

NYS Medical Indemnity Fund

Effective date: 6/18/14

SUMMARY OF EXPRESS TERMS

As required by section 2999-j(15) of the Public Health Law (“PHL”), the New York State Commissioner of Health, in consultation with the Superintendent of Financial Services, has promulgated these regulations to provide the structure within which the New York State Medical Indemnity Fund (“Fund”) will operate. Included are (a) critical definitions such as “birth-related neurological injury” and “qualifying health care costs” for purposes of coverage, (b) what the application process for enrollment in the Fund will be, (c) what qualifying health care costs will require prior approval, (d) what the claims submission process will be, (e) what the review process will be for claims denials, (f) what the review process will be for prior approval denials, and (g) how and when the required actuarial calculations will be done.

The application process itself has been developed to be as streamlined as possible. Submission of (a) a completed application form, (b) a signed release form, (c) a certified copy of a judgment or court-ordered settlement that finds or deems the plaintiff to have sustained a birth-related neurological injury, (d) documentation regarding the specific nature and degree of the applicant’s neurological injury or injuries at present, (e) copies of medical records that substantiate the allegation that the applicant sustained a “birth-related neurological injury,” and (f) documentation of any other health insurance the applicant may have are required for actual enrollment in the Fund.

The parent or other authorized person must submit the name, address, and phone number of all providers providing care to the applicant at the time of enrollment for purposes of both

claims processing and case management. To the extent that documents prepared for litigation and/or other health related purposes contain the required background information, such documentation may be submitted to meet these requirements as well, provided that this documentation still accurately describes the applicant's condition and treatment being provided.

Those expenses that will or can be covered as qualifying health care costs are defined very broadly. Prior approval is required only for very costly items, items that involve major construction, and/or out of the ordinary expenses. Such prior approval requirements are similar to the prior approval requirements of various Medicaid waiver programs and to commercial insurance prior approval requirements for certain items and/or services.

Reviews of denials of claims and denials of requests for prior approval will provide enrollees with full due process and prompt decisions. Enrollees are entitled to a conference with the Fund Administrator or his or her designee and a review, which will involve either a hearing before or a document review by a Department of Health hearing officer. In all reviews, the hearing officer will make a recommendation regarding the issue and the Commissioner or his designee will make the final determination. An expedited review procedure has also been developed for emergency situations.

Pursuant to the authority vested in the Commissioner of Health by section 2999-j of the Public Health Law, Part 69 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended to be effective upon publication of a Notice of Adoption in the New York State Register by adding a new Subpart 69-10, to read as follows:

§ 69-10.1 Definitions.

As used in this Subpart:

(a) “Activities of daily living” mean basic self-care tasks such as dressing and undressing, self-feeding, bowel and bladder management, ambulation with or without the use of an assistive device, communication, functional transfers from one place to another, and personal hygiene and grooming.

(b) “Assistive technology” (“AT”) means those devices, controls, appliances, items, pieces of equipment, or supplies of either a communication or an adaptive type, determined necessary by a physician for purposes of the enrollee’s habilitation, ability to function or safety in his or her current or desired residence which are not listed in the Medicaid Durable Medical Equipment (DME) Provider Manual at <https://www.emedny.org/ProviderManuals/DME/index.aspx>.

Such technology may also be referred to as adaptive technology or adaptive equipment. In the event that a particular item or piece of equipment falls within the definition of both “assistive technology” and an “environmental modification” as defined in subdivision (m) of this section, it will be considered to be an environmental modification for purposes of these regulations.

(c) “Birth-related neurological injury” means an injury to the brain or spinal cord of a live infant caused by the deprivation of oxygen or mechanical injury that occurred in the course of labor, delivery or resuscitation or by other medical services provided or not provided during

delivery admission that rendered the infant with a permanent and substantial motor impairment or with a developmental disability as that term is defined by section 1.03 of the mental hygiene law, or both.

(d) “Case manager” means a person who performs the functions set out in section 69-10.4 of this Subpart.

(e) “Claims assistance manager” means the person or persons who perform(s) the functions set out in section 69-10.3 of this Subpart.

(f) “Commissioner of Health” or “Commissioner” means the New York State Commissioner of Health.

(g) “Commissioner of Taxation” means the New York State Commissioner of Taxation and Finance.

(h) “Delivery admission” means a hospital admission for the specific purpose of giving birth.

(i) “Department of Financial Services” means the New York State Department of Financial Services.

(j) “Durable medical equipment” means devices and equipment that have been ordered by a physician in the treatment of a specific medical condition and that have all of the following characteristics:

- (1) can withstand repeated use for a protracted period of time;
- (2) are primarily and customarily used for medical purposes;
- (3) are generally not useful in the absence of an illness or injury;
- (4) are not usually fitted, designed or fashioned for a particular individual’s use; and

(5) if intended for use by only one patient, the equipment may be either custom-made or customized.

For purposes of this Subpart, durable medical equipment also includes medical/surgical supplies, orthotic appliances and devices and orthopedic footwear as defined in 18 NYCRR § 505.5 and listed in the Medicaid DME Provider Manual at <https://www.emedny.org/ProviderManuals/DME/index.aspx>.

(k) “Emergency” means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in placing the patient’s health in serious jeopardy, serious impairment of bodily functions, or serious dysfunction of any bodily organ or part. Only a qualified ordering practitioner may determine, using his or her professional judgment, whether a situation constitutes an emergency.

(l) “Enrollee” means a qualified plaintiff accepted into the Fund or for notification and decision making purposes only, the person authorized to act on his or her behalf; provided, however, that nothing in this Subpart shall be read to authorize payment or reimbursement of medical services provided to any person other than the qualified plaintiff.

(m) “Environmental modification” (“Emod”) means an interior or exterior physical adaptation to the residence in which an enrollee lives that is necessary to ensure the health, welfare, and safety of the enrollee, enables him or her to function with greater independence in the community and/or helps avoid institutionalization, and has been ordered by a physician. Emods include but are not limited to: ramps, widened doorways and handrails, roll-in showers, vertical lifts, elevators only when there is no other safe and cost effective alternative, and cabinet and shelving adaptations. Emods do not include any routine home maintenance. Emods also do

not include adaptations or modifications that are of general utility and that do not provide direct medical or remedial benefit to the enrollee. With respect to new construction, Emods do not include modifications needed as a result of avoidable barriers created by the new construction floor plan.

(n) “Experimental treatment” means a drug, device, or treatment for which:

(1) there is insufficient outcome data available from controlled clinical trials published in the peer-reviewed literature to substantiate its safety and effectiveness for the illness or injury involved; or

(2) approval required from the FDA for marketing to the public has not been granted; or

(3) a recognized national medical or dental society or regulatory agency has determined, in writing, that it is experimental or investigational, or for research purposes; or

(4) it is a type of drug, device or treatment that is the subject of an investigational new drug treatment pursuant to 21 C.F.R. § 312.21, or is the subject of an investigational device treatment pursuant to 21 C.F.R § 812.36; or

(5) the written protocol or protocols used by the treating facility or by another facility studying the same drug, device, procedure, or treatment, states that it is experimental or investigational.

(o) “Fund” means the “New York State Medical Indemnity Fund” created pursuant to Chapter 59 of the Laws of 2011 to provide a funding source for future health care costs associated with birth-related neurological injuries.

(p) “Fund Administrator” means the Superintendent of Financial Services or any person or entity designated by the Superintendent for purposes of administering the Fund.

(q) “Habilitation services” mean services designed to provide assistance with the retention, acquisition or improvement of the enrollee’s activities of daily living such as personal grooming and cleanliness, eating and dressing, communication, and mobilization; and when appropriate, the instrumental activities of daily living such as household chores, food preparation, mobility training for maximum independence involving local travel, including the use of public transportation, socially appropriate behavior, the development of basic health and safety skills, and simple money management.

(r) “Hospital” means a general hospital or a maternity hospital, including a birthing center located in a general hospital or a maternity hospital, or a birthing center operating as a diagnostic and treatment center, as defined by section 2801 of the public health law.

(s) “Informal supports” means those immediate family members, other family members, friends, volunteers, and other people in the enrollee’s community who provide or are willing to provide unpaid care and services for the enrollee.

(t) “Instrumental activities of daily living” mean those functions not necessary for fundamental functioning but necessary for an individual to be able to live independently in the community such as taking medications as prescribed, performing housekeeping tasks, managing money, using the telephone or other form of communication, shopping for groceries and clothing, and managing transportation within the community.

(u) “Nurse practitioner” means an individual (1) certified to practice as a nurse practitioner pursuant to Article 139 of the New York State Education Law, (2) duly authorized to practice as a nurse practitioner or the equivalent of a nurse practitioner in any other state in the United States or in the District of Columbia, or (3) duly authorized to practice as a nurse practitioner or the equivalent of a nurse practitioner in another country.

(v) “Physician” means a physician licensed to practice in New York State pursuant to Article 131 of the New York State Education Law, (2) duly authorized to practice in any other state in the United States or in the District of Columbia, or (3) duly authorized to practice as a physician in another country.

(w) “Physician assistant” means an individual (1) licensed to practice as a physician assistant in New York State pursuant to Article 131-B of the New York State Education Law, (2) duly authorized to practice as a physician assistant or the equivalent of a physician assistant in any other state in the United States or in the District of Columbia, or (3) duly authorized to practice as a physician assistant or the equivalent in another country.

(x) “Prior approval” means the process set forth in section 69-10.6 of this Subpart for review of proposed, non-routine expenditures such as Emods, vehicle modifications, assistive technology, private duty nursing, planned specialist appointments and/or hospital treatment requiring travel and accommodations, hearing aids, custom made equipment, myo-electric limbs, treatment with specialty drugs, and experimental treatments and/or procedures, including the review process for any denial of a request for prior approval.

(y) “Qualified plaintiff” means every plaintiff or claimant who:

(1) has been found by a jury or court to have sustained a birth-related neurological injury as the result of medical malpractice, or

(2) has sustained a birth-related neurological injury as the result of alleged medical malpractice and has settled his or her lawsuit or claim therefor.

(z) “Qualifying health care costs” mean the future costs for medical, hospital, surgical, nursing, dental, rehabilitation services, habilitation services, and custodial care; respite care, subject to a maximum of 1080 hours per year unless prior approval has been obtained for

additional respite care; durable medical equipment; environmental home modifications (“Emods”), assistive technology, and vehicle modifications; prescription and over the counter medications when prescribed by a physician, dentist, nurse practitioner, certified nutritionist or physician assistant; psychological, social work, nutritional counseling, chiropractic, hospice and palliative care; transportation for purposes of health care related appointments in accordance with section 69-10.12 of this Subpart; copayments and deductibles for services, items, equipment or medication paid for by commercial insurance; and any other health care costs actually incurred for services rendered to and supplies utilized by a qualified plaintiff that his or her physician, physician assistant, or nurse practitioner has stated in writing on his or her letterhead, or on the supervising or collaborating physician’s letterhead, if applicable, is necessary to meet the qualified plaintiff’s health care needs. The statement of necessity may be based on the assessment of a dentist, podiatrist, psychologist, physical therapist, occupational therapist, chiropractor, certified nutritionist or dietician, and/or speech pathologist. The Fund Administrator may make coverage of ongoing therapeutic services subject to the receipt of periodic treatment plans and progress reports. Qualifying health care costs shall not include:

(1) any services, supplies, items or equipment potentially available to the enrollee under an Individualized Education Program, Preschool Supportive Health Services Program, Early Intervention Program or equivalent program in another country, unless the enrollee’s parent or guardian can demonstrate that he or she made a reasonable effort to obtain the services, supplies, items or equipment through such program; or

(2) any services, supplies, items, equipment or medications that any commercial insurance under which the enrollee is covered is legally obligated to provide.

(aa) “Respite” means the provision of paid intermittent, temporary substitute care, including care provided in an institutional setting, for the benefit of the primary caregiver, who is a family member, a guardian or other informal support functioning as the enrollee’s non-paid primary caregiver, for the purpose of providing relief from the responsibilities of daily caregiving of the enrollee, including any substitute care provided to an enrollee and paid for by the Fund because the primary caregiver is not at home because of work and/or school. All respite care in excess of 1080 hours a year will require prior approval.

(ab) “Specialty drug” means a drug that is typically high in cost and has one or more of the following characteristics:

- (1) is a component of complex therapy for treatment of a complex disease;
- (2) requires specialized patient training and coordination of care prior to therapy initiation and/or during therapy;
- (3) requires unique patient adherence to treatment regimen and safety monitoring of the patient during treatment with the drug;
- (4) requires unique handling, shipping, and storage; and
- (5) presents a potential for significant waste because of the manner in which the drug is packaged/dispensed or the failure to follow accepted clinical protocols prior to administration to the patient or both.

(ac) “Superintendent of Financial Services” means the Superintendent of the New York State Department of Financial Services.

(ad) “Usual and customary charges” mean the usual, customary and reasonable (“UCR”) charges for services provided in private physician practices as described in section 69-10.21 of this Subpart.

(ae) “Vehicle modifications” mean:

(1) adaptive equipment designed to enable an enrollee to operate a vehicle or be transported in a vehicle such as hand controls, deep dish steering wheels, spinner knobs, wheelchair lock down devices, parking brake extensions, foot controls, wheelchair lifts, left foot gas pedals; or

(2) changes to the structure, internal design, or existing equipment of a vehicle, such as replacement of the roof with an elevated fiberglass top, floor cut-outs, extension of the steering column, raised door, repositioning of seats, wheelchair floor, and dashboard adaptations.

§ 69-10.2 Application and Enrollment Process.

(a) An application for enrollment into the Fund may be submitted by:

(1) a qualified plaintiff;

(2) a person who is authorized to act on a qualified plaintiff’s behalf; or

(3) a defendant in a medical malpractice claim or action that results in a court-approved settlement or judgment issued on or after April 1, 2011, stating that the plaintiff sustained a “birth-related neurological injury.”

(b) An application for enrollment shall be submitted on the application form provided by the Fund Administrator, which may be obtained either by downloading it from the Fund Administrator’s website or by requesting a form from the Fund Administrator by phone or by making a written request. The completed application shall be accompanied by the following:

(1) a medical release form, which shall be in compliance with applicable laws and regulations pertaining to patient confidentiality and shall be made available by the Fund Administrator, and signed by a person authorized to act on the plaintiff’s or claimant’s behalf;

(2) a certified copy of the court-approved settlement or judgment, including all documents and/or exhibits referenced in the settlement or judgment;

(3) documentation regarding the specific nature and degree of the applicant's birth-related neurological injury or injuries, including diagnoses and impact on the applicant's activities of daily living and instrumental activities of daily living. A copy of the life plan or the summary provided by the applicant's treating physician or other such documentation that was provided to the court in support of the settlement agreement or as part of the applicant's medical malpractice action and contains the required information or any other documentation submitted on behalf of the enrollee for purposes of enrollment in another health related program can be provided in lieu of submitting entirely new documentation, provided that such documentation still accurately reflects the applicant's condition;

(4) documentation in the form of copies of medical records that supports the allegation that the applicant's injuries, condition or impairments occurred as a result of oxygen deprivation, a mechanical injury or other action or failure to act during the birth delivery admission;

(5) the names, addresses, and phone numbers of all providers providing services to the applicant at time of enrollment; and

(6) documentation of all other present sources of health care coverage or reimbursement, including commercial insurance and/or government program(s).

(c) Documentation submitted on behalf of the applicant for purposes of enrollment in another health related program also may be submitted for purposes of paragraphs (b)(4) and (5) of this section if the documentation is still current.

(d) Upon receipt of an application, the Fund Administrator shall review the court approved settlement or the judgment, whichever is applicable, to ensure that the document states

that the plaintiff or claimant has been deemed or found to have sustained a birth-related neurological injury as defined in section 69-10.1 of this Subpart and that the settlement or judgment provides that, in the event the plaintiff becomes an enrollee of the Fund, all future medical expenses of the plaintiff or claimant will be paid by the Fund in lieu of that portion of the settlement or award that provides for payment of future medical expenses. If the language regarding the nature of the injury and/or the Fund being the payor of the future medical expenses of the plaintiff or claimant is missing or is not clear, the application shall not be considered complete and the Fund Administrator shall inform the applicant to go back to the court that approved the settlement or issued the judgment to add clarifying language.

(e) The Fund Administrator shall also review all additional required documentation provided with the application and shall notify the person who submitted the application on behalf of the plaintiff or claimant of any information still needed to complete the application within fifteen business days from receipt of the application. No application will be deemed to have been submitted until all required documentation has been provided to the Fund Administrator.

(f) Upon (1) determining that the court-approved settlement or the judgment deems or finds the plaintiff or claimant to have sustained a birth-related neurological injury and provides that the Fund shall be the payer of all future medical expenses for the plaintiff or claimant in lieu of that portion of the settlement or award that provides for payment of future medical expenses, and (2) the receipt of all required documentation set forth in subdivision (b) of the section, the Fund Administrator shall enroll the qualified plaintiff within five business days of such determination and provide written notification of enrollment to the qualified plaintiff or a person who is authorized to act on the qualified plaintiff's behalf, if known to the Fund Administrator, and to the defendant. The Fund will reimburse all appropriate costs incurred to meet the

enrollee's health care needs between the date the court approved the settlement or judgment for the qualified plaintiff and the date the qualified plaintiff becomes a Fund enrollee.

(g) Upon enrolling a qualified plaintiff, the Fund Administrator shall assign the enrollee to a case manager and notify the enrollee of the name of and contact information for such case manager within seven business days from the date of enrollment.

(h) The Fund Administrator shall provide each enrollee with an enrollment card that contains a unique enrollment identification number.

§ 69-10.3 Claims Assistance Manager.

Duties of the claims assistance manager shall include, but not be limited to, the following:

(a) answering questions regarding the information and documentation needed for completion of the application process;

(b) handling any issues raised about alleged delays by the Fund Administrator in processing applications, claims, reviews of claim denials, prior approval initial determinations, and prior approval reviews; and

(c) assisting in resolving any issues involving enrollees and case managers or the assignment of case managers.

§ 69-10.4 Case Management

(a) "Case management" means functions, including but not limited to:

(1) conducting an initial assessment and periodic reassessments of the enrollee's medical needs;

(2) evaluating the enrollee's strengths, informal support system and environmental factors relevant to his/her care;

(3) reviewing information provided by the enrollee, the enrollee's informal support system, and current providers (including any school related or habilitation services) regarding the services presently being provided to the enrollee and any existing gaps in the services being provided to the enrollee;

(4) establishing a comprehensive, written case management plan to assist the enrollee or the enrollee's caregiver to manage the delivery of all qualifying health care services needed by the enrollee;

(5) assisting an enrollee or the enrollee's caregiver to obtain services set forth in the case management plan for the enrollee through referral to agencies or persons qualified to provide those services;

(6) assisting the enrollee with any forms necessary for the receipt of or payment for services;

(7) assisting with crisis intervention in the event that the enrollee has emergency service needs;

(8) developing and maintaining a list of alternative provider sources that may be available to the enrollee in the event of service disruption, and making that list available upon the request of the enrollee or the enrollee's caregiver; and

(9) monitoring the services provided under the case management plan by:

(i) verifying that the services identified in the case management plan are being received by the enrollee in the amount and frequency specified in the case plan; and

(ii) documenting the case record regarding the enrollee's medical condition and progress made.

If the enrollee already has a case manager in another health related program, the Fund Administrator's case manager shall coordinate the enrollee's care in conjunction with the other case manager.

(b) Case manager qualifications. A case manager shall have significant experience or educational training in health or social services, preferably including work experience or a practicum that involved the performance of assessments and the development of case management plans. Voluntary or part-time experience that can be verified will be accepted on a pro rata basis.

(c) Case manager reassignment. An enrollee or person acting on an enrollee's behalf can request a change in case manager at any time by submitting a written request for reassignment on a form provided by the Fund Administrator. Reassignments will occur as promptly as possible based on case manager availability and existing caseloads.

(d) Responsibilities of an enrollee or enrollee's parent, guardian or legal representative. The enrollee or the enrollee's parent, guardian or legal representative is responsible for participating in an initial case management conference and subsequent, periodic case management conferences on a schedule determined by the needs of the enrollee. The repeated failure of the responsible individual to participate in necessary case management conferences may result in the Fund Administrator not processing any claims or requests until compliance with this requirement occurs.

§ 69-10.5 Claims Submission Process.

(a) All providers providing services to an enrollee must accept assignment of payment from the Fund.

(b) The claims submission process will include both electronic and manual options for submission of claims.

(c) The unique enrollee identifier must be included in the designated area of the claim form.

(d) Claims shall be submitted within 90 days of the date of service and will be paid within 45 days of receipt of an acceptable claim form. A request for permission to submit a claim later than 90 days from the date of service may be granted by the Fund Administrator upon a showing of good cause for the delay.

§ 69-10.6 Prior Approval Request Process.

(a) Expenses that require prior approval. Assistive technology, vehicle modifications, environmental modifications, myo-electric limbs, certain types of transportation for medical care and services (including travel involving overnight accommodations), private duty nursing, treatment with a specialty drug, experimental treatment for which the enrollee's provider has submitted documentation that complies with the same standards set out in section 4910(2)(b)(i)-(iii) of the Public Health Law, custom-made durable medical equipment, hearing aids, and more than 1080 hours of respite care in a calendar year.

(b) Prior approval requests, other than emergency requests as set forth in § 69-10.15, will be determined within thirty days from the date all necessary documentation in support of the request has been received.

(c) General documentation requirements. In the absence of more specific requirements for particular types of expenses, every request for prior approval except for private duty nursing, which is subject to the requirements of § 69-10.10, must be accompanied by a written statement from the enrollee's treating physician stating why the service, equipment, or treatment in issue is necessary.

§ 69-10.7 Prior Approval Requests for Emods.

(a) An Emod may be approved only when made to the enrollee's primary residence, except that if physical custody is being shared pursuant to a court order, an Emod may also be approved pursuant to this section when made to the primary residence of the enrollee's non-custodial parent. Proof of ownership of the residence to which the modification(s) are being requested must be submitted to the Fund Administrator. If the requesting party does not own the residence, written permission of the property owner must be provided. A non-custodial parent applying for an Emod to his or her primary residence must also provide a certified copy of the court order awarding shared physical custody.

(b) Any Emod approved by the Fund Administrator must meet all applicable State and local building codes.

(c) The Fund Administrator may not approve any Emod that (1) constitutes an improvement to the home that is not medically necessary to ensure the health, welfare and safety of the enrollee by enabling him or her to function with greater independence in the community and/or by helping him or her to avoid institutionalization or (2) does not comply with Americans with Disabilities Act ("ADA") Accessibility Standards or Guidelines or the Fair Housing Act, if

applicable, or has not been determined to be safe by a rehabilitative evaluation agency or specialist or a building contractor as required in subdivision (d) (2) below.

(d) An Emod request must be accompanied by the following documentation:

(1) a written statement from the enrollee's treating physician on the physician's letterhead explaining why the Emod requested is medically necessary; and

(2) a comprehensive evaluation of the proposed project by a rehabilitative evaluation agency, rehabilitative specialist, or an independent building contractor who has significant experience working with ADA building standards and accessibility guidelines, including pictures of the specific location in which the Emod will be built or installed. The evaluation must specify: a description of the proposed Emod; the need for the Emod; the reason the proposed Emod was selected; whether it is the most cost effective approach to fulfilling the enrollee's need for the Emod; and whether there are any safety concerns associated with the proposed Emod and if so, how they will be addressed. The evaluation must also explain how the materials to be used in constructing the Emod are cost effective in comparison to alternative materials.

(e) Once the request has been reviewed by the Fund Administrator, the Fund Administrator shall notify the enrollee or person authorized to act on the enrollee's behalf in writing which services or items have been approved and/or denied and inform the enrollee or person authorized to act on the enrollee's behalf of the bidding process that is required prior to the Fund Administrator approving payment for the Emod. The enrollee or person authorized to act on the enrollee's behalf is then required to obtain a minimum of three acceptable bids from qualified contractors.

(f) Once the Fund Administrator receives from the enrollee or person authorized to act on the enrollee's behalf a minimum of three acceptable bids from qualified contractors, the Fund

Administrator shall evaluate the qualifications of each bidder and the content of each bid to determine whether each bid is acceptable. In determining whether a bidding contractor is qualified, the Fund Administrator will take into account whether the contractor has any outstanding judgments on file and whether any complaints have been upheld against the contractor by the Better Business Bureau or the New York State Department of Law. If the enrollee lives in another state or in the District of Columbia, the same type of investigation will be undertaken in that jurisdiction.

(g) An acceptable bid is one that includes:

(1) a description of the scope of work and specifications of the Emod;
(2) proof of appropriate and adequate insurance for the duration of the project; and
(3) a statement signed by the contractor or a person duly authorized to sign for the contractor that the work will be done in a workmanlike manner, using materials suitable for purposes of the project and the safety of the enrollee and household members, and will comply with all applicable building and zoning laws.

(h) If less than three bids are submitted, a written explanation of why three acceptable bids were not obtained must be provided, as well as a written explanation of how the determination was made that the one or two bids being considered are reasonably priced.

(i) If the two lowest comparable bids are within ten percent of each other, the enrollee or his or her legally authorized representative may choose one of the two lowest bids. If there is more than a ten percent difference between the two lowest comparable bids, the Fund Administrator shall choose the bid that represents the best value for both the Fund and the enrollee based on factors including not only the price offered by each bidder but also the quality, durability, extent of any warranties provided, safety of the product itself, and workmanship

offered by each bidder. The successful bidder will be notified after the Fund Administrator or a designee of the Fund Administrator (1) discusses the bids received with the enrollee or the person authorized to act on the enrollee's behalf and the reasons why a particular bid is chosen by the Fund Administrator, and (2) obtains the written consent of the enrollee or the person authorized to act on the enrollee's behalf to have the Emod constructed or installed by that bidder. If the enrollee or the person authorized to act on the enrollee's behalf disagrees with the Fund Administrator's decision, the enrollee or his or her authorized representative can request a review of the Fund Administrator's decision.

(j) The Fund Administrator will authorize payment to the successful bidder of no more than one-third of the accepted bid amount upon acceptance of the bid unless there are extenuating circumstances about which the Fund Administrator receives advance notice such as a project that can be completed in one day or a project that involves the purchase of a product prior to installation or construction.

(k) Any change from either the specifications in terms of alternative or substitute equipment or the scope of work involved in the modification that will result in a cost increase from the bid price will require approval from the Fund Administrator.

(l) No additional payment will be authorized until the Fund Administrator has received a post-modification evaluation stating that the modification meets the participant's functional needs and is in compliance with the initial evaluation, including adherence to safety and all applicable building code standards.

(m) Payment for the Emod shall include the cost of the comprehensive evaluation of the proposed project, the evaluation of required bids if the Fund Administrator finds it necessary to engage an outside expert, the evaluation of the completed Emod, a one year maintenance

contract, if deemed appropriate by the Fund Administrator, as well as the cost of construction or installation of the Emod itself.

(n) Repairs for Emods that are cost effective may be allowed if appropriate.

Modifications that have worn out through normal use (e.g., faucet, controls, ramps, handrails) may be replaced using the same prior approval process required for new Emods.

§ 69-10.8 Conditional Prior Approval for Emods to Prospective Primary Residences

(a) An Emod may be conditionally approved for a prospective primary residence of an enrollee, including new construction, provided payment is conditioned upon the following:

(1) the Fund Administrator approves the Emods to be made to the specified property in accordance with the requirements of this section;

(2) the enrollee or the enrollee's custodial guardian has or obtains lawful title to the property to which the Emods are to be made;

(3) installation or construction of the Emod is completed; and

(4) the Fund Administrator has received a post-modification evaluation stating that the modification meets the enrollee's functional needs and is in compliance with the initial evaluation, including adherence to safety and all applicable building code standards.

(b) Any Emod approved by the Fund Administrator must meet all applicable State and local building codes.

(c) The Fund Administrator may not approve any Emod that (1) constitutes an improvement to the home that is not medically necessary to ensure the health, welfare and safety of the enrollee by enabling him or her to function with greater independence in the community and/or by helping him or her to avoid institutionalization or (2) does not comply with Americans

with Disabilities Act (“ADA”) Accessibility Standards or Guidelines or the Fair Housing Act, if applicable, or has not been determined to be safe by a rehabilitative evaluation agency or specialist or a building contractor as required in subdivision (d) (3) below.

(d) An application for a conditional approval for an Emod to a prospective primary residence shall include the following documentation:

(1) a written statement from the enrollee’s treating physician on the physician’s letterhead explaining why the Emod requested is medically necessary;

(2) a comprehensive evaluation of the proposed project by a rehabilitative evaluation agency, rehabilitative specialist, or an independent building contractor who has significant experience working with ADA building standards and accessibility guidelines, including a copy of the floor plan which indicates the specific location in which the Emod will be built or installed. The evaluation must specify: a description of the proposed Emod; the need for the Emod; the reason the proposed Emod was selected; whether it is the most cost effective approach to fulfilling the enrollee’s need for the Emod; and whether there are any safety concerns associated with the proposed Emod and if so, how they will be addressed. The evaluation must also explain how the materials to be used in constructing the Emod are cost effective in comparison to alternative materials; and

(3) if the residence is to be constructed or is under construction, a statement from the contractor or the party who completed the comprehensive evaluation describing how the construction of the home is designed to minimize the cost of the Emods to be installed, such as reducing the amount of deconstruction necessary by leaving appropriate spaces for installation of the Emod. Payment for Emods to new construction shall not include the cost of removing any

avoidable barrier to the enrollee's access that is created by the floor plan or during the construction process.

(e) Once the request has been reviewed by the Fund Administrator, the Fund Administrator shall notify the enrollee or person authorized to act on the enrollee's behalf in writing which services or items have been conditionally approved and/or denied and inform the enrollee or person authorized to act on the enrollee's behalf of the bidding process that is required prior to the Fund Administrator approving payment for the Emod. The enrollee or person authorized to act on the enrollee's behalf is then required to obtain a minimum of three acceptable bids from qualified contractors. With respect to new construction to which the enrollee or the enrollee's custodial guardian has not yet taken title, the requirement for bidding may be satisfied by the general contractor obtaining three acceptable bids for the Emods to be constructed which must then be submitted to the Fund Administrator.

(f) Once the Fund Administrator receives from the enrollee, person authorized to act on the enrollee's behalf, or the general contractor, a minimum of three acceptable bids from qualified contractors, the Fund Administrator shall evaluate the qualifications of each bidder and the content of each bid to determine whether each bid is acceptable. In determining whether a bidding contractor is qualified, the Fund Administrator will take into account whether the contractor has any outstanding judgments on file and whether any complaints have been upheld against the contractor by the Better Business Bureau or the New York State Department of Law. If the enrollee lives in another state or in the District of Columbia, the same type of investigation will be undertaken in that jurisdiction.

(g) An acceptable bid is one that includes:

(1) a description of the scope of work and specifications of the Emod;

(2) proof of appropriate and adequate insurance for the duration of the project; and

(3) a statement signed by the contractor or a person duly authorized to sign for the contractor that the work will be done in a workmanlike manner, using materials suitable for purposes of the project and the safety of the enrollee and household members, and will comply with all applicable building and zoning laws.

(h) If less than three bids are submitted, a written explanation of why three acceptable bids were not obtained must be provided, as well as a written explanation of how the determination was made that the one or two bids being considered are reasonably priced.

(i) If the two lowest comparable bids are within ten percent of each other, the enrollee or his or her legally authorized representative may choose one of the two lowest bids. If there is more than a ten percent difference between the two lowest comparable bids, the Fund Administrator shall choose the bid that represents the best value for both the Fund and the enrollee based on factors including not only the price offered by each bidder but also the quality, durability, extent of any warranties provided, safety of the product itself, and workmanship offered by each bidder. The successful bidder will be notified after the Fund Administrator or a designee of the Fund Administrator (1) discusses the bids received with the enrollee or the person authorized to act on the enrollee's behalf and the reasons why a particular bid is chosen by the Fund Administrator, and (2) obtains the written consent of the enrollee or the person authorized to act on the enrollee's behalf to have the Emod constructed or installed by that bidder. If the enrollee or the person authorized to act on the enrollee's behalf disagrees with the Fund Administrator's decision, the enrollee or his or her authorized representative can request a review of the Fund Administrator's decision.

(j) Any change from either the specifications in terms of alternative or substitute equipment or the scope of work involved in the modification that will result in a cost increase from the bid price will require approval from the Fund Administrator.

(k) Payment for the Emod shall include the cost of the comprehensive evaluation of the proposed project, the evaluation of required bids if the Fund Administrator finds it necessary to engage an outside expert, the evaluation of the completed Emod, a one year maintenance contract, if deemed appropriate by the Fund Administrator, as well as the cost of construction or installation of the Emod itself.

§ 69-10.9 Prior Approval Requests for Vehicle Modifications.

(a) A vehicle modification request may only be made for a vehicle owned by the enrollee or a member of the enrollee's household who has consistent and ongoing contact with the enrollee and provides unpaid primary, long-term support to the enrollee. Proof of ownership of the vehicle by the enrollee or the enrollee's legal representative must be provided to the Fund Administrator. A modification will be approved only if the vehicle is the primary source of transportation for the participant and is used to access services and supports in the community and to improve the enrollee's independence and inclusion in the community.

(b) The vehicle modification request must be accompanied by a Vehicle Modifications and Equipment Evaluation, based on the enrollee's needs, that has been obtained from a Driver Rehabilitation Specialist who has been certified by the Association of Driver Rehabilitation Specialists. The evaluation must specify the most cost effective and least complicated vehicle modification that will ensure safe transportation, and exit from and entrance into the vehicle for the participant, and include a detailed scope of work and specifications.

(c) Modifications can only be made to vehicles that are registered, insured and meet state inspection standards before and after the modifications are completed.

(d) Modifications may be made either to a vehicle that is being purchased by the enrollee or a member of the enrollee's household or to a vehicle that is structurally sound, not in need of mechanical repair as determined by the vehicle modifier, and is less than five years old or registers less than 50,000 miles.

(e) Modifications to a vehicle that the enrollee will not be driving are limited to modifications that are necessary to ensure safe transportation and safe access into and out of the vehicle.

(f) Only contractors that meet Acces-VR's qualifications or, if the enrollee lives in the District of Columbia or a state other than New York, the qualifications required by the district or other state for performing vehicle modifications, may submit bids for modifications.

(g) Once the initial request has been reviewed by the Fund Administrator, the Fund Administrator shall notify the enrollee or person authorized to act on the enrollee's behalf in writing which services or items have been approved and/or denied and inform the enrollee or person authorized to act on the enrollee's behalf of the bidding process that is required prior to the Fund Administrator approving payment for the vehicle modification. The enrollee or person authorized to act on the enrollee's behalf is then required to obtain a minimum of three acceptable bids from qualified contractors.

(h) Once the Fund Administrator receives from the enrollee or person authorized to act on the enrollee's behalf a minimum of three acceptable bids from qualified contractors, the Fund Administrator shall evaluate the qualifications of each bidder and the content of each bid to determine whether each bid is acceptable. If less than three are submitted, a written explanation

of why three accepted bids were not obtained must be provided, as well as a written explanation of how the determination was made that the one or two bids being considered are reasonably priced. In order to be acceptable, a bid must:

(1) be signed by the contractor or a person duly authorized to sign on behalf of the contractor;

(2) specify the scope of work and specifications of the work; and

(3) state that all work will be done in a workmanlike manner, using materials suitable for purposes of the modification.

(i) If the two lowest bids are within ten percent of each other, the enrollee or his or her legally authorized representative may choose one of the two lowest bids. If there is more than a ten percent difference between the two lowest bids, the Fund Administrator shall choose the bid that represents the best overall value for the Fund and the enrollee based on factors including not only the price offered by each bidder but also the quality, durability, extent of any warranties provided, and the safety of the product itself. The successful bidder will be notified after the Fund Administrator or a designee of the Fund Administrator (1) discusses the bids received with the enrollee or the person authorized to act on the enrollee's behalf and the reasons why a particular bid is chosen by the Fund Administrator, and (2) obtains the written consent of the enrollee or the person authorized to act on the enrollee's behalf to have the installation done by that bidder. If the enrollee or person authorized to act on the enrollee's behalf disagrees with the Fund Administrator's decision, the enrollee or person authorized to act on the enrollee's behalf can request a review of the decision. The Fund Administrator will authorize payment to the successful bidder of no more than one-third of the accepted bid amount unless there are extenuating circumstances about which the Fund Administrator receives advance notice such as a

project that can be completed in one day or involves the purchase of a product prior to installation.

(j) Any change from the specifications in terms of alternative or substitute equipment or the scope of work involved in the modification that will result in a cost increase from the bid price will require approval from the Fund Administrator.

(k) No additional payment will be authorized until the Fund Administrator has received a post-modification evaluation stating that the vehicle meets or exceeds Acces-VR Vehicle Modification Standards and that the modifications meet the enrollee's functional needs.

(l) Payment for vehicle modifications shall include, in addition to the cost of the vehicle modification itself, the cost of the Vehicle Modifications and Equipment Evaluation, the evaluation of required bids if the Fund Administrator finds it necessary to engage an outside expert, the post-modification evaluation, and reimbursement for travel in those instances in which the enrollee and his or her informal supports must travel outside of the geographic area in which the enrollee's community commonly obtains its medical care and services for fittings and vehicle tests.

§ 69-10.10 Prior Approval Requests for Assistive Technology (AT).

(a) A request for AT, as defined in section 69-10.1 of this Subpart, will be considered to include a request for AT services, which is assistance provided to the enrollee in the selection, acquisition, and use of the appropriate AT device and necessary training of the enrollee, the enrollee's informal supports, and any paid staff who provide assistance to the enrollee at a time when he or she will be using the AT.

(b) Providers of AT to enrollees of the Fund must meet one of the following qualifications:

(1) be approved as provider pursuant to 18 NYCRR Part 504;

(2) be a provider of AT services to the Home and Community Based Services Waiver Program administered by the New York State Office for Persons with Developmental Disabilities or, if the enrollee lives in the District of Columbia or a state other than New York, be a provider for a similar waiver program in the district or other state;

(3) be a licensed and registered pharmacist;

(4) be a Durable Medical Equipment (DME) provider; or

(5) for Personal Emergency Response Systems (PERS), be an approved PERS provider with existing contracts with Local Social Services Districts or, if provided in another state, or the District of Columbia be approved by the appropriate state agency in that state or in the District of Columbia.

(c) A person or organization providing assessments must be:

(1) a New York State Acces-VR approved provider of rehabilitation technology or the equivalent in another state;

(2) a present or former Independent Living Skills Trainer for one or more of New York State's Home and Community Based Services Waivers; or

(3) another professional who is knowledgeable about the full range of devices and/or technology available to assist individuals with disabilities.

(d) Any AT device or supply requested from the Fund must meet standards established by Underwriters Laboratory and/or comply with any applicable Federal Communications Commission requirements, if applicable. Any AT that would constitute a fixture in the enrollee's

residence or on the premises of the residence must meet any applicable ADA, Fair Housing Act, or other safety standards or guidelines that apply.

(e) A request for an AT must include:

(1) a written statement from the enrollee's treating physician on the physician's letterhead explaining why the requested AT is medically necessary, including how the specific equipment being requested will meet the needs and goals of the enrollee in terms of maintaining, increasing or improving his or her functional capacities in a safe, efficient, and reasonably cost effective manner;

(2) copies of all assessments made to determine the necessary AT, including an assessment of the enrollee's unique functional needs and the intended purpose and expected use of the requested AT. Any assessment submitted must include:

(i) information about the individual's expressed needs and preferences, functional limitations and prognosis;

(ii) information about the environment in and circumstances under which the AT will be used;

(iii) the basis for selecting the particular AT being requested, including advantages over other options, how it addresses the enrollee's functional limitations, how it meets the enrollee's needs safely, maintenance expenses, and cost/benefits;

(iv) a description of the alternatives to the particular AT that were considered, including a comparison of features, future expansion or adaptation capabilities, the safety of the enrollee, the overall cost, and the reliability, and if less than three options were considered, the reason for considering less than three must be provided; and

(v) a written explanation of why the AT requested was chosen.

(f) Once the request has been reviewed by the Fund Administrator, the Fund Administrator shall notify the enrollee or person authorized to act on the enrollee's behalf in writing which services or items have been approved and/or denied and inform the enrollee or person authorized to act on the enrollee's behalf of the bidding process that is required prior to the Fund Administrator approving payment for the requested AT. The enrollee or person authorized to act on the enrollee's behalf is then required to obtain a minimum of three acceptable bids from qualified providers for the particular AT requested, except as provided in subdivision (i) of this section.

(g) If the enrollee or person authorized to act on the enrollee's behalf obtains less than three bids for the requested AT, a written explanation of why three acceptable bids were not obtained must be provided as well as a written explanation of how the determination was made that the one or two bids being considered are reasonably priced.

(h) If the two lowest bids are within ten percent of each other, the enrollee or his or her legally authorized representative may choose one of the two lowest bids. If there is more than a ten percent difference between the two lowest bids, the Fund Administrator shall choose the bid that represents the best overall value for the Fund and the enrollee based on factors including not only the price offered by each bidder but also the quality, durability, extent of any warranties provided, and safety of the product itself. The successful bidder will be notified after the Fund Administrator or a designee of the Fund Administrator (1) discusses the bids received with the enrollee or the person authorized to act on the enrollee's behalf and why a particular bid is chosen by the Fund Administrator and (2) obtains the consent of the enrollee or the person authorized to act on the enrollee's behalf to purchase that particular AT. If the enrollee or person authorized to act on behalf of the enrollee disagrees with the Fund Administrator's decision, the

enrollee or person authorized to act for the enrollee can request a review of the Fund Administrator's decision.

(i) If the enrollee or the enrollee's authorized representative is able to obtain the AT equipment for less than twenty-five hundred dollars (\$2,500), the enrollee or the enrollee's authorized representative may submit documentation showing the prices from three different suppliers of the AT equipment in lieu of obtaining formal bids from such suppliers, and the Fund Administrator will pay the lowest of the three prices. Documentation may include copies of catalog pages, webpages or price lists.

(j) Cost-effective repairs may be allowed. Items that wear out as a result of normal wear and tear (for example, keyboards and switches) may be replaced by submitting a request stating the item that needs to be replaced, the reason the item needs to be replaced, and two or more estimates for the repair. If appropriate, approval for repairs will be made contingent on development of a plan to minimize future loss or damage.

(k) Except for AT equipment priced pursuant to subdivision (i) of this section, payment for the AT equipment cannot be more than the wholesale cost of the equipment plus fifty percent. If deemed appropriate by the Fund Administrator, the cost of a one year maintenance contract for the AT also may be paid for by the Fund. Repairs, including the installation of replacement parts, will be paid for at full cost.

(1) In addition to the cost of AT equipment, payment for AT equipment shall include the cost of the assessment required by subdivision (c) of this section and the cost of the evaluation of required bids if the Fund Administrator finds it necessary to engage an outside expert.

§ 69-10.11 Prior Approval for Private Duty Nursing.

(a) A request for private duty nursing in the hospital or in the home must be accompanied by a physician's written order and treatment plan.

(b) In a hospital setting, the physician's order must state that the enrollee is in need of individual and continuous care beyond that available by the staff of a hospital, including that which is available in the hospital's critical care area.

(c) For nursing services to be provided in the enrollee's home, the physician's order must state either that there is no approved home health agency available to provide the intermittent or part-time nursing services needed by the enrollee or that the enrollee is in need of individual and continuous care beyond that available from an approved home health agency. The Fund Administrator may request such periodic treatment plans and other medical information as he or she determines the particular circumstances warrant prior to approving additional periods of private duty nursing.

(d) In an emergency situation, the treating physician may order the services of a private duty nurse for no more than two nursing days and immediately submit a prior approval request for private duty nursing services on behalf of the enrollee on an expedited basis pursuant to § 69-10.15.

§ 69-10.12 Prior Approval Requests for Certain Transportation for Medical Care and Services.

(a) Requests for prior approval for transportation for medical care and services may be made by the enrollee or a person authorized to act on the enrollee's behalf. Such a request may be made for a one-time appointment or for multiple appointments during a specific period of time. A request for prior approval for non-emergency ambulance transportation or transportation

by ambulette must be accompanied by the order of the practitioner who is the enrollee's attending physician, nurse practitioner, or physician assistant.

(b) Payments will only be made to commercial providers of transportation that met all applicable requirements for providing the transportation services requested on the date(s) that the transportation is provided.

(c) The following criteria will be used in determining whether to approve a transportation prior approval request:

(1) whether the nature and/or severity of the enrollee's condition necessitates a mode of transportation other than that ordinarily used by the enrollee or the transportation requested is the only mode of transportation that can safely be used by the enrollee;

(2) whether the enrollee needs multiple treatments or visits over a short period of time that would cause an undue financial hardship to the enrollee or the enrollee's family if required to pay for the transportation for such visits even though the transportation being used is the same transportation used by the enrollee for other activities in his or her community;

(3) whether the geographic location of the enrollee and the provider of medical care and/or services are such that the usual mode of transportation would be inappropriate;

(4) whether the distance to be traveled for the medical care and/or services would require a large transportation expense that would result in an undue financial hardship for the enrollee or the enrollee's family;

(5) whether the need to continue a regimen of medical care or services with a specific provider requires travel outside of the geographic region in which the enrollee's community customarily obtains its medical care and services; and

(6) whether there are any other circumstances that are unique to the enrollee and support the payment of the transportation expenses requested.

§ 69-10.13 Prior Approval for Treatment with a Specialty Drug.

A request for prior approval of treatment with a specialty drug must be accompanied by a written statement from the enrollee's treating physician stating why treatment with the specialty drug is necessary, what other alternatives have been tried or explored, and what testing the enrollee has undergone for purposes of determining whether treatment with the specialty drug is appropriate and safe for the enrollee. All requests for prior approval for treatment with a specialty drug will be reviewed by the Pharmacy Benefits Manager for the Fund Administrator and a determination will be made within three business days of receipt of all necessary information from the enrollee's treating physician.

§ 69-10.14 Prior Approval Requests for Experimental Treatment.

(a) A request for prior approval for experimental treatment must be accompanied by a letter from the treating physician explaining why the enrollee needs the experimental treatment being requested and documentation that either no standard treatment has been effective in treating the enrollee or there is no standard treatment available to treat the enrollee's condition, injury or impairment.

(b) All requests for prior approval for experimental treatment involving the use of an experimental medication will be reviewed by the Fund Administrator's Pharmacy Benefits Manager.

§ 69-10.15 Expedited Prior Approval Process.

(a) An expedited prior approval determination will be made within two business days of receiving a prior approval request of a physician on the physician's letterhead that states that the enrollee has an emergency need for a service or item that requires prior approval and the reason that the service or item is needed on an expedited basis and any other supporting documentation provided by the physician.

(b) The service or item may be provided to the enrollee in an emergency situation when there is no one from the Fund Administrator available to approve the request, provided that an expedited approval request is submitted within two business days of the determination of the emergency need. A claim for the provision of the service or item for the period from the time the emergency need was determined to the time of issuance of the review determination, if applicable, can be submitted to the Fund Administrator for payment, provided that there are no delays as the result of an untimely submission of supporting documentation or a request for an extension of time on the part of the enrollee or any person acting on the enrollee's behalf.

§ 69-10.16 Claim and Prior Authorization Denial Review Process.

(a) A request for review of a denial of a claim or of a prior approval request shall be made by completing and submitting a review request form provided by the Fund Administrator for denial of a claim or a prior approval request no later than thirty days from receipt of the denial. The form shall be provided to all enrollees and/or their parents(s), guardian(s) or legal representative(s) and shall be available on the Fund Administrator's website; and when completed, shall be submitted electronically, mailed or faxed to the Fund Administrator's office.

(b) A request for review of a denial of a claim or a prior approval request shall specify the denial that the enrollee is seeking to appeal and include the reason(s) the enrollee believes that the decision was incorrect and whether the requestor wants (1) a review based on documents submitted by both parties, (2) a review in the form of a hearing conducted by telephone, or (3) a review in the form of a hearing conducted in person. The review option chosen by the enrollee shall be the only form of review conducted by the Commissioner or his or her designee. A hearing officer, assigned by the Commissioner or his or her designee, will conduct the review regardless of whether the review is to be a document review or a review in the form of a hearing.

(c) If an enrollee who has had a prior approval request denied requests an informal conference in addition to a formal review, the Fund Administrator will designate a person to participate in an informal conference with the enrollee and/or his authorized representative to discuss the reason(s) for the denial. Any such conference will be scheduled to occur no later than one week before the formal review is scheduled to be held.

(d) Document Based Reviews. If the person representing the enrollee wishes a review based on documents instead of a hearing or if the hearing officer believes that the review can be conducted on the basis of documentation submitted by both parties without a hearing and neither party objects, the hearing officer will confer with both parties and set up a schedule for the submission and exchange of the documents on which each party intends to rely.

(1) No hearing officer shall review a matter toward which he or she has a personal bias. Prior to the submission of any documentation for review, any party may request that hearing officer be removed for personal bias or for other good cause by filing a request for removal accompanied by a supporting affidavit stating the basis for the request.

(2) A hearing officer may disqualify himself or herself for bias on his or her own determination.

(3) Any request for removal of a hearing officer on the basis of personal bias or for other good cause shall be reviewed by the Department of Health's Chief Administrative Law Judge, and the review shall not proceed until the Chief Administrative Law Judge reaches a decision on the request. Such decision shall be made within ten business days from receipt of the request for removal. If the Chief Administrative Law Judge determines there is good cause for removal, the review will be assigned to a different hearing officer simultaneously with the Chief Administrative Law Judge's determination.

(4) After reviewing all of the parties' submissions, the hearing officer shall render a written recommendation to the Commissioner within thirty days of receiving all submissions that includes the issues(s) raised on review, the relevant facts, and the applicable law, regulations, and official policies, if any, upon which the recommendation is based;

(5) The Commissioner or his or her designee shall review the documentation submitted by both parties and the hearing officer's recommendation and issue a decision that contains findings of fact, conclusions of law and the reason(s) for the determination and, when appropriate, directs the Fund Administrator to take specific action. The decision shall be issued promptly but no later than thirty days from issuance of the hearing officer's recommendation.

(6) A copy of the written decision shall be mailed to the parties and to the Fund Administrator. The decision of the Commissioner shall be final, provided that the enrollee or the provider may seek judicial review by a court of competent jurisdiction.

(7) The parties may enter into a stipulation to resolve the matter in dispute at any time prior to issuance of the decision. In the event that such a resolution is reached, the hearing officer will issue a consent order that incorporates the parties' stipulation. Such a consent order shall have the same force and effect as an order issued by the Commissioner.

(e) Hearings. Upon receipt of a request for a hearing, a hearing officer will be assigned; and the Commissioner or his or her designee shall serve a notice of hearing upon the party who requested the hearing and the Fund Administrator. If the requestor is an attorney, the notice will also be sent to the enrollee or, when applicable, his or her parent or other person authorized to act on his or her behalf.

(1) The notice of hearing shall, at a minimum:

(i) specify the date, time and place of the hearing, which, if conducted in person, shall be at a location within a reasonable distance from the requestor;

(ii) briefly state the issues that will be the subject of the hearing;

(iii) explain the manner in which the hearing will be conducted;

(iv) advise the requestor, if not an attorney, of the right to be represented by counsel and to be accompanied by any person of his or her choice. An interpreter may also be present when necessary.

(2) All notices and papers connected with the hearing may be served by ordinary mail, and service will be deemed complete three days after mailing.

(3) The assigned hearing officer shall preside over the hearing and related proceedings. The hearing and related proceedings shall be conducted in an impartial manner in accordance with the following procedures:

(i) No hearing officer shall preside over a matter toward which he or she has a personal bias. Prior to the hearing, any party may request that hearing officer be removed for personal bias or for other good cause by filing a request for removal accompanied by a supporting affidavit stating the basis for the request.

(ii) A hearing officer may disqualify himself or herself for bias on his or her own motion.

(iii) During the hearing, any party may request that the hearing officer be removed for bias by making such a request either orally or in writing on the record and stating the grounds for requesting removal of the hearing officer. The burden of proof shall be on the party seeking disqualification.

(iv) The hearing officer shall rule on the request for disqualification. If the hearing officer denies the request, the hearing shall proceed; but the Commissioner or his designee will review the entire record of the proceeding before a decision is issued. A written determination regarding whether the hearing officer should be removed from the proceeding will be issued within fifteen business days of the close of the hearing and will be made part of the record.

(4) The hearing officer shall conduct the hearing in a fair and impartial manner and shall have the power to:

(i) rule upon requests by all parties to the hearing, including requests for adjournments;

(ii) administer oaths and affirmations, issue subpoenas requiring the attendance of witnesses and the production of books, records and other evidence pertinent to the hearing;

(iii) admit or exclude evidence;

(iv) limit repetitious examination or cross-examination and the amount of corroborative or duplicative testimony;

(v) hear arguments on facts and law;

(vi) order the parties to present opening statements summarizing why the party believes the Fund Administrator's position was or was not correct;

(vii) order the parties to appear at a pre-hearing conference in an effort to simplify the issues, expedite the hearing, and/or to ensure that the parties understand the procedure;

(viii) ensure that a written or electronic verbatim record of the proceedings is made and is made available to the parties;

(ix) perform such other acts as are necessary for the maintenance of order and the efficient conduct of the hearing unless otherwise prohibited by law or regulation; and

(x) adjourn the hearing to another time upon the request of any party for good cause shown or, upon the hearing officer's own motion, when the hearing officer determines that it would be prejudicial to a party's due process rights to go forward with the hearing on the scheduled date.

(5) The proceedings used to conduct the hearing shall provide the parties with a fair and prompt resolution of any dispute in accordance with the following procedures:

(i) The parties to the hearing may be represented by legal counsel or other individuals with specialized training relevant to the hearing and may be accompanied by a person of his or her choice.

(ii) The hearing shall be closed to the public unless the enrollee, or the enrollee's parent or other person authorized to act on his or her behalf if the enrollee is a minor, requests an open hearing.

(iii) The parties to the hearing and their respective counsel or representative shall have an opportunity to present evidence and to question all witnesses at the hearing.

(iv) Every witness shall be sworn or given an affirmation by the hearing officer.

(v) The hearing officer shall consider all relevant evidence and shall include all records, documents, and memoranda submitted into evidence. The formal rules of evidence shall not apply.

(vi) The parties may enter into a stipulation to resolve the matter in dispute at any time prior to issuance of the decision. In the event that such a resolution is reached, the hearing officer will issue a consent order that incorporates the parties' stipulation. Such a consent order shall have the same force and effect as an order issued by the Commissioner.

(6) Upon conclusion of the hearing, the hearing officer shall render a written recommendation to the Commissioner within thirty days of the hearing that includes the issues(s) raised at the hearing, the relevant facts, and the applicable law, regulations, and official policies, if any, upon which the recommendation is based;

(7) The Commissioner or his or her designee shall review the hearing record and the hearing officer's recommendation and issue a decision that contains findings of fact, conclusions of law and the reason(s) for the determination and, when appropriate, directs the Fund Administrator to take specific action. The decision shall be issued promptly but no later than thirty days from issuance of the hearing officer's recommendation.

(8) A copy of the written decision shall be mailed to the parties to the hearing and to the Fund Administrator. The decision of the Commissioner shall be final, provided that the enrollee or the provider may seek judicial review by a court of competent jurisdiction.

§ 69-10.17 Right to Expedited Review of Denials of Requests for Prior Approval.

(a) An expedited review will be provided upon an enrollee showing that (1) he or she submitted a written statement from a physician, physician assistant, or nurse practitioner on the

practitioner's letterhead or on the letterhead of the supervising or collaborating physician, if applicable, that the enrollee had an emergency need for the medical service(s) or item(s) in issue and the reason the service or item was needed on an expedited basis and (2) the Fund Administrator denied the request for expedited prior approval. Such reviews must be conducted within ten business days from receipt of the request for expedited review and all documentation supporting the request.

(b) The hearing officer shall make a written recommendation to the Commissioner consistent with the recommendation requirements set forth in § 69-10.16 within five business days of the document based review or hearing.

(c) The Commissioner or his or her designee shall issue a written decision consistent with the decision requirements set forth in § 69-10.16 of this Subpart within five business days of receiving the hearing officer's written recommendation.

(d) As set forth in § 69-10.15 of this Subpart, the service or item may be provided to the enrollee in such a situation pending the expedited prior approval determination and any review of the determination; and a claim for the provision of the service or item during the time period while the prior review decision was pending or, in the event of a review, pending issuance of the review determination, can be submitted to the Fund Administrator for payment, provided that there are no delays as the result of an untimely submission of supporting documentation or a request for an extension of time on the part of the enrollee or any person acting on the enrollee's behalf.

§ 69-10.18 Withdrawal or Abandonment of Review Request.

(a) A request for review of a claim or prior approval request denial will be considered to have been withdrawn under the following circumstances:

(1) The Fund Administrator has received a written statement from the enrollee or the enrollee's authorized representative stating that the request for review is withdrawn; or

(2) The enrollee or the enrollee's authorized representative has made a statement withdrawing the request to the hearing officer on the record at the hearing.

(b) A request for review will be considered to have been abandoned if neither the enrollee nor the enrollee's authorized representative appears at the hearing unless the enrollee or the enrollee's authorized representative provides the Fund Administrator, within thirty days of the scheduled date of the hearing, a good cause explanation for such failure to appear.

§ 69-10.19 Actuarial Calculations for the Fund.

(a) Following the annual deposit set forth in section 2999-i(5) of the Public Health Law, and quarterly thereafter, the Superintendent shall conduct an actuarial calculation of the estimated liabilities of the Fund for the year following such annual deposit, resulting from qualified plaintiffs enrolled in the Fund.

(b) The analysis pursuant to subdivision (a) of this section shall include a review of the various elements contributing to the amount of benefits paid by the Fund and to the expenses of administration of the Fund, including:

(1) the number of qualified plaintiffs admitted in the Fund, and estimates of the number of qualified plaintiffs not yet admitted;

(2) the mortality experience of the qualified plaintiffs admitted to the Fund;

- (3) the amounts of benefits paid by the Fund by types of services provided;
- (4) the patterns of utilization by types of services provided;
- (5) the inflationary patterns by types of services provided;
- (6) the expenses of administration of the Fund;
- (7) the impact available health insurance has on the benefits paid by the Fund; and
- (8) the investment earnings on the assets held by the Fund.

§ 69-10.20 Suspension of the Fund.

(a) When the Fund's current liabilities equal or exceed eighty percent of the Fund's assets, as determined by the actuarial calculation performed under section 69-10.19 of this Subpart, the Fund Administrator shall suspend enrollment in the Fund and new enrollments will no longer be accepted.

(b) When the Fund's current liabilities no longer equal or exceed eighty percent of the Fund's assets, as determined by the actuarial calculation performed under section 69-10.19 of this Subpart, the Fund Administrator shall resume enrollment in the Fund and new enrollments will be accepted if otherwise eligible.

(c) The Fund Administrator will provide prompt notice on the Fund Administrator's website of any suspension or reinstatement of enrollment.

(d) Once enrolled, a qualified plaintiff will remain in the Fund for his or her lifetime, and will not be impacted by a suspension in enrollment.

§ 69-10.21 Rates of Payment.

(a) Physicians shall be paid at the eightieth percentile of the usual and customary charges for services provided in private physician practices, as reported by FAIR Health, Inc. in its Usual, Customary and Reasonable (“UCR”) database at the time of billing. Payment of these charges shall constitute payment in full for any such services provided to an enrollee of the Fund.

(b) Emods, vehicle modifications and assistive technology will be paid at an amount established by the prior approval process pursuant to sections 69-10.7, 69-10.8, 69-10.9 and 69-10.10 of this Subpart.

(c) Services, supplies, and equipment for which there is a Medicaid fee or rate available will be paid at that fee or rate.

(d) Medications will be paid at the Medicaid rate, provided however, if the Department of Health determines that Medicaid rates are not available due to technological issues and related administrative costs, a pharmacy benefits manager designated by the Fund Administrator and approved by the Department of Health may be used to price medications.

(e) Any other service will be paid at a reasonable rate for that type of service in that geographic area as determined by the Fund Administrator. Rates shall be deemed reasonable if they are sufficient to provide the enrollee with access to services and are not in excess of the prevailing rates paid by other payers in the region. When Fair Health, Inc.’s UCR database specifies a rate for a particular service, the Fund Administrator shall pay at the 80th percentile of such rate.

§ 69-10.22 Residence of Qualified Plaintiffs and Enrollees.

(a) Eligibility for or continued enrollment in the Fund is not dependent on the current or past residency of a qualified plaintiff or enrollee.

(b) The Fund Administrator shall advise enrollees to notify the Fund Administrator of any changes in address within ten business days from the date of the move in order to prevent delays.

REGULATORY IMPACT STATEMENT

Statutory Authority:

Title 4 of Article 29 of the Public Health Law (PHL) creates the New York State Medical Indemnity Fund (Fund) to provide a source of funding for all future qualifying health care costs of a plaintiff or claimant who sustained birth-related neurological injuries as the result of medical malpractice in order to reduce premium costs for medical malpractice insurance coverage.

Subdivision 3 of section 2999-h of the PHL sets forth a broad definition of “qualifying health care costs” for services and supplies provided to qualified plaintiffs and provides authority for the Commissioner of Health (Commissioner) to further define such qualifying health care costs in regulation.

Section 2999-i of the PHL requires the Superintendent of Insurance (Superintendent) to administer the Fund and the Commissioner of Taxation and Finance to be the custodian of the Fund for which a special account is created pursuant to section 99-t of the State Finance Law. Subdivision 2 of section 2999-i of the PHL authorizes the Superintendent to enter into a contract to administer the Fund (Administrator) and subdivision 6 requires the Superintendent to conduct actuarial calculations of the estimated liabilities of the Fund and suspend enrollment in the Fund if the estimated liabilities equal or exceed 80% of the Fund’s assets.

Section 2999-j of the PHL governs payments from the Fund and includes broad standards for the Fund enrollment process, payment of costs by collateral sources, rates to be paid to providers of qualifying health care services, prior authorization for certain services, and the claims processing requirements for reimbursement of qualifying health care costs. Subdivision 2 of section 2999-j of the PHL requires any applicable prior authorization requirements to be

promulgated by the Commissioner in regulation and subdivision 4 of such section requires the Commissioner to define in regulation “the basis of one hundred percent of the usual and customary rates” to be paid for services provided by private physician practices and for all other services, any rates of payment to be paid on a basis other than Medicaid rates.

Lastly, subdivision 15 of section 2999-j of the PHL specifically states that the Commissioner, in consultation with the Superintendent, “ shall promulgate . . . all rules and regulations necessary for the proper administration of the fund in accordance with the provisions of this section, including, but not limited to those concerning the payment of claims and concerning the actuarial calculations necessary to determine, annually, the total amount to be paid into the fund as otherwise needed to implement this title.”

Legislative Objectives:

The Legislature delegated the details of the Fund’s operation to the Department of Financial Services (DFS) and the Department of Health (DOH), the two State agencies that have the appropriate expertise to develop, implement and enforce all aspects of the Fund’s operations. These proposed regulations reflect the collaboration of both agencies in providing the administrative details of the manner in which the Fund will operate. Specifically, the regulations provide a clear process for enrollment of plaintiffs or claimants who sustained birth-related neurological injuries as the result of medical malpractice. And they create standards governing the qualifying health care costs to be paid by the Fund and the rates at which they will be paid, keeping in mind the two Legislative objectives of lifetime coverage for all current and future enrollees and reducing premium costs for medical malpractice insurance coverage.

Needs and Benefits:

These regulations are needed because Title 4 of Article 29 of the PHL provides only broad standards governing operation of the Fund, some of which include a specific requirement to further define criteria in regulation, and to provide the details necessary to make the Fund operationally successful for all parties, including qualified plaintiffs, Fund enrollees, providers of qualifying health care services, the Administrator, and the two agencies charged with operating the Fund. All parties will benefit from specific standards governing their respective roles regarding the Fund by providing: (1) a smooth application and enrollment process, including specific requirements for the actuarial calculations to be made by DFS and any ensuing suspension of enrollment in the Fund; (2) a clear concept of the qualifying health care costs for which the Fund will pay and their applicable rates of payment; (3) a step-by-step prior approval process required only for certain costly services, including environmental modifications, vehicle modifications, assistive technology, private duty nursing, transportation for medical care and services, treatment with a specialty drug, and experimental treatment; (4) a claims submission process that allows timely payment to providers; and (5) a fair review process if an enrollee's claims or prior authorization requests are denied, including document based reviews and hearings conducted by DOH.

Costs to Regulated Parties:

There are no costs imposed on regulated parties by these regulations. Qualified plaintiffs will not incur any costs in connection with applying for enrollment in the Fund or coverage by the Fund.

Costs to the Administering Agencies, the State, and Local Governments:

Costs to administering agencies and the State associated with the Fund will be covered by applicable appropriations, as provided in subdivisions 3 through 5 of section 2999-i of the PHL. There are no costs imposed on local governments by these regulations.

Local Government Mandates:

The proposed regulations do not impose any new programs, services, duties of responsibilities upon any county, city, town, village, school district, fire district or other special district.

Paperwork:

The proposed regulations impose paperwork requirements on regulated parties by requiring (1) a qualified applicant, person authorized to act on behalf of a qualified applicant, or certain defendants to submit an application and supporting documentation for a qualified applicant's enrollment into the Fund; (2) an enrollee to submit electronic or manual claims for reimbursement of qualified health care services, documentation to support any prior approval request and payment thereof, a review request form for denial of a claim or prior approval request, and notice of a change in address; (3) DOH to issue a notice of hearing, if applicable; and (4) DFS to issue a notice of any suspension or reinstatement of enrollment into the Fund.

Duplication:

There are no other State or Federal requirements that duplicate, overlap, or conflict with the statute and the proposed regulations. Although some of the services to be provided by the Fund are the same as those available under certain Medicaid waivers, the waivers have limited slots and the Fund becomes the primary payer for dually enrolled individuals. Coordination of benefits will be one of the responsibilities of the Fund Administrator. Health care services,

equipment, medications or other items that any commercial insurer providing coverage to a qualified plaintiff is legally obligated to provide will not be covered by the Fund (except for copayments and/or deductibles) nor will the Fund cover any health care service, equipment, or other item that is potentially available through another State or Federal program (except Medicaid and Medicare) or similar program in another country, if applicable, such as the Early Intervention Program or as part of an Individualized Education Plan unless the parent or guardian can demonstrate that he or she has made a reasonable effort to obtain such service, equipment or item for the qualified plaintiff through the applicable program.

Alternatives:

DFS and DOH have considered multiple alternatives to the proposed regulatory requirements and have made recent changes to the Express Terms to reflect more reasonable approaches to certain situations enrollees might face. For example:

(1) In the case of divorced parents, the regulations used to allow environmental modifications only to the primary residence of a custodial parent. The agencies considered the limitation placed on a child's ability to spend time at the home of the noncustodial parent and changed the Express Terms to allow environmental modifications to the primary residence of a noncustodial parent.

(2) When the Administrator received a request for approval of environmental modifications to a home that had yet to be built, the regulations had no process to allow for such approval. The agencies considered the benefit to families in having adaptations built in for their child making the home move-in ready on completion, in addition to the cost effectiveness of environmental modifications made during construction, as opposed to after construction, and changed the Express Terms to provide an approval process for these types of requests.

(3) The prior approval process for assistive technology used to require 3 acceptable bids for every item requested. The agencies considered this process to be cumbersome for less costly items, especially when prices are readily available in catalogues or online, and changed the Express Terms to allow for the submission of 3 prices in lieu of 3 bids for items costing less than \$2500.

Federal Standards:

There are no minimum Federal standards regarding this subject.

Compliance Schedule:

The Fund was statutorily required to be operational by October 1, 2011.

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**STATEMENT IN LIEU OF
REGULATORY FLEXIBILITY ANALYSIS**

No regulatory flexibility analysis is required pursuant to section 202-b(3)(a) of the State Administrative Procedure Act. The proposed amendment does not impose an adverse economic impact on small businesses or local governments, and it does not impose reporting, record keeping or other compliance requirements on small businesses or local governments.

Cure Period:

Chapter 524 of the Laws of 2011 requires agencies to include a “cure period” or other opportunity for ameliorative action to prevent the imposition of penalties on the party or parties subject to enforcement when developing a regulation or explain in the Regulatory Flexibility Analysis why one was not included. This regulation creates no new penalty or sanction. Hence, a cure period is not necessary.

**STATEMENT IN LIEU OF
RURAL AREA FLEXIBILITY ANALYSIS**

No rural area flexibility analysis is required pursuant to section 202-bb(4)(a) of the State Administrative Procedure Act. The proposed amendment does not impose an adverse impact on rural areas, and it does not impose reporting, record keeping or other compliance requirements on public or private entities in rural areas.

**STATEMENT IN LIEU OF
JOB IMPACT STATEMENT**

No job impact statement is required pursuant to section 201-a(2)(a) of the State Administrative Procedure Act. It is apparent, from the nature of the proposed amendment, that it will not have an adverse impact on jobs and employment opportunities.