SUMMARY OF EXPRESS TERMS

As authorized 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 regulatory amendments to provide more detail on the structure within which the New York State Medical Indemnity Fund ("Fund") will operate. These amendments provide the following:

(1) revisions to the definition of "assistive technology" to clarify which items fall within the definition;

(2) revisions to the definition of "environmental modification" to clarify which items do not fall within the definition;

(3) a new definition for "exterior physical adaptation" to clarify which items will be covered as environmental modifications;

(4) revisions to the definition of "qualifying health care costs" to include co-insurance, amounts paid toward a deductible, and services provided in accordance with an Individualized Education Program, and to exclude tuition;

(5) revisions to the definition of the term "respite" to clarify what is covered;

(6) revisions to the enrollment process to clearly set forth the Fund Administrator's responsibilities regarding application review, eligibility determinations and notifications;

(7) revisions to the general prior approval language to provide a six month effective period for such approvals unless a different time period is specified in the approval letter and to make it clear that if prior approval is required but not obtained, the claim will not be paid by the Fund;

(8) revisions to the prior approval requirements for environmental modifications to clearly specify standards for comprehensive evaluations, provide detail on approving repairs or replacements, waive prior approval requirements for repairs or replacements that cost $500 or less, and limit conditional prior approval to environmental modifications needed to ensure the enrollee's safety;

(9) revisions to the prior approval requirements for specialty drugs to require the Fund Administrator to publish a list of specialty drugs on its website and to clarify which documents are needed to approve such requests; and

(10) revisions to the rate regulation to provide rates related to travel costs and services provided outside the United States, allow use of alternate UCR databases, and clarify that the Fund will pay no more than the actual amount billed.

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 amending Subpart 69-10 to read as follows:

Subdivisions (b), (m), (z) and (aa) of section 69-10.1 are amended to read as follows:

(b) "Assistive technology" ("AT") means those devices, controls, appliances, items, or pieces of equipment[, or supplies of] that are:

(1) either a communication aid or device or an adaptive [type, determined necessary by a physician for purposes of the enrollee's habilitation, ability to function] aid or device;

(2) essential for the enrollee's activities of daily living or safety [in his or her current or desired residence which are];

(3) specifically designed for persons with disabilities;

(4) not useful in the absence of injury;

(5) limited to the direct needs of the enrollee; and

(6) not listed in the Medicaid Durable Medical Equipment (DME) Provider Manual at https://www.emedny.org/ProviderManuals/DME/index.aspx or at the most current Medicaid fiscal agent website.

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. Assistive technology shall not include items to be used or intended for recreational or therapeutic purposes.

(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 engage in activities of daily living, as defined in this section, 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] stair lifts and cabinet and shelving adaptations. Emods do not include any [routine home maintenance. Emods also do not include] of the following:

(1) home maintenance or repairs, including maintenance or repairs required by state or local building codes, or by other state and local laws and regulations;

(2) remediation of health hazards, including but not limited to asbestos, lead paint, mold, toxic gases, pests, or chemical pollutants;

(3) any part of the construction of a new home, or construction that adds square footage to an existing home;

(4) renovation of existing rooms or construction of new rooms within the existing home for the purpose of providing therapy, training, education, or storage;

(5) the purchase, installation, repair, modification or maintenance of elevators, swimming pools, hot tubs, spas, intercom systems, fencing, home security systems or security gates;

(6) the purchase, installation, repair or maintenance of central air conditioning, central heating systems, or utilities including but not limited to telephone, internet access, cable or satellite television, and water or sewer systems;

(7) the purchase, installation, repair, or maintenance of or upgrade to electrical systems or connections, except those modifications to an otherwise safe and compliant system that are necessary for and limited to providing power for the enrollee's medical equipment or assistive technology;

(8) 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] to other members of the household and that are not limited to the direct needs of the enrollee;

(9) the cost of any construction of the home or modifications needed as a result of avoidable barriers created by the new construction floor plan; and

(10) the cost of any modification to the basement of a home; provided, however, a modification to provide access to a basement may be approved if such access is necessary for an enrollee to perform an activity of daily living or an instrumental activity of daily living, as defined in subdivisions (a) and (t) of this section, respectively, that cannot be accomplished elsewhere in the home and for which there is no more cost effective alternative.

(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; enteral formula; 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; certain transportation [for purposes of health care

related appointments] in accordance with section 69-10.12 of this Subpart; copayments [and deductibles], coinsurance and amounts applied towards a deductible for services, items, equipment or medication paid for by commercial health insurance covering the enrollee; scheduled maintenance services for Emods and assistive technology; and any other health care costs actually incurred for services rendered to and supplies utilized by [a qualified plaintiff] an enrollee 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] are covered under insurance [under which the enrollee is covered is legally obligated to provide] or a government program of a state or foreign country, other than Medicaid or Medicare;

(2) tuition, fees or any other expenses for educational, recreational or social activities, such as schools, classes, camps, clubs, or memberships;

(3) services that are provided by a person other than a licensed healthcare professional acting in the scope of his or her license, or a person approved to provide such service by the Medicaid program or one of New York's Home and Community-Based Medicaid Waiver programs, or a similar program in another state or country;

(4) supplies, equipment or other items used customarily and primarily for nonmedical purposes;

(5) service or therapy animals and any related costs; and

(6) any costs for any services, supplies, items, equipment or medications that exceed the payment rates under section 69-10.21.

(aa) "Respite" means the provision of paid intermittent, temporary substitute care, including care provided in an institutional setting, by a respite provider approved for one of New York's Home and Community-Based Medicaid Waiver programs, or similar program in another state or country, 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]. No more than 1080 hours of respite may be provided during a twelve month period. Respite may not be provided by a relative or a member of the household.

Subdivisions (o) through (ae) of section 69-10.1 are relettered (p) through (af) and a new subdivision (o) is added to read as follows:

(o) "Exterior physical adaptation," for purposes of subdivision (m) of this section, means a modification to an existing entrance or exit of an enrollee's primary residence that is necessary to ensure the enrollee has up to two safe and accessible entrances/exits from the residence. An exterior physical adaptation does not include landscaping; fencing; alterations to the yard; construction of a driveway, or modifications to an existing driveway; any construction or improvement of a walkway that is not necessary to facilitate the enrollee's access to the home's entrance by wheelchair or other mobility assistance device; patios; decks; or any other adaptation that is not necessary for entrance into or exit from the home.

The opening paragraph of subdivision (b) of section 69-10.2 is amended and subdivisions (d), (e), (f), (g) and (h) are repealed and new subdivisions (d), (e), (f), (g) and (h) are added to read as follows:

(b) An application for enrollment shall be submitted on the application form provided by the Fund Administrator, which may be obtained by either 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 form shall be accompanied by the following:

(d) Upon receipt of an application, the Fund Administrator shall review the application to determine whether the applicant is eligible for enrollment pursuant to subdivision (e) of this section, or whether the application is incomplete or the Fund Administrator needs additional information to make a determination. If the application is not complete or the Fund

Administrator needs additional information, the Fund Administrator shall notify the person who submitted the application within fifteen business days from receipt of the application, or as soon as possible thereafter.

(e) An applicant is eligible for enrollment if the Fund Administrator determines that (i) the applicant has submitted a complete application meeting the requirements of subdivision (b) of this section, (ii) the court approved settlement or the judgment, whichever is applicable, meets the requirements set forth in subdivision (f) of this section, and (iii) the plaintiff is a qualified plaintiff.

(f) 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 request clarifying language from the court that approved the settlement or issued the judgment.

(g) If the Fund Administrator makes the determination that the applicant is eligible for enrollment in the Fund, the Fund Administrator shall provide written notification 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 at the rates established pursuant to this Subpart.

(h) The Fund Administrator shall assign the enrollee to a case manager and notify the enrollee of the name and contact information of such case manager within seven business days from the date of enrollment, and provide the enrollee with an enrollment card that contains a unique enrollment identification number.

The title of and subdivision (b) of Section 69-10.5 are amended and new subdivisions (e) and (f) are added to read as follows:

§69-10.5 Claims Submission [Process] and Processing

(b) The claims submission process will include both electronic and manual options for the submission of claims. Claims shall be filed on forms designated by the Fund Administrator. The Fund Administrator may require additional information in order to determine the validity of or to process the claim.

(e) The Fund Administrator shall consult with the most current manual on bill coding published by the American Medical Association to verify that a bill for provider services is appropriately coded. The Fund Administrator shall request corrections to a bill, as appropriate. The Fund Administrator may not pay separately for any item that is included within the charge for a particular code.

(f) The Fund Administrator may deny a claim for an item or service that is duplicative of another item or service that has been previously provided to an enrollee by the Fund, the enrollee's health insurer or other governmental program. The Fund Administrator may request

from the enrollee or the enrollee's provider any such information necessary for the Fund Administrator to determine whether an item or service is duplicative pursuant to this subdivision.

Subdivision (a) of section 69-10.6 is amended and new subdivisions (d) and (e) added to read as follows:

(a) Expenses that require prior approval. [Assistive] The following expenses 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) pursuant to section 69-10.12 of this Subpart, 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, and hearing aids[, and more than 1080 hours of respite care in a calendar year].

(d) Once the Fund has approved a request for prior approval, the approval shall be valid for a period of six months, unless a different time period is specified in the approval letter.

(e) When prior approval is required but not obtained by the enrollee or the enrollee's representative, the claim will not be paid.

Subdivisions (c), (d), (g), (h), (m) and (n) of section 69-10.7 are amended to read as follows:

(c) The Fund Administrator may [not] approve [any] an Emod [that] only if the Emod (1) constitutes [an improvement] a modification 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] complies with Americans with Disabilities Act ("ADA")

Accessibility Standards or Guidelines or the Fair Housing Act, if applicable, [or] and has [not] been determined to be safe by a rehabilitative evaluation agency or specialist or a building contractor as required in paragraph (d) (2) of this section, and (3) is the most cost effective approach to fulfilling the enrollee's medical need.

(d) [An Emod] (1) A request for an Emod must be made on an application form provided by the Fund Administrator. The application shall 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 describing the enrollee's physical capabilities and limitations in relation to the enrollee's access to his or her home[;].

(2) [a] After the completed application and written statement from the physician has been reviewed by the Fund Administrator, the Fund Administrator shall notify the enrollee or person authorized to act on behalf of the enrollee which requests could potentially be covered as Emods and that a comprehensive evaluation must be completed by an evaluator approved in advance by the Fund Administrator.

(3) A comprehensive evaluation of the proposed project may be completed only 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].

(4) The evaluation [must] shall specify: a description of the barriers in the home that are directly related to the enrollee's capabilities and limitations, as identified by the enrollee's treating physician; a description of other Emods that could be constructed or installed as an

alternative to the recommended Emod; a description of the proposed Emod; the need for the Emod recommended by the evaluator; the reason the proposed Emod was selected over the alternatives; whether [it] the Emod recommended is the most cost effective approach to fulfilling the enrollee's medical 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.] The evaluation shall also include a diagram, which need not be drawn to scale, of the interior of the house, showing the sizes of the rooms and doorways, the location of the bathrooms and the enrollee's bedroom, and the purpose for which each room is currently used; and photographs of the specific location or locations in which the Emod will be built or installed with appropriate labels that identify the location in each picture.

(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 building and zoning laws;

(4) a scope of work that does not exceed those services or items that have been approved by the Fund Administrator; and

(5) an explanation of how the materials to be used in the construction of the Emod are the most cost-effective in comparison to all alternative materials that are available.

(h) [If less than three bids are submitted,] The enrollee or person authorized to act on the enrollee's behalf may request permission to obtain less than three bids when existing facts demonstrate that three bids cannot be obtained. A request for permission shall include a written explanation of why three acceptable bids [were not] cannot be obtained [must be provided, as well as a written explanation of] and how the determination [was] will be made that the one or two bids being considered are reasonably priced.

(m) [Payment for the Emod shall include] In addition to the cost of the Emod, the Fund shall cover the cost of the comprehensive evaluation of the proposed project, provided such evaluation meets the requirements set forth in paragraph (2) of subdivision (d) of this section, the evaluation of required bids if the Fund Administrator finds it necessary to engage an outside expert, the evaluation of the completed Emod, and 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.] (1) Emods that are broken or worn out due to normal wear and tear, may be repaired or replaced provided that the Emod is still necessary for the enrollee pursuant to the standards set forth in paragraph (1) of subdivision (c) of this section.

(2) If the cost to repair or replace the Emod is $500 or less, the enrollee may arrange for the repair or replacement without prior authorization from the Fund Administrator, provided that the Fund Administrator may not pay the claim unless the enrollee, the enrollee's representative

or the enrollee's treating physician submits to the Fund Administrator documentation from the enrollee's physician explaining why the Emod is medically necessary.

(3) If the cost to repair or replace the Emod exceeds $500, prior approval from the Fund Administrator is required.

(i) A request for prior approval for the repair or replacement of an Emod shall include the following:

(a) a completed application for prior approval;

(b) a statement from the enrollee's treating physician stating the Emod is 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 explaining the reason for the physician's determination;

(c) two estimates for either:

(i) the cost to repair the Emod by a qualified professional, which must include an estimate for replacement of the Emod, or

(ii) if the Emod cannot be repaired, the cost to replace the Emod, with a statement from a qualified professional explaining why the Emod cannot be repaired; and

(d) the Fund Administrator shall review the documentation provided and if the application is complete, the Fund Administrator shall determine whether the repair of the Emod is cost-effective compared to the cost to replace the Emod, or whether the Emod must instead be replaced because it is more cost-effective to replace the Emod, or the Emod cannot be repaired. If repair of the Emod is cost-effective, the Fund Administrator shall approve the lowest cost estimate for the repair. If the Emod must be replaced, the Fund Administrator shall inform the

enrollee or the enrollee's representative of its determination and to obtain a minimum of three acceptable bids from qualified contractors.

Section 69-10.8 is repealed and a new section is added to read as follows:

Section 69-10.8 Conditional prior approval for certain emods to prospective primary residences.

(a) The Fund Administrator may grant conditional prior approval for an Emod before the enrollee has moved into a residence when the enrollee cannot otherwise safely move into the residence without the modification. A request for conditional prior approval shall include a letter signed by the enrollee's treating physician in support of the request. Such conditional approval shall be limited to those modifications which are required for the enrollee's safety.

(b) The conditional prior approval may be granted only if the enrollee or the enrollee's representative attests that the residence will be the enrollee's primary residence after it is modified and the requirements of section 69-10.7 are otherwise met.

(c) Conditional prior approval shall not be granted for Emods to a residence that is being constructed.

(d) The Fund Administrator shall not make any payment for the Emod until after the enrollee has moved into the residence, and the post-modification evaluation required by section 69-10.7(l) has been submitted to the Fund Administrator.

Section 69-10.10 is repealed and a new section is added to read as follows:

Section 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 training in the use of the AT, if necessary, for 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. A request for AT shall also include the fitting, set-up, or assembly of the AT.

(b) A request for prior approval for AT shall be made on an application form provided by the Fund Administrator. The request shall also include a written statement from the enrollee's treating physician on the physician's letterhead explaining why AT is medically necessary for the enrollee, including how AT will directly assist the enrollee in performing activities of daily living in a safe, efficient, and reasonably cost effective manner or meet a safety need of the enrollee, and describing the enrollee's physical capabilities and limitations that will be addressed by AT.

(c) After the completed application and written statement from the physician has been reviewed by the Fund Administrator, the Fund Administrator shall notify the enrollee or person authorized to act on behalf of the enrollee which requests could potentially be covered as AT and that an AT assessment must be completed by an assessor approved in advance by the Fund Administrator.

(d) An AT assessment shall be made by one of the following:

(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) a licensed healthcare professional, including a rehabilitation technologist, physical therapist or occupational therapist, who is knowledgeable about the full range of devices and/or technology available to assist individuals with disabilities.

(e) The AT assessment shall include the following:

(1) an assessment of the enrollee's current functional capabilities and limitations, including the current need for AT;

(2) a list of the AT that the enrollee currently has and an explanation of how that current AT either meets or does not meet the AT needs of the enrollee;

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

(4) information about the individual's expressed needs and preferences;

(5) a description of the kinds of AT that could be used to address the functional limitations of the enrollee and the intended purpose and expected benefit from the enrollee's use of such AT;

(6) a description of the AT that the assessor recommends be provided to the enrollee and the reasons for selecting that AT; and

(7) a description of the alternatives to the recommended AT, including the enrollee's current AT, that were considered, including similar kinds of AT, and a comparison of the features, future expansion or adaptation capabilities, the safety of the enrollee, the overall cost and benefits, and the reliability, of such alternatives, and if less than three alternatives were considered, the reason for considering less than three must be provided.

