

SUMMARY OF EXPRESS TERMS

The proposed rulemaking would amend 18 NYCRR § 505.14, related to personal care services (PCS), and 18 NYCRR § 505.28, related to consumer directed personal assistance program services (CDPAS), to implement recent statutory changes resulting from recommendations of the Medicaid Redesign Team II as adopted in the State Fiscal Year 2020-21 Enacted Budget and to make other conforming changes.

Section 505.14(a)(1) is amended to align the “personal care services” definition with statutory requirements that such services be ordered by a qualified and independent practitioner, and not the individual’s attending physician.

Section 505.14(a)(3)(iii) is amended to fully align the scope of services with local social services departments (LDSSs) and Medicaid Managed Care Organizations (MMCOs) evaluation responsibilities. Both LDSSs and MMCOs must evaluate the cost effectiveness of the provision of services relative to other services and supports available to the individual. Services may not be provided if they are not cost-effective in comparison to other appropriate alternatives.

Sections 505.14(a)(3)(iv), (a)(9) and 505.28(b)(1), (b)(14), (c)(8) are added to update the scope and needs requirements for PCS and CDPAS. Consistent with statutory requirements, recipients would need to demonstrate a minimum need for assistance with activities of daily living (ADL) before such services may be authorized. Specifically, individuals with dementia or Alzheimer’s must need at least supervision with more than one ADL, and all others must need at least limited assistance with physical maneuvering with more than two ADLs.

Subparagraph 505.14(a)(5)(iii) is added to clarify and codify existing Department of Health policy that supervision and cueing may be provided as a means of assisting an individual to perform nutritional and environmental support functions or personal care functions, but are not a standalone personal care service, and may not be authorized, paid for or reimbursed, except if they are provided to assist with one of the enumerated functions in section 505.14(a)(5)(ii).

Sections 505.14(a)(7) and 505.28(b)(12) are added to define the term “Medicaid Managed Care Organization (MMCO).” The proposed regulations add express references to MMCOs, in addition to existing references to LDSSs. Except where the amendments would implement new requirements and procedures, the addition of MMCOs acts to codify existing policies and practices with respect to MMCOs and the provision of PCS and CDPAS, such as those based on Federal regulations, the Department of Health’s model contract requirements, and Department guidance. The term MMCO does not include an entity approved to operate a Program of All-inclusive Care for the Elderly (PACE) organization.

Section 505.14(a)(8) is added to provide a definition for “medical assistance” or “Medicaid” or “MA” to clarify that these terms as used throughout the regulation refer to the same program.

Section 505.28(b)(4) is amended to align the definition of “consumer directed personal assistant” with State law.

Section 505.28(b)(5) is added to provide a definition for “consumer directed personal assistance program” or “consumer directed program” or “the program” to clarify that these terms as used throughout the regulation refer to the same program.

Section 505.28(b)(15) amends the definition for “self-directing consumer” to include the capability of performing the consumer responsibilities outlined in section 505.28(g).

Section 505.14(b)(1) and the opening paragraph of section 505.28(d) provide an overview of the assessment process, which include an independent assessment, a medical examination and practitioner order, an evaluation of the need and cost-effectiveness of services, the development of the plan of care, and, when required, an additional independent medical review for high needs cases. The paragraph further provides for how portions of the process may be conducted through telehealth modalities.

Sections 505.14(b)(2)(i) and 505.28(d)(1) describe the independent assessment which is performed by an independent assessor as opposed to the LDSS or MMCO. The independent assessment contains most of the elements of the current social and nursing assessments. Other portions of the current social and nursing assessments have either become unnecessary or remain the responsibility of the LDSS or MMCO to perform. For example, the nursing assessment requirements to review the practitioner order and document the primary diagnosis code have become moot because, under the proposed regulation, the medical examination that leads to a practitioner order will occur after the independent assessment.

Sections 505.14(b)(2)(ii) and 505.28(d)(2) describe the independent medical examination and practitioner order. Most of the examination and practitioner order requirements remain the same, such as the licensure, documentation, and practitioner signature requirements. However, the medical professionals who perform the examination and sign the practitioner order must be employed by or contracted with an entity designated by the Department of Health. Consequently, the 30-day deadline for the order to be provided after the examination has been eliminated. Also, as required by statute, the medical professionals who perform the examination and sign the practitioner order must be independent, meaning that they must not have a prior established provider-patient relationship with the individual.

Sections 505.14(b)(2)(iii) and 505.28(d)(3) describe the LDSS or MMCO responsibilities related to the assessment process. The LDSS or MMCO remain responsible for significant portions of the current assessment process requirements, including a) the review of other available services and supports to determine cost-effectiveness, b) determining frequency of nursing supervision, c) determining the individual's preferences and social and cultural considerations for the receipt of care; d) heightened documentation requirements for 24-hour cases, and e) the development of the plan of care. In addition, before developing a plan of care or authorizing services, the LDSS or MMCO must review the independent assessment and practitioner order by the independent assessor and independent medical professional. Also, prior to authorizing more than 12 hours of services per day on average, the LDSS or MMCO must refer the case to the independent review panel, for an additional independent medical review of the individual and plan of care, and must consider the recommendation of the independent

review panel when finalizing the plan of care and in its decision to authorize such services.

Sections 505.14(b)(2)(iv) and 505.28(d)(4) are added to require the LDSS or MMCO to coordinate with the entity or entities providing independent assessment and practitioner services. These sections also describe the process for resolving mistakes and clinical disagreements in the assessment process, as well as sanctions for failure to cooperate and abuse of the resolution process.

Sections 505.14(b)(2)(v) and 505.28(d)(5) describe the revised independent medical review process. Under the revised process, an independent medical review must be obtained when the LDSS or MMCO proposes to authorize more than 12 hours of services per day on average. The review is performed by an independent panel of medical professionals, and coordinated by a lead physician. The lead physician cannot be the practitioner who was involved in the initial examination or practitioner order. The lead physician, or another member of the panel, may evaluate the individual, consult with other providers and individuals, and obtain other medical records that may be relevant to the panel's recommendation. When the independent medical review is complete, the lead physician shall produce a report to the LDSS or MMCO providing the panel's recommendation on whether the plan of care is reasonable and appropriate to maintain the individual's health and safety in his or her home. The recommendation may not include a specific amount or change in amount of services.

Sections 505.14(b)(3)(i) and 505.28(g)(1) require the independent assessment and practitioner order processes to be completed at least annually and in sufficient time to

allow LDSSs and MMCOs to, when needed, comply with all applicable federal and state time frames for notice and determination of services.

Sections 505.14(b)(3)(ii) and 505.28(g)(2) require that all determinations by the LDSS must be made with reasonable promptness, not to exceed seven business days after receipt of both the independent assessment and practitioner order, or the independent review panel recommendation if applicable, except as provided under the immediate need process.

Sections 505.14(b)(3)(iii) and 505.28(g)(3) provide that MMCOs must make a determination and provide notice to current enrollees within the timeframes provided in their contract with the Department of Health, or as otherwise required by Federal or state statute or regulation.

Sections 505.14(b)(4)(i), (ii) and 505.28(e)(1)(i), (ii) are added to provide that an individual's eligibility for services must be established prior to authorization, and that authorization must occur prior to the provision of services.

Sections 505.14(b)(4)(iii) and 505.28(e)(1)(iii) are added to provide that the authorization and reauthorization of services must be based on and reflect the assessment process and any exceptions to that process applicable to reauthorizations.

Section 505.28(e)(1)(v) is added to prohibit the authorization of services provided through more than one fiscal intermediary per consumer.

Sections 505.14(b)(4)(vi) and 505.28(e)(4) are added to require the LDSS or MMCO to consider the recommendation of the independent review panel prior to authorizing more than 12 hours of services.

Sections 505.14(b)(4)(viii)(b) and 505.28(i)(4) are amended to provide the Department of Health greater flexibility in determining when the LDSS or MMCO must use Department-developed forms in providing notice of service authorization, reauthorization, increase, decrease, discontinuance or denial.

Sections 505.14(b)(4)(viii)(c)(1) and 505.28(i)(4)(iii) are added to require LDSSs or MMCOs to document in the notice and plan of care the factors and clinical rationale specific to the client that went into the medical necessity determination that PCS or CDPAS should be denied, reduced, or discontinued.

Sections 505.14(b)(4)(viii)(c)(2)(vi) and (3)(iv) and 505.28(i)(4)(i)(e) and (ii)(d) are amended to clarify and provide examples of technological developments that may obviate the need for PCS or CDPAS.

Sections 505.14(b)(4)(viii)(c)(2)(i) and 505.28(i)(4)(ii)(a) are amended to clarify that a denial may be made if the clients health and safety cannot be “reasonably” assured with the provision of personal care services or consumer directed personal assistance.

Sections 505.14(b)(4)(viii)(c)(2)(vii) and 505.14(b)(4)(viii)(c)(3)(v) are amended to clarify that a denial may be made or services may be reduced or discontinued on the basis of residence in a facility if the client is not seeking to transition into a less restrictive setting or whose health and safety cannot be reasonably assured in such setting.

Sections 505.14(b)(4)(viii)(c)(3)(i) and 505.28(i)(4)(iii)(a) are amended to provide that services may be reduced or discontinued in cases where voluntary informal supports that are acceptable to the client have become available to meet some or all of the client's needs.

Sections 505.14(b)(4)(viii)(c)(2)(ix) and (b)(4)(viii)(c)(3)(vii) and 505.28(i)(4)(i)(g), (i)(4)(i)(h), (i)(4)(ii)(g), and (i)(4)(ii)(h) are added to provide additional examples for denying, reducing, or discontinuing services. Section 505.28(i) is also amended to remove the requirement to notify those receiving other home care services about CDPAS in alignment with State law.

Sections 505.14(b)(4)(xi), (b)(4)(xii), and (b)(4)(vii) and 505.28(f)(1)(i), (f)(2), and (e)(5) are amended to clarify and align the required reassessment procedures when reauthorizing services under the new assessment process. In particular, an independent assessment and practitioner order are not needed to reauthorize services provided that they occur annually, rather than every six months, to maintain authorization or for another enumerated reason.

Sections 505.14(b)(4)(xiii) and 505.28(f)(3) are added to provide that the LDSS or MMCO shall document any changes in an individual's need for services in the plan of care, and consider and make any necessary authorization changes.

Sections 505.14(b)(6) and (7) and 505.28(l) align the immediate need process with the new assessment process. An individual must first provide to the LDSS a statement of need for personal care services from a physician with direct knowledge of

the applicant's condition and an attestation of immediate need, before the individual is considered to have an immediate need.

Sections 505.14(b)(8) and 505.28(m) are added to allow the Department of Health to permit the current assessment process to continue until such time as the independent assessment and practitioner services are established at capacity or if the Department has not contracted with or designated an entity to provide independent assessment and practitioner services.

Section 505.14(c) is amended to remove the requirement for LDSSs to maintain contracts for the provision of nursing services.

Section 505.14(f)(3)(vi) is amended to remove references to the nursing assessment and clarify that the LDSS and MMCO are responsible for determining nursing supervision frequency.

Section 505.14(g) is amended to remove from case management responsibilities related to the coordination and performance of the practitioner order and the social and nursing assessments, and align requirements with the new assessment process.

Section 505.28(h)(2) requires consumer designated representatives to make themselves available to ensure that they can carry out the consumer responsibilities, and must be present at scheduled assessments or visits for nonself-directing consumers.

Section 505.28(h)(3) prohibits consumers from working with more than one fiscal intermediary at a time.

Pursuant to the authority vested in the Commissioner of Health by Social Services Law sections 363-a, 365-a(2)(e), and 365-f(5)(b) and Public Health Law sections 201(1)(v) and 206(1)(f), sections 505.14 and 505.28 of Title 18 of the Official Compilation of Codes, Rules and Regulations of the State of New York (NYCRR) are amended, to become effective on the 60th day following publication of a Notice of Adoption in the New York State Register, to read as follows:

Paragraph (1) of subdivision (a) of section 505.14 is amended to read as follows:

(1) *Personal care services* means assistance with nutritional and environmental support functions and personal care functions, as specified in clauses (5)(i)(a) and (5)(ii)(a) of this subdivision. Such services must be [essential to the maintenance of the patient's] medically necessary for maintaining an individual's health and safety in his or her own home, as determined by the social services district or Medicaid managed care organization in accordance with this section; ordered by [the attending physician] a qualified independent practitioner; based on an assessment of the [patient's] individual's needs and of the appropriateness and cost-effectiveness of services specified in subparagraph [(b)(3)(iv)] (b)(2)(iii) of this section; provided by a qualified person in accordance with a plan of care; and supervised by a registered professional nurse.

The opening paragraph of paragraph (3) of subdivision (a) of section 505.14 is amended to read as follows:

(3) Personal care services, as defined in this section, can be provided only if the [services are medically necessary] individual meets applicable minimum needs requirements described in subparagraph (iv) of this paragraph, and the social services district or Medicaid managed care organization reasonably expects that the [patient's] individual's health and safety in the home can be maintained by the provision of such services, as determined in accordance with this section.

Subparagraph (iii) of paragraph (3) of subdivision (a) of section 505.14 is amended and new subparagraph (iv) is added to read as follows:

(iii)

[(a)] Personal care services, including continuous personal care services and live-in 24-hour personal care services [as defined in paragraphs (2) and (4), respectively, of this subdivision], shall not be authorized to the extent that the social services district or Medicaid managed care organization determines that any of the services or supports identified in subclauses (11) through (13) of subdivision (b)(2)(iii)(a) of this section are available and appropriate to meet the [patient's need for assistance can be met by the following:] individual's needs and are cost-effective if provided instead of personal care services.

(1) voluntary assistance available from informal caregivers including, but not limited to, the patient's family, friends, or other responsible adult;

(2) formal services provided or funded by an entity, agency or program other than the medical assistance program; or

(3) adaptive or specialized equipment or supplies including, but not limited to, bedside commodes, urinals, walkers, and wheelchairs, when such equipment or supplies can be provided safely and cost-effectively.

(b) The social services district must first determine whether the patient, because of the patient's medical condition, would be otherwise eligible for personal care services, including continuous personal care services or live-in 24-hour personal care services. For patients who would be otherwise eligible for personal care services, the district must then determine whether, and the extent to which, the patient's need for assistance can be met by voluntary assistance from informal caregivers, by formal services, or by adaptive or specialized equipment or supplies, as specified in subclauses (a)(1) through (a)(3) of this subparagraph.]

(iv) Individuals must meet minimum needs requirements in accordance with state statute to be eligible for personal care services. For purposes of this section, *minimum needs requirements* means:

(a) for individuals with a diagnosis by a physician of dementia or Alzheimer's, being assessed in accordance with subdivision (b) of this section as needing at least supervision with more than one activity of daily living.

(b) for all other individuals, being assessed in accordance with subdivision (b) of this section as needing at least limited assistance with physical maneuvering with more than two activities of daily living.

Clause (b) of subparagraph (ii) of paragraph (5) of subdivision (a) of section 505.14 is amended to read as follows:

(b) Before more than 12 hours of personal care services per day on average, including continuous personal care services or live-in 24-hour personal care services, may be authorized, additional requirements for the authorization of such services, as specified in [clause (b)(4)(i)(c)] subdivision (b)(2)(v) of this section, must be [met] satisfied.

A new subparagraph (iii) is added to paragraph (5) of subdivision (a) of section 505.14 to read as follows:

(iii) The personal care aide may perform nutritional and environmental support functions and personal care functions for the recipient and may also assist the recipient to perform such tasks themselves. Assistance may include supervision and cueing to help the recipient perform a nutritional and environmental support function or personal care function if the recipient could not perform the task without such assistance. Supervision and cueing are not standalone personal care services and may not be authorized, paid for or reimbursed except for providing assistance with nutritional and environmental support functions or personal care functions.

New paragraphs (7), (8), (9) and (10) are added to subdivision (a) of section 505.14 to read as follows:

(7) *Medicaid managed care organization* or *MMCO* means an entity, other than an entity approved to operate a Program of All-inclusive Care for the Elderly (PACE) plan, that is approved to provide medical assistance services, pursuant to a contract between the entity and the Department of Health, and that is: (i) certified under article forty-four of the Public Health Law, or (ii) licensed under article forty-three of the Insurance Law.

(8) *Medical assistance* or *Medicaid* or *MA* means the program to provide services and benefits under title 11 or article 5 of the Social Services Law.

(9) *Activities of daily living* means those activities recognized as activities of daily living by the evidence based validated assessment tool in accordance with section 2-a of part MM of chapter 56 of the laws of 2020.

(10) For the purposes of this section *individual* and *patient* are used interchangeably, except as otherwise dictated by context.

The opening paragraph and paragraphs (1) through (4) of subdivision (b) of section 505.14 are amended to read as follows:

(b) Criteria for the assessment and authorization [for provision] of services.

[(1) When the local social services department receives a request for services, that department shall determine the applicant's eligibility for medical assistance.

(2) The initial authorization for personal care services must be based on the following:

(i) a physician's order that meets the requirements of subparagraph (3)(i) of this subdivision;

(ii) a social assessment that meets the requirements of subparagraph (3)(ii) of this subdivision;

(iii) a nursing assessment that meets the requirements of subparagraph (3)(iii) of this subdivision;

(iv) an assessment of the patient's appropriateness for hospice services and assessment of the appropriateness and cost-effectiveness of the services specified in subparagraph (3)(iv) of this subdivision; and

(v) such other factors as may be required by paragraph (4) of this subdivision.]

(1) The assessment process includes an independent assessment, a medical examination and practitioner order, an evaluation of the need and cost-effectiveness of services, the development of the plan of care, and, when required under paragraph (2) of this subdivision, a referral for an independent review. The independent assessment, medical examination and independent review panel may utilize telehealth modalities for all or a

portion of such assessments provided that the individual is given an opportunity for an in-person assessment and receives any necessary support during the telehealth assessment, which may include the participation of an on-site representative or support-staff.

~~(3)~~ (2) The initial [authorization] assessment process shall include the following procedures:

(i) A physician's order must be completed on the form required by the department.

(a) The physician's order form must be completed by a physician licensed in accordance with article 131 of the Education Law, a physician's assistant or a specialist's assistant registered in accordance with article 131-B of the Education Law, or a nurse practitioner certified in accordance with article 139 of the Education Law.

(1) Such medical professional must complete the physician's order form within 30 calendar days after he or she conducts a medical examination of the patient, and the physician's order form must be forwarded to a social services district or another

entity in accordance with clause (c) of this subparagraph.

(2) Such medical professional must complete the physician's order form by accurately describing the patient's medical condition and regimens, including any medication regimens, and the patient's need for assistance with personal care services tasks and by providing only such other information as the physician's order form requires.

(3) Such medical professional must not recommend the number of hours of personal care services that the patient should be authorized to receive.

(b) A physician must sign the physician's order form and certify that the patient can be cared for at home and that the information provided in the physician's order form accurately describes the patient's medical condition and regimens, including any medication regimens, and the patient's need for assistance with personal care services tasks, at the time of the medical examination.

(c) Within 30 calendar days after the medical examination of the patient, the physician, other medical professional, the patient or the patient's representative must forward a completed and signed copy of the physician's order form to the social services district for completion of the social assessment; however, when the social services district has delegated, pursuant to subdivision (g) of this section, the responsibility for completing the social assessment to another agency, the physician, other medical professional, the patient or the patient's representative must forward a completed and signed copy of the physician's order form to such other agency rather than to the social services district.

(d) When the social services district, or the district's designee pursuant to subdivision (g) of this section, is responsible for completing the social assessment but is not also responsible for completing the nursing assessment, the district or its designee must forward a completed and signed copy of the physician's order form to the person or agency responsible for completing the nursing assessment.

(e) The physician's order is subject to the provisions of Parts 515, 516, 517 and 518 of this Title. These Parts

permit the department to impose monetary penalties on, or sanction and recover overpayments from, providers or prescribers of medical care, services, or supplies when medical care, services, or supplies that are unnecessary, improper or exceed patients' documented medical needs are provided or ordered.]

[(ii)] (i) Independent assessment. [The social] An assessment shall be completed by [professional staff of the social services district] an independent assessor employed or contracted by an entity designated by the Department of Health to provide independent assessment services on forms approved by the [department.] Department of Health in accordance with the following:

(a) The independent assessment must be performed by a nurse with the following minimum qualifications:

(1) a license and current registration to practice as a registered professional nurse in New York State;
and

(2) at least two years of satisfactory recent experience in home health care.

(b) The independent assessment shall include the following:

(1) an assessment of the functions and tasks required by the individual, including an assessment of whether the individual meets minimum needs requirements;

[(a)] (2) [The social assessment shall include] a discussion with the [patient] individual to determine perception of his/her circumstances and preferences[.]; and

[(b)] (3) [The social] an assessment [shall include an evaluation] of the potential contribution of informal caregivers, such as family and friends, to the [patient's] individual's care, and shall consider all of the following:

[(1)] (i) number and kind of informal caregivers available to the [patient] individual;

[(2)] (ii) ability and motivation of informal caregivers to assist in care;

[(3)] (iii) extent of informal caregivers' potential involvement;

[(4)] (iv) availability of informal caregivers for future assistance; and

[(5)] (v) acceptability to the [patient] individual of the informal caregivers' involvement in his/her care.

(c) [When live-in 24-hour personal care services is indicated, the social assessment shall evaluate whether the patient's home has adequate sleeping accommodations for a personal care aide.] The independent assessment must assess the individual where the individual is located including the individual's home, a nursing facility, rehabilitation facility or hospital, provided that the individual's home or residence shall be evaluated as well if necessary to support the proposed plan of care and authorization or to ensure a safe discharge. This provision

shall not be construed to prevent or limit the use of telehealth in the assessment of an individual.

[(d) The social assessment shall be completed on a timely basis and shall be current.

(iii) The nursing assessment shall be completed by a nurse from the certified home health agency, a nurse employed by, or under contract with, the local social services department, or a nurse employed by a voluntary or proprietary agency under contract with the local social services department.

(a) A nurse employed by, or under contract with, the local social services department or by a voluntary or proprietary agency under contract with the local social services department shall have the following minimum qualifications:

(1) a license and current registration to practice as a registered professional nurse in New York State;
and

(2) at least two years of satisfactory recent experience in home health care.

(b) The nursing assessment shall be completed within five working days of the request and shall include the following:

(1) a review and interpretation of the physician's order;

(2) the primary diagnosis code from the ICD-9-CM;

(3) an evaluation of the functions and tasks required by the patient;

(4) an evaluation whether adaptive or specialized equipment or supplies including, but not limited to, bedside commodes, urinals, walkers, and wheelchairs, can meet the patient's need for assistance with personal care functions and whether such equipment or supplies can be provided safely and cost-effectively;

(5) development of a plan of care in collaboration with the patient or his/her representative; and

(6) recommendations for authorization of services.]

(ii) Independent medical examination and practitioner order.

(a) Each individual seeking personal care services must have an examination by a medical professional employed or contracted by an entity designated by the Department of Health to provide independent practitioner services.

(b) The medical professional who examines the individual must be a physician licensed in accordance with article 131 of the Education Law, a physician assistant or a specialist assistant registered in accordance with article 131-B of the Education Law, or a nurse practitioner certified in accordance with article 139 of the Education Law.

(c) The medical professional must be independent with respect to the individual, meaning that medical professional that conducts the exam must not have established a provider-patient relationship with the individual prior to the

clinical encounter from which the practitioner order is completed.

(d) The medical professional must examine the individual and accurately describe the individual's medical condition and regimens, including any medication regimens and the individual's need for assistance with personal care services tasks.

(e) The medical professional must review the independent assessment and may review other medical records and consult with the individual's providers and others involved with the individual's care if available to and determined necessary by the medical professional.

(f) The medical professional must complete a form required or approved by the Department of Health (the "practitioner order form").

(g) The medical professional must sign the practitioner order form, certify that the information provided in the form accurately describes the individual's medical condition and regimens at the time of the medical

examination, and indicate whether the individual is self-directing and whether the individual is medically stable.

(h) The practitioