinement of animals exposing people to rabies, quarantine of animals exposed to rabies, and county responsibility for establishing provisions for animal control related to rabies.

5-1 Public Water Systems - Amend the regulation to incorporate 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); conform to 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 typographic errors, and restructure Appendix C to update and simplify listings of approved analytical methods for drinking water. The revisions to make the regulations consistent with federal regulation 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.

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 that will be effective April 1, 2016, 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 Chapter 501, 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 vulnerable people that receive care 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, staff training and incident management.

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 NYS 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 for consistency with federal requirements applicable to industrial use of radioactive material, radiation protection standards and license termination/decommissioning standards; update the quality assurance requirements for diagnostic x-ray equipment, including computed tomography, 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 DOH/CEH/BERP program in 2006.

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; 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.

23.2 Sexually Transmitted Diseases Treatment Facilities - Update the billing requirement related to local health department providing to STD services to conform to recent statutory changes, and make other technical modifications.

34-2 Laboratory Business Practices - Amend the regulation to be consistent with the recently published Federal rules that permit

HIPAA-covered laboratories to provide, upon the request of a patient, or the patient's personal representative, copies of completed test reports.

46 Physically Handicapped Children - Amend the existing regulations to update and clarify current policy regarding 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 - 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, and 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); amend certificates of approvals to include the category of medical marijuana; add a new section describing requirements for laboratories performing testing for medical marijuana.

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 NY SED 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 Chapter 10 of 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.

58-2 Blood Banks - Amend the regulations to permit emergency medical technicians, with additional training, to administer transfusions during inter-facility transport; enhance donor and patient safeguards; update technical requirements; eliminate obsolete requirements; clarify regulatory intent; meet federal requirements as directed by the Centers for Medicare and Medicaid Services; provide regulated parties with greater flexibility in complying with regulations regarding emergency transfusions, qualifying donors over 75 and apheresis donors, and provide options for equivalent electronic records.

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 the regulation to create consistency with the HIV testing 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 pertaining to the certification of ignition interlock devices to comply with model specifications adopted by National Highway Traffic Safety Act (NHTSA) as published in the Federal Register on May 8, 2013 (78 Fed. Reg. 26849 - 26867); the requirements for the issuance of permits for blood, urine, and saliva alcohol analysis; and the requirements for the issuance of permits for breath analysis operators.

60-1.13 Vendor Applicant Enrollment Criteria - Amend the regulation to maintain compliance with 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 the regulation 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 (except 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 enacted State.

63.4 Filing of reports - Amend the regulation to describe 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 truly 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 modification is required to be consistent with statutory amendments to PHL section 2135.

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.

69-4 Early Intervention Program - Amend the regulations, as needed, to comply with 34 CFR Parts 300 and 303. Amendments are also needed to comply with statutory changes enacted with the SFY 2012-13 budget. Section 10 NYCRR Section 69-4.30 will be amended to clarify the commissioner's authority to establish a fixed payment methodology for service coordination services. Amendments may also be needed to address other areas of regulation 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.

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 incorporate changes made by the New York State Department of Labor to Code Rule 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; add new regulations for individual water wells in order to establish water quality reference standards for individual household 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 requesting consent for an anatomical donation.

80 Controlled Substances - Amend the regulations to reflect recent statutory changes pertaining to the implementation of an upgraded Prescription Monitoring Program (PMP) Registry for collecting, monitoring and reporting data concerning the prescribing and dispensing of controlled substances. The amended regulations will address the statutory requirements for prescribing controlled substances, including consulting the PMP Registry prior to prescribing controlled substances, providing pharmacists and designees access to the PMP Registry, and providing for more timely reporting of prescription information. The amended regulations 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; will update reporting requirements for Methadone Maintenance Treatment Programs enacted by Public Health Law section 3352 statutory changes; 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.

80-1 Medical Use of Marihuana – Add new regulations to implement Title 5-A of Article 33 of the Public Health Law related to the medical use of marihuana.

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.

80.138 Opioid Overdose Prevention Programs – Public Health Law (PHL) Section 3309 was amended in 2014 to permit prescribing and dispensing of an opioid antagonist pursuant to a non-patient specific prescription. The amended law also permits the shared access to—and use of—an opioid antagonist by trained individuals. Emergency regulations which amended 10 NYCRR 80.138 was published on February 25, 2014 to address changes in the law warranting immediate action. The Department intends to proceed with a Notice of Proposed Rulemaking to make the regulations permanent.

