RULE REVIEW

Department of Health

Pursuant to the State Administrative Procedure Act Section 207 and 202-d, the Department of Health invites public comment on the continuation or modification of the following rules. Public comments will be accepted for 45 days from the date of publication in the State Register and should be submitted to Katherine Ceroalo, Bureau of House Counsel, Regulatory Affairs Unit, Corning Tower, Room 2438, Empire State Plaza, Albany, NY 12237 by email at REGSQNA@health.ny.gov.

Title 10 NYCRR - Three Year Review

Amendment of Part 80 of Title 10

(Prescription Monitoring Program)

Statutory Authority:

Public Health Law Sections 3333, 3343-a and 3371

Description of the regulation:

The regulations set forth the duty of practitioners to consult the Prescription Monitoring Program Registry (PMP), the duty of pharmacies to update the PMP in real time, the ability of pharmacists to consult the PMP, the ability of practitioners and pharmacists to appoint designees to access the PMP on their behalf, and exceptions to such duties. The Department intends to amend the regulation by clarifying the documentation required when an exception to the duty to consult the Prescription Monitoring Program is asserted by a practitioner.

Title 10 NYCRR - Five Year Review

Amendment of Section 2.10 of Title 10 NYCRR

(Sexually Transmitted Disease Reporting and Treatment Requirements)

Statutory Authority:

Public Health Law Sections 206(1), 225

Description of the regulation:

The regulation establishes reporting requirements for cases, suspected cases and outbreaks of communicable diseases. The regulation should continue without modification.

Amendment of Part 23 of Title 10 NYCRR

(Sexually Transmitted Disease Reporting and Treatment Requirements)

Statutory Authority:

Public Health Law Section 2311

Description of the regulation:

The regulation establishes the list of sexually transmitted diseases, requirements for STD diagnosis and treatment by local health departments, and requirements for STD treatment by other providers. Furthermore, the rule permits health care providers to provide Chlamydia trachomatis patients with antibiotics, or a written prescription for antibiotics to deliver to his or her sexual partner(s) without prior clinical assessment of those partners.

Amendment of Subpart 7-2, Subpart 6-1, and Subpart 6-2 of Title 10 NYCRR

(Children's Camps, Swimming Pools, Bathing Beaches)

Statutory Authority:

Public Health Law Sections 225 and 1394

Description of the regulation:

The amendments to 10 NYCRR Subpart 7-2 implemented chapter laws pertaining to camp permit fees, definition of a summer day camp, and sleeping cabins at overnight camps. The amendments incorporated Public Health Law (PHL) requirements for screening camp staff through the State Sex Offender Registry and providing meningococcal meningitis information to parents. The regulations also modified the requirements for camp aquatic directors and lifeguards, clarified first aid and CPR requirements, and added reflective triangles as an acceptable alternative to flares required for vehicles. The amendments to Subparts 6-1 and 6-2 added course curriculum standards for "Lifeguard Supervision and Management. This regulation should continue without modification.

Amendment of Subpart 5-1 of Title 10 NYCRR

(Public Water Systems)

Statutory Authority:

Public Health Law Section 201(1)(l) and 225(8)

Description of the regulation:

The public water system regulations were revised to incorporate changes required by the 2006 federal Ground Water Rule. Additional minor changes were made to correct errors and clarify required actions by public water systems under specific conditions. This regulation should continue without modification.

Amendment of Part 59 of Title 10 NYCRR

(Chemical Analyses of Blood, Urine, Breath or Saliva for Alcoholic Content)

Statutory Authority:

Vehicle and Traffic Law, Sections 1194(4)(c) and 1198(6) and Dept. of Environmental Conservation Law, Section 11-1205(6)

Description of the regulation:

This regulation describes the requirements that need to be met for the analysis of alcohol content in blood, urine, breath and saliva. The regulation describes the following: the techniques and methods that are used for chemical testing by law enforcement for the presence of alcohol in a person's blood, breath, urine or saliva; requirements that need to be met by agencies that perform training of law enforcement officers; permit requirements for law enforcement officers performing breath analysis; certification requirements for supervisory staff that train law enforcement officers on breath alcohol analysis; certification requirements for ignition interlock devices; approved breath alcohol measurement devices. The regulation should continue with modifications that will 1) allow a designee of the commissioner to effectuate the regulation; 2) update the list of approved evidential breath measurement devices and 3) update the reference to specifications for breath alcohol ignition interlock devices adopted by NHTSA.

Amendment of Section 69-1.2 of Subpart 69-1 of Title 10 NYCRR

(NYS Newborn Screening Panel)

Statutory Authority:

Public Health Law Section 2500-a

Description of the regulation:

New York State's Newborn Screening Program was first implemented in 1965 with a screen for a single metabolic disorder. Public Health Law Section 2500-a requires institutions caring for infants 28 days of age or under to cause newborns to be tested for phenylketonuria, branched-chain ketonuria, homocystinuria, galactosemia, homozygous sickle cell disease, hypothyroidism, and other conditions to be designated by the Commissioner of Health pursuant to regulation. Scientific discoveries and improved technology allow the Department to expand test capabilities, screening newborns for more diseases. Section 69-1.2 of Subpart 69-1 of Title 10 provides a list of the diseases and conditions to be tested. The regulation should continue. Amendments have been proposed to include Adrenoleukodystrophy (XALD) and Pompe disease to the list of diseases or conditions for newborn testing. Additional amendments will be proposed to 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.

Amendment of Subpart 86-1 of Title 10

(Per-Patient Spending Limits for Certified Home Health Agencies (CHHA))

Statutory Authority:

Public Health Law Section 3614(12)

Description of the regulation:

The regulation establishes average per-patient spending limits for CHHAs for a period of one year (April 1, 2011 through March 31, 2012), based on a weighted average of the provider's per-patient claims totals in 2009 and statewide average per-patient claims in 2009, adjusted for case mix and regional wage differences. The regulation should continue without modification.

Amendment of Sections 86-1.2 through 86-1.89 of Title 10

(Hospital Inpatient Reimbursement)

Statutory Authority:

Public Health Law Sections 2803(2), 2807(3) and 2807(4)

Description of the regulation:

The regulation modifies current reimbursement for hospital inpatient services due to the implementation of APG DRGs and rebasing of hospital inpatient rates. The regulation should continue without modification.

Amendment of Section 86-1.37 of Title 10

(Potentially Preventable Readmissions)

Statutory Authority:

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

Description of the regulation:

The regulation implemented a revised reimbursement policy related to hospital readmissions that are determined to be potentially preventable. The regulation will not continue. The legislation expired March 31, 2015.

Amendment of Subpart 86-8 of Title 10

(Ambulatory Patient Groups (APGs) Payment Methodology)

Statutory Authority:

Public Health Law Section 2807(2-a)(e), Section 79(u) of Part C of Chapter 58 of laws of 2008 and Section 129(1) of Part C of Chapter 58 of laws of 2009

Description of the regulation:

To refine the APG payment methodology. The regulation should continue without modification.

Amendment of Subpart 86-8 of Title 10

(January 2011 Ambulatory Patient Groups (APGs) Payment Methodology)

Statutory Authority:

Public Health Law Section 2807(2-a)(e), Section 79(u) of Part C of Chapter 58 of laws of 2008 and Section 129(1) of Part C of Chapter 58 of laws of 2009

Description of the regulation:

To refine the APG payment methodology. The regulation should continue without modification

Title 18 NYCRR - Three Year Review

Amendment of Parts 486 and 487 of Title 18

(Adult Homes)

Statutory Authority:

Social Services Law Sections 460-d, 461, and 461-e

Description of the regulation:

The regulations define "Transitional Adult Homes" as adult homes with a certified capacity of 80 beds or more in which 25% or more of the resident population are persons with serious mental illness, and prohibit operators of Transitional Adult Homes from admitting individuals whose admission would increase the facility's mental health census. The regulations require operators of Transitional Adult Homes to submit compliance plans to the Department of Health setting forth how they will reduce the facility's mental health census to a level that is under 25%, lawfully and over a reasonable period of time.

Title 18 NYCRR - Five Year Review

Addition of Section 505.28 to Part 505 of Title 18

(Consumer Directed Personal Assistance Program)

Statutory Authority:

Social Services Law Sections 365-f

Description of the regulation:

Establishes standards for Medicaid funded Consumer Directed Personal Assistance Program. The regulation should continue with modification. A conforming change should be made to reflect 2015 statutory amendment relating to persons who may serve as a consumer directed personal assistance aide.

Title 10 NYCRR - Ten Year Review

Pursuant to the State Administrative Procedure Act Sections 207 and 202-d, the Department of Health invites public comment on the continuation or modification of the following rules. Public comment should be submitted to Katherine Ceroalo, Bureau of House Counsel, Regulatory Affairs Unit, Corning Tower, Room 2438, Empire State Plaza, Albany, NY 12237.

Amendments to Sections 5-1.52, 5-1.72(f)(12)(i), 5-1.91 of Subpart 5-1 and Appendix 5-C of Part 5 of Title 10 - Standards for Arsenic in Drinking Water

Statutory Authority:

Public Health Law (PHL) § 225

Description of the regulation:

This regulation established a lower Maximum Contaminant Level (MCL) and revised monitoring frequencies for arsenic in drinking water, conforming to the federal Arsenic Rule requirements. The lower MCL has reduced the risk of exposure to this contaminant and has had a positive impact on public health for those served by public water systems in New York State (federally mandated). This regulation should continue without modification.

Amendment of Subpart 7-5 of Title 10 - Camping at Agricultural Fairgrounds

Statutory Authority:

PHL §§ 225(5)(a) and 201(l) and (m)

Description of the regulation:

The regulation established the campsite size and camping unit separation distance requirements at Agricultural Fairgrounds. The changes addressed the difference between camping at agricultural fairgrounds, which typically provide accommodations for workers and owners of livestock, and recreational camping by the vacationing public. The regulation should continue without modification.

Amendment of Paragraph (7) of Subdivision 58-1.12(b) and Addition of a New Subparagraph (iv) of Title 10 - Cytotechnologists Work Standards

Statutory Authority:

PHL § 576-a

Description of the regulation:

Section 576-a of the Public Health Law establishes a work standard for cytotechnologists who examine cytology slides (e.g., Pap smears) at clinical laboratories. Section 576-a also authorizes the Department to promulgate regulations to specify maximum number of cytology slides that may be examined in a workday by cytotechnologists who use cytology slide examination or preparation technologies approved by the federal Food and Drug Administration (FDA). Subdivision 58-1.12(b) defines the workload standards for cytotechnologists. This regulation should continue and be modified to bring the workload standards in alignment with current federal CLIA standards.

Amendment of Section 63.4(a)(4)(i) and Repeal of Section 63.11; Renumber 63.12 to 63.11 of Title 10 - HIV Laboratory Test Reporting

Statutory Authority:

PHL Article 21, Title III, §§ 2130-2139

Description of the regulation:

This regulation describes the protocols and procedures required for HIV reporting, including confidentiality of such reports.

Amendments to the regulation are in process. The amendments will allow local and state health departments to share HIV surveillance information with health care providers for purposes of patient linkage and retention in care.

Repeal of Current Part 70 and Addition of New Part 70 of Title 10 - Regulated Medical Waste

Statutory Authority:

PHL §§ 1389-bb-ff

Description of the Regulation:

This regulation sets forth the requirements that hospitals, residential health care facilities, diagnostic and treatment centers and clinical laboratories must follow regarding regulated medical waste. This regulation describes the policies and procedures that need to be in place for the handling and treatment of regulated medical waste and requirements for the use and approval of autoclaves and alternative regulated medical waste treatment technologies. The regulation should continue without modification.

Sections 80.11(b)(6) and (f), 80.47, 80.49 and 80.50 of Part 80 of Title 10 - Administering Controlled Substances in Emergency Kits for Class 3A Facilities

Statutory Authority:

PHL §§ 3300-a and 3308(2)

Description of the regulation:

The regulations allow for patients who reside in a residential health care facility that is licensed as an "Institutional Dispenser, Limited", to receive controlled substances in a timely manner, via an emergency kit, when immediate administration is necessary and when no alternative treatment is available. This regulation should continue without modification.

Amendment of Sections 86-1.62 and 86-1.63 of Title 10 - NYS-DRGs, SIW, Group Average Arithmetic Inlier Lengths of Stay

Statutory Authority:

PHL § 2807-c(3)

Description of the regulation:

This regulation modifies the service intensity weights for DRGs. This provision has been repealed under Sections 86-1.62 and 86-1.63; however, the provision has been incorporated into inpatient reform under Section 86-1.18.

Amendment of Section 86-1.89 of Title 10 - Supplemental Distribution of the Regional Professional Education Pools

Statutory Authority:

PHL § 2807-m(5)

Description of the regulation:

This regulation establishes reform goals and specifies the distribution methodology. DOH repealed this regulation.

Amendment of Section 94.2(e)(6) of Title 10 – Physician Assistants and Specialist Assistants – Inpatient Medical Orders

Statutory Authority:

PHL §§ 3308, 3701 and 3703

Description of the regulation:

This regulation removed the requirement that inpatient medical orders written by a registered physician assistant (RPA), including those for controlled substances, for inpatients under the care of a physician responsible for such RPA, be countersigned by the supervising physician within 24 hours, but not prior to the execution of any such order. New language was added to specify that countersignature of such orders may be required if deemed necessary and appropriate by the supervising physician or the hospital, but in no event shall countersignature be required prior to execution.

Compliance with the mandatory requirement that a supervising physician countersign RPAs inpatient orders within 24 hours was difficult for the supervising physician. Furthermore, inpatient medical orders written by RPAs are executed prior to the supervising physician's countersignature. It is believed that meaningful supervision comes from the relationship from the supervising physician and the RPA, the credentialing process, the documentation of ongoing competency, and other internal review mechanisms. The Legislature determined that a decision to require countersignature should be determined by the supervising physician or the hospital. The regulation was out of compliance with Chapter 351 of the Laws of 2005 and was amended. This regulation should continue without modification.

Addition of Section 400.22 of Title 10 - Establishment of Statewide Perinatal Data System

Statutory Authority:

PHL §§ 206(1)(e), 2500, 2803(2), 2803(4), 2803-j(3),2805-j, 2805-m, and Article 41; Social Services Law (SSL) § 366-g

Description of the regulation:

The regulation enabled the Department to establish a Statewide Perinatal Data System (SPDS) to consolidate collection, analysis and reporting of birth-related data into a single internet-based, statewide system. The SPDS also facilitated expedited Medicaid enrollment of newborns, ensure they have access to needed health services. SPDS improved the Commissioner's ability to fulfill statutory duties to identify and address public health matters related to perinatal care. The regulation should continue without modification.

Amendment of Section 405.7 of Part 405 and Section 751.9 of Part 751 of Title 10 - Language Assistance Services/Patients' Rights

Statutory Authority:

PHL §§ 2803 and 2805-r

Description of the regulation:

To address the increased need for language services in the hospital setting, the Department strengthened its regulation regarding communication services. This regulation required hospital to develop a Language Assistance Program to ensure meaningful access to the hospital's services and reasonable accommodation for all patients who require language assistance. This regulation also made technical amendments to the hospital and diagnostic and treatment center patients' rights provisions to include two rights that are in statute and in the Department's Your Rights as a Hospital Patient provisions (now online), but were never added to the regulation. This regulation should continue without modification.

Amendment of Section 415.18(g) and (i) of Title 10 - Pharmacy Services in Nursing Homes

Statutory Authority:

PHL Article 33

Description of the regulation:

The provisions contained in 415.18(g) outline the nursing home provider's responsibilities for assuring the availability, administration and safe storage of emergency medications, including controlled substances to be used in emergency situations. The provisions contained in 415.18(i) outline the nursing home provider's responsibility to ensure that legally authorized practitioners/prescribers of medications promptly countersign verbal orders for medications administered to residents within 48 hours, otherwise the order is terminated. This regulation should continue without modification to ensure resident health and safety.

Title 10 NYCRR - Fifteen Year Review

Amendment of Subpart 5-1 - Public Water Systems – Annual Water Supply Statements

Statutory Authority:

PHL § 225

Description of the regulation:

This regulation provides a framework that water suppliers will use to give consumers information on their drinking water, including the water source, contaminants detected in finished water, health effects of contaminants when violations occur, likely sources of detected contaminants, and availability of source water assessments. By understanding their water supplies, customers, especially those with special health needs, can make informed decisions regarding their use of drinking water. The 2001 regulatory amendments also incorporated federal consumer reporting requirements mandated under the 1996 Safe Drinking Water Act Amendments and enacted under the federal Consumer Confidence Report Rule, effective August 19, 1998. This regulation should continue without modification.

Amendment of Section 5-1.72 and Subpart 5-4 – Classification of Community and Transient Non-Community Water System Operators

Statutory Authority:

PHL § 225

Description of the regulation:

This regulation established that all community water systems (CWS) and nontransient noncommunity (NTNC) water systems serving 15 or more service connections or 25 or more persons have the appropriate certified operator(s). Owners of all CWS and NTNC water systems must place the direct supervision of their water system, including each treatment plant and/or the distribution system, under the responsible charge of water treatment operator(s), holding a valid certification equal to or greater than that required for the classification of the treatment plant and/or distribution system. All operating personnel making process control/system integrity decisions about water quality or quantity that effect public health must be appropriately certified and under the direction of an operator in responsible charge. A designated certified operator must be available during plant operation. The regulation should continue with minor modifications to reflect updated training and certification objectives, as well as reflect improved consistency of existing regulatory language between subparts 5-4 and 5-1, and to provide greater flexibility to the regulated community. The regulation is under consideration for modification.

Addition of Subpart 7-3 - Campgrounds

Statutory Authority:

PHL §§ 225(4) and 225(5)

Description of the regulation:

Prior to the addition of Subpart 7-3, campgrounds were regulated as a subset of temporary residences under Subpart 7-1. Many sections of Subpart 7-1 are not applicable or relevant to campgrounds. Subpart 7-3 contains only those sections applicable to campgrounds and clarifies and consolidates all regulations regarding the construction, operation and maintenance of campgrounds. The regulation should continue without modification.

Amendment of Sections 16.10, 16.21, 16.40, 16.41 and 16.50 - Ionizing Radiation

Statutory Authority:

PHL §§ 225(5)(p) and (q)

Description of the regulation:

Part 16 of the State Sanitary Code was amended to revise the schedule for fees charged to radiation equipment facilities registered by the department and instituted new fees for radioactive material users who are issued licenses by the department. The fees are based on the type of facility registered or licensed by the Department. Larger facilities require more staff to regulate and are charged a higher fee while smaller facilities are charged a lesser fee. The fees are typically less than the fees charged in other states and are much less than the fees charged by the United States Nuclear Regulatory Commission (NRC) for its radioactive material licensees. The fees are necessary in order to conduct a regulatory program which covers both radiation equipment and radioactive material and which meets the legislative mandate and maintains compatibility with NRC's program.

Although the current fees are not sufficient to support the regulatory program the Department is not intending to modify the regulation for a fee increase at this time. Rather, the program will continue to implement cost cutting efforts to maintain the current fees. Accordingly, the regulation should continue without modification.

Amendment of Part 34 - Health Care Practitioner Referrals

Statutory Authority:

PHL §§ 238-a, and 586-587

Description of the regulation:

Part 34 regulations, including Subpart 34-1 Health Care Practitioner Referrals and Subpart 34-2 Laboratory Business Practices, were established to prohibit health service purveyors and practitioners from engaging in compensation or business arrangements that improperly induce referrals while allowing arrangements with a beneficial effect. The regulation should continue with minor modifications to update the section relating to recall letters and reporting of test results.

Amendment of Subpart 69-8 – Newborn Hearing Screening Program

Statutory Authority:

PHL § 2500-g and Chapter 585 of the Laws of 1999

Description of the regulation:

Subpart 69-8 is needed to set forth the requirements upon all regulated parties, including hospitals and birthing centers responsible for administering newborn hearing screening programs. Subpart 69-8 defines relevant terms; sets forth general requirements for administration of the newborn hearing screening program and sets forth requirements for newborn hearing screening procedures, including requirements for follow-up of all infants for whom a referral for follow-up screening and care are warranted. The regulations also provide general requirements for institutions caring for infants that provide a referral for infants to obtain initial hearing screening subsequent to discharge from the hospital after birth (institutions with fewer than 400 births annually). Finally, the regulations set forth the responsibilities of institutions caring for infants in special circumstances, including requirements for newborn hearing screening when an infant is transferred from one facility to another such facility or when infants are medically unstable.

All existing requirements under Subpart 69-8 are necessary to ensure universal screening for hearing problems of all newborn infants in New York State. These regulations are needed to ensure hospitals and birth centers appropriately administer newborn hearing screening programs; ensure that newborn hearing screening is conducted by qualified personnel using appropriate equipment and clinical standards and procedures; and, ensure appropriate and timely follow-up of all infants with a hearing loss or potential for hearing loss. These regulations are also necessary to provide the Department with appropriate oversight of hospital newborn hearing screening programs, including collection and analyses of data on the effectiveness of newborn hearing screening. Subsequent to implementation of universal newborn hearing screening, data reported by hospitals to the Department indicate that 95% of all newborn infants in New York State are now screened for hearing loss.

The Department has identified a need to review and propose revisions to these regulations. These revisions would amend the regulation to specify follow-up actions where conditions of the screening are considered to contribute to invalid results; conform regulations to statutory changes; 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 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.

Amendment of Sections 80.131 and 80.137 - Expanded Syringe Access Demonstration Program

Statutory Authority:

PHL § 3381(c)

Description of the regulation:

These regulations implement Public Health Law Section 3381 regarding the sale of hypodermic needles and syringes without a prescription under the Expanded Syringe Access Demonstration Project (ESAP). They support the effort to combat the spread of infectious diseases, including HIV and hepatitis C, via the sharing of needles and syringes and to facilitate access for those having a medical condition requiring regular self-injection. These regulations should be retained and amended to remove the word ''Demonstration'' from the title of the program and formally adopt ''Expanded Syringe Access Program'' as the name of the program.

Amendment of Sections 80.73 and 80.74 - Partial Filling and Electronic Transmission of Prescriptions

Statutory Authority:

PHL § 3333

Description of the regulation:

Article 33 of the Public Health Law (Controlled Substances) was amended in 1999 to provide for electronic pharmacy controlled substance prescription data submission requirements. The law also provided that a pharmacy could partially fill Official New York State prescriptions in certain specified circumstances.

Effective August 27, 2013, the Department amended 10 NYCRR §§ 80.73 and 80.74 to reflect changes to Article 33 of the Public Health Law made pursuant to Chapter 178 of the Laws of 2010 and Chapter 447 of the Laws of 2012 that require pharmacies to electronically submit controlled substance dispensing data to the Department of Health and further specifies the time frame (within 24 hours) in which the data must be submitted to support the Department's Prescription Monitoring Program. No changes were made to the partial filling of controlled substance regulations.

The regulations should continue without modification.

Amendment of Section 86-1.89 - Professional Education Supplemental Pool

Statutory Authority:

PHL § 2807-m(5).

Description of the regulation:

Supplemental distributions of the regional professional education pools. The rule was discontinued.

Addition of Subpart 98-2 - External Appeals of Adverse Determinations

Statutory Authority:

Title II of Article 49 of the Public Health and Insurance Laws, which was enacted by the legislature as Chapter 586 of the Laws of 1998.

Description of the regulation:

The external appeals program provides enrollees of managed care plans and insureds the right to an objective, independent external appeal of a final adverse determination made by their health care plan. The legislature enacted this law in response to charges that health care plans were unilaterally denying health care services based on the health plan's determination that a requested treatment was not medically necessary and/or was experimental or investigational. The law was intended to strengthen the rights of consumers to challenge their health plans' decisions through an objective body of medical experts, at the health plan's expense.

Regulations at Subpart 98-2 are necessary for a number of reasons. First, a right is only a right to the extent that it is understood and accessible. The regulations establish requirements for a standard description of the program which is provided to enrollees and/or their designees to educate them concerning the scope and rules of the external appeals program, as well as enrollees' rights and obligations under the program. Further, the regulations ensure that the program is accessible to enrollees by clarifying eligibility criteria, providing some flexibility for preserving an enrollee's right to an external appeal when they submit an incomplete application and establishing time frames within which the New York State Department of Financial Services must act on an application and inform affected parties of its eligibility determination. Second, to ensure that the program is fair and objective, the regulations establish a process for certifying external appeal agents, including requirements for applicants to demonstrate that clinical peer reviewers will have no material conflicts of interest in assigned external appeals. This process ensures that only capable entities with a sufficient pool of clinical expertise may be certified to review external appeals. The regulations further establish a strong framework for minimizing the potential for conflicts of interest. Third, all parties must understand their respective responsibilities within the program for it to work effectively. The regulations clarify the responsibilities of health plans, certified external appeal agents and enrollees so that the integrity and timeliness of the external appeals program is ensured. The regulations also establish confidentiality requirements concerning enrollee medical records.

Effective December 3, 2008, the regulations were revised, consistent with PHL Section 4914(c) and Insurance Law Section 4914(c) to provide that an external appeal agent and the agent's clinical peer reviewers are not subject to court proceedings to review an external appeal determination absent bad faith or involved gross negligence. In addition, the definition of "designee" was removed to conform to a 2002 caselaw.

The rule should continue with modifications necessitated by changes to Article 49 of the Public Health Law made by Chapter 62 of the Laws of 2011; Chapter 219 of the Laws of 2011; Chapter 514 of the Laws of 2013; and Chapter 60 of the Laws of 2014; as well as passage of the federal Patient Protection and Affordable Care Act (PPACA).

Title 18 NYCRR - Ten Year Review

Amendment of 360-2.3(c)(3) of Title 18 - Self Attestation of Resources for Medicaid Applicants and Recipients

Statutory Authority:

SSL § 366-a(2)

Description of regulation:

This regulation allows self-attestation of resources for certain Medicaid applicants/recipients. This regulation needs to continue without modification.

Repeal existing subdivision (a) of Section 360-7.5 and Add New Subdivision (a) to Section 360-7.5 to Title 18 - Reimbursement of Paid Medical Expenses.

Statutory Authority:

The regulations reflect several federal and State court decisions: the federal district court orders in Greenstein v. Dowling (1994) and Carroll v. DeBuono (1998) and the New York State Court of Appeals decision in Seittelman v. Sabol (1998).

Description of regulation:

The regulations at 18 NYCRR 360-7.5(a) govern the circumstances in which direct reimbursement of paid medical bills may be made to eligible Medicaid or Family Health Plus recipients or their representatives. This regulation needs to continue without modification.

Amendment of Sections 486.4 and 493.2 of Title 18 - Adult Care Facility Operating Certificates

Statutory Authority:

SSL § 460(d)(4)

Description of the regulation:

The regulations were modified to extend the maximum period for which the Department of Health may suspend or limit an Operating Certificate without a hearing from 30 days to 60 days. This regulation should continue without modification.

Amendment of Section 505.14 of Title 18 - Personal Care Services

Statutory Authority:

SSL §§ 363-a(1) and 365-a(2)(e)

Description of the regulation:

The regulations were amended in December 2006 to repeal obsolete provisions of the Department's Personal Care Services regulations at

18 NYCRR 505.14. The repealed provisions represent non-implementable content and obsolete content resulting from expired statutory authority and court decisions. Removal of content from the regulations that is not in effect makes the regulations accurate and consistent with current policy and procedures for the program's operations. This regulation should continue without modification.

Title 18 NYCRR - Fifteen Year Review

Amendment to Section 505.14(b)(5)(v)(c)(1)-(10) of Title 18 - Personal Care Services

Statutory Authority:

SSL §§ 363-1(1), 363-a(2) and 365-1(2)(e)

Description of the regulation:

This section of the Personal Care Services regulations was amended to be compliant with a Mayer v. Wing court settlement; and, to help terminate the Mayer court's jurisdiction over the Department in this case.

Consistent with State policy, the Mayer case stands for the general principle that social services districts cannot arbitrarily or capriciously reduce or discontinue Medicaid recipients' personal care services. To the contrary, the districts must have a legitimate reason, grounded in law or regulation, to reduce or discontinue services. Further, the fair hearing notice must state the particular reason for the proposed reduction or discontinuance sufficient to apprise the recipient of the basis for the district's action. The Mayer court also ordered that districts may not use so-called task-based assessment plans when authorizing personal care services for any recipient whom the district has determined needs 24 hour care. Under the 1997 settlement in this case, the Department agreed to adopt regulations by November 1, 2001, that substantially complied with the court's various orders in this case. Although the regulations were new when added in 2001, their content should be familiar to all social services districts. The regulations essentially reiterate previous instructions that the Department issued to districts on the Mayer court order. This regulation should continue as modified by a recent Notice of Adoption.