(f) The Fund Administrator may approve AT only if after reviewing the letter from the enrollee's physician, and the assessment, the Fund Administrator determines that the AT meets the definition of AT provided in section 69-10.1 of this part in relation to the enrollee's specific circumstances, the AT is a cost-effective and safe means of meeting the enrollee's specific medical need and it is not duplicative of any other AT that the enrollee already has. Any AT

requested from the Fund must meet standards established by Underwriters Laboratory and/or comply with any applicable Federal Communications Commission requirements, if applicable.

(g) Once the Fund Administrator determines the AT to be covered, 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 provide information on the bidding process that is required prior to the Fund Administrator approving payment for 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 (k) of this section.

(h) A qualified provider includes only a provider that is:

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

(2) 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 a state other than New York or in the District of Columbia, be a provider for a similar waiver program in such state or district;

(3) a licensed and registered pharmacist with respect to items that are commonly purchased in a pharmacy;

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

(5) an approved PERS provider with existing contracts with Local Social Services District 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, with respect to Personal Emergency Response Systems (PERS).

(i) The enrollee or person authorized to act on the enrollee's behalf may request permission to obtain less than three bids when existing facts demonstrate that three bids cannot be obtained. A request for permission shall include a written explanation of why three acceptable bids could not be obtained and how the determination will be made that the one or two bids being considered are reasonably priced.

(j) 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. Otherwise, the Fund Administrator shall choose the bid that represents the best overall value for the Fund and provide notification to the enrollee of its decision. The best overall value shall be determined based on the price offered by each bidder; the quality, durability and safety of the product; and the extent of any warranties provided. 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 decision.

(k) If the enrollee or the enrollee's authorized representative is able to obtain the AT equipment for less than two thousand 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.

(l) 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.

(m) 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.

Section 69-10.12 is amended to read as follows:

Section 69-10.12 Prior approval requests for certain transportation [for medical care and services].

(a) [Requests] A request for prior approval for transportation for the purpose of obtaining 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 may also be made for one-way transportation by ambulance or ambulette for the purpose of relocating the enrollee to a new permanent primary residence.

(b) 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. The order must provide an explanation of why the enrollee's medical needs require transportation by ambulance or ambulette.

(c) A request for prior approval for transportation for the purpose of obtaining medical care and services may include a request for travel costs, the amounts of which will also be subject to prior approval and approved only to the extent such expenses are necessary.

[(b)] (d) 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)] (e) The following [criteria] factors will be [used] considered 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; and

(7) whether the transportation is the most cost-effective way to meet the enrollee's medical needs.

(f) Prior approval is not required for emergency transportation.

Section 69-10.13 is amended to read as follows:

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

The Fund Administrator will publish on its website a list of medications determined by the Fund Administrator to meet the definition of a specialty drug, as defined in subdivision 69-10.1(ac), and which shall require prior approval pursuant to this section. 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] identifying the other alternatives that have been tried or explored and explaining how those alternatives were not sufficient to meet the enrollee's medical needs, 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.

Subdivision (a) of section 69-10.14 is amended to read as follows:

(a) A request for prior approval for experimental treatment must be accompanied by the following:

(1) a letter from the treating physician [explaining] which:

(i) identifies the condition to be treated with the experimental treatment;

(ii) explains why the enrollee needs the experimental treatment being requested;

(iii) describes the potential risks and benefits to the enrollee from the treatment;

(iv) states the physician's opinion that the benefits of the experimental treatment outweigh the risks; and [documentation]

(v) states 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; and

(2) documentation in the form of peer reviewed studies that the physician is relying upon to conclude that the treatment may be effective in treating the enrollee's condition, injury or impairment.

Subparagraph (i) of paragraph (1) of subdivision (e) of section 69-10.16 is amended to read as follows:

(i) specify the date, time and place of hearing, which, if conducted in person, shall be [at a location] located in New York State within a reasonable distance from the requestor, if the requestor resides in New York State. For requestors residing out-of-State, hearings shall be conducted either in New York State, if the requestor so chooses, or by telephone;

Subdivisions (a) and (e) of section 69-10.21 are amended and a new subdivision (g) is added to read as follows:

(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. If no rate exists in Fair Health, Inc.'s UCR database for the services provided, an alternate UCR database may be used subject to approval by the Fund Administrator. Payment of these charges shall constitute payment in full for any such services provided to an enrollee of the Fund.

(e) Travel costs approved by the Fund Administrator for the enrollee and up to two family members or caregivers shall be paid at rates determined as follows:

(i) airfare, railway or bus tickets shall be reimbursed for the most cost effective flight or ticket that meets the enrollee's medical needs;

(ii) mileage for use of personal vehicles of the enrollee or the enrollee's family shall be reimbursed at the business mileage rate set forth at http://www.irs.gov/2014-Standard-Mileage-Rates-for-Business,-Medical-and-Moving-Announced, as updated on an annual basis;

(iii) passes for public transportation, parking fees, taxi fares, and tolls shall be reimbursed at the amount paid as evidenced by a receipt; and

(iv) reimbursement for overnight accommodations and meals for overnight travel shall be the amount paid as evidenced by receipt up to the federal per diem amounts found at http://www.gsa.gov/portal/content/104877, as updated on an annual basis.

(f) 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 shall be used as the reasonable rate for such service. If no rate exists in Fair Health, Inc.'s UCR database for the services provided, an alternate UCR database may be used subject to

approval by the Fund Administrator. For services provided to an enrollee outside the United States, reasonable rates shall be based on the U.S. national average or U.S. national benchmark contained in a UCR database.

(g) In no event shall the amount paid pursuant to this section exceed the billed amount.

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. Additionally, 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 clearer and more detailed standards regarding the Fund Administrator's responsibilities for processing such applications; (2) clearer definitions of "assistive technology," "environmental modification," "qualifying health care costs," and "respite" and a new definition of "exterior physical adaptation" to provide greater enrollee understanding of the items for which the Fund will pay; (3) revisions to the prior approval requirements for environmental modifications, assistive technology, and treatment with a specialty drug, in order to make each process work more efficiently, including clearer standards for comprehensive evaluations, waiving requirements for repairs and replacements that cost $500 or less, limiting conditional prior approval to environmental modifications needed to ensure an enrollee's safety, and publishing a list of specialty drugs on the Fund Administrator's website; (4) expanded coverage of certain transportation which is medically necessary to relocate an enrollee to a new primary residence, in addition to transportation which may be needed to medical appointments, and including specific rates for travel costs consistent with rates in the Medicaid program as required by PHL Section 2999-j(4) and (5) guidelines for rates related to services provided to enrollees outside the United States.

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 or 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) during the enrollment process, the Fund Administrator must notify the applicant if additional information is required, when the applicant is enrolled in the Fund, and provide the name and contact information of the assigned case manager; (2) during the prior approval process for environmental modifications, the Fund Administrator must notify the enrollee that a comprehensive evaluation must be completed after the written statement from the enrollee's physician has been reviewed; and (3) regarding specialty drugs, the Fund Administrator must publish on its website a list of medications that meet the definition of specialty drugs.

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.

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 prior approval requests for environmental modifications, the amendments provide more detail about which items do not fall within the definition. The agencies considered leaving the definition broad but changed the Express Terms to avoid continued enrollee confusion about which items are approvable as qualifying health care costs.

(2) In the case of prior approval for assistive technology (AT), the amendments provide significantly more detail on the prior approval process, including what is required to be provided in an AT assessment. The agencies considered leaving the process more general but changed the

Express Terms to avoid continued enrollee confusion regarding what is required when seeking approval for these items.

(3) The prior approval process for repairs or replacement of an environmental modification used to require three acceptable bids for all items or service. The agencies considered this process to be cumbersome for less costly items or service and changed the Express Terms to allow an enrollee to arrange for the repair or replacement of an environmental modification without prior approval if the cost is $500 or less.

Federal Standards:

There are no minimum Federal standards regarding this subject.

Compliance Schedule:

There is no compliance schedule imposed by these amendment and they shall be effective upon publication of a notice of adoption.

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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.