85.13 Physically Handicapped Children - Delete 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 rebase current hospital inpatient rates.

86-1.45 Language Assistance Medicaid Reimbursement for Hospital Inpatient Services - Add regulations and develop rates for the payment of Language Assistance services provided by hospitals to inpatients.

86-2 Nursing Home Quality Incentive - Amend the regulation to provide an incentive for nursing homes to improve quality by linking payments to quality.

86-2.9 Adult Day Health Care in Residential Health Communities – Amend the regulations describing reimbursement for adult day health care (ADHC) programs based in residential health care facilities (RHCFs) to include a subsection specific to reimbursement for AIDS ADHC programs. The proposed amendment to Section 86-2.9 is intended to establish a new reimbursement model that is based on the assessed needs of the client. Other modifications are necessary to conform the regulation to proposed changes to Part 759, and to add program guidelines.

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. The proposed amendment to Section 86-4.41 is intended to establish a new model of reimbursement that is based on the assessed needs of the client. Other modifications are necessary 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 establish Medicaid rates and billing policies to allow hospitals and clinics to be reimbursed for physician home visits for chronically ill patients.

94.1 Physician Assistants - Amend the regulation to allow a Physician Assistant (PA) to prescribe controlled substances, including Schedule II substances, for patient’s under the care of the supervising physician in conformance with Public Health Law section 3703(3). Update to conform with recent changes in the Education Law regarding licensure and physician supervision including allowing physicians to supervise up to four PAs instead of up to 2 PAs in the private practice setting.

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(6)(e)(2) the MCO management functions to reflect that if an IPA is delegated MCO management functions, then a separate management contract is required and it must be 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). Modify section (b)(6)(vii)(e)(2) to specify that an independent provider association (IPA) performing management functions should have requirements detailed in a contract separate and apart from the IPA provider agreement.

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.

98-1.11(e) Operational and Financial Requirements for MCOs -

Amend Section 98-1.11(e) to extend the lower contingent reserve requirement applied to revenues from the Medicaid managed care, Family Health Plus and HIV SNP programs.

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 4) promote consistency of initial adverse determination notices issued in accordance with section 4903(5) by clarifying notice content requirements.

98-1.16(c) Preparation and Filing of Audited Financial Statements - Amend this part and new section 98-3 to establish standards for the preparation and filing of audited financial statements by Prepaid Health Services Plans, HIV Special Needs Plans, and managed long term care plans that are consistent with the National Association of Insurance Commissioners (NAIC) model audit rules already adopted by the Department of Financial Services for other insurers.

98-1.18(a) MCO Agreements - Amend the regulations to add this section as it applies to MCO agreements with licensed pharmacies and laboratories acting as benefit managers arranging for services, equipment and supplies.

114.20 Watershed Rules and Regulations for the Town of Schroon Lake Water and Its Sources - Repeal the regulation to remove provisions 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)(b).

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 select hospital acquired infections using methods, definitions and protocols defined by the Department, ensures patient privacy in collection and release of data and creates standards for publication and release of the data reported.

405.19 Emergency Services Observation Units - Repeal the provisions in subdivision (g) regarding Observation Units.

405.19, 700.2, 709 Emergency Services - Amend existing regulations to allow hospitals to operate emergency services at a location that is geographically separate from the main hospital campus and that does not operate inpatient beds.

405.21 Perinatal Services - Amend the regulations in Section 405.21 to encourage breastfeeding through policies and procedures, consistent with U.S. and international recommendations; and to 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.

405.21 Perinatal Services - Amend the regulations relating to billing and transfer. Technical amendments are required in Section 405.21 Perinatal Services. A specialty hospital releasing a neonate back to the hospital of birth would be entitled to billing as a discharge, while

transfer to another community hospital would be considered a transfer and therefore reimbursed at a lower rate. Transfer back to the hospital of birth or another lower level perinatal service hospital is strongly encouraged to ensure proximity to parents, and to ensure that neonates who no longer need the higher level of care do not use higher level resources. It is anticipated that 86-1.15 will be amended as well. Therefore, to ensure consistency, amend the perinatal services regulations to conform to Sections 86-1.15 and current language in Section 721.4(c)(1).

405.21 Perinatal Services - Amend the regulations in Section 405.21(c)(2)(ii) to cross reference 405.9(b)(12) of this Part, which is the correct regulatory reference instead of 405.9(b)(11).

405.25 Organ and Tissue Donation Anatomical Gifts - Amend the regulation to reflect changes to Article 43 of the Public Health Law made by Chapter 348 of the Laws of 2009.

405.27 Information, Policy and Other Reporting Requirements - Amend the regulations to repeal this section because the authority for the reporting requirements are detailed in either section 400.18 (SPARCS data) or section 86-1.2 and 86-1.3 (Uniform financial report and uniform statistical reports).

405.32 Observation Services - Amend the regulation to update operational standards for observation services. This will conform the regulation with recent legislation, help ease administrative burdens by increasing consistency with Medicare rules, reduce unnecessary emergency room visits by allowing direct referrals and reduce unnecessary inpatient admissions by increasing the maximum time allowed in observation status.

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).

415.3(h) Resident Rights - Amend the regulations to require nursing home providers to issue a valid written transfer/discharge notice to the resident and his or her designated representative. Such notice shall include date of notice, resident's identity, effective date of proposed transfer/discharge, reason for proposed discharge or transfer, notice of the resident's right to an evidentiary hearing to appeal the proposed discharge, contact information for the NYS Long Term Care Ombudsman, contact information for the agency responsible for the protection and advocacy of individuals with mental illness or development disabilities, and notice of the resident's right to remain in the facility (except in cases of imminent danger), pending the appeal hearing decision. The proposed amendment outlines the Department's interim policy in effect since December 1, 2004.

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 - 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.

600.3 Certificate of Need (CON) Applications - Amend the regulation to simplify the process for review of amendments to Certificate of Need (CON) applications that have received approval for establishment by the Public Health and Health Planning Council (PHHPC) but which have not yet proceeded to actual establishment.

610 Special Requirements for Nonprofit Corporations - 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 documents; except for members appointed to exercise powers set forth in subdivision (d) of section 405.1. 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 update them consistent with section 4002 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.

709.6 Extracorporeal Shockwave Lithotripters - Repeal this regulation, which is 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.

710.1 Medical Facility Construction - Amend the regulation to reflect amendments to PHL 2802 that substitute written notice for limited review, CON administrative review and CON full review for projects confined to non-clinical infrastructure, repair and maintenance, and one-for-one equipment replacement and further amend to allow greater flexibility in the relocation of extension clinics in rural areas.

710.5 Certificate of Need (CON) Applications - Amend the regulation to simplify the process for review of amendments to Certificate of Need (CON) applications that have received approval for construction by the Public Health and Health Planning Council (PHHPC) but which have not yet proceeded to actual construction.

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. Also amend 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 existing 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.

757 Chronic Renal Dialysis Services - Amend the regulations to be consistent with federal changes to 42 CFR regarding Medicare and Medicaid Programs; Conditions for Coverage for End-Stage Renal Disease Facilities.

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.

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; codify regulatory requirements for Advance Life support First Response Agencies; codify regulatory requirements for Basic Life Support Providers; make updates to EMS certification and training regulations. 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. Establish a new section on the mobilization and/or sharing of resources in the event of a declared disaster. Amend to reflect current ambulance vehicle construction requirements, technology and safety for the patients and EMS providers.

800.3, 800.6, 800.8, 800.9, 800.15 and 800.16 Emergency Medical Services - Amend regulations as they relate to certification, recertification and continuing medical education recertification requirements, required conduct of every person certified under Part 800 and the suspension or revocation of certification.

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, 494 and 1001 Adult Homes, Enriched Housing Programs, Residences for Adults, Assisted Living Programs and Assisted Living Residences - Amend the regulations to consolidate and streamline provisions relating to adult homes, enriched housing programs, residences for adults, assisted living programs and assisted living residences to reflect recent legislative changes and 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.

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 regulations to reflect the statutory change regarding the limitation of housekeeping services to 8 hours weekly, and to clarify eligibility requirements for continuous and live-in personal care services.

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.

505.28 Consumer Directed Personal Assistance Program (CDPAP) - Amend the regulations to reflect the statutory change regarding the limitation of housekeeping services to 8 hours weekly, and to clarify eligibility requirements for continuous and live-in consumer directed personal assistance.

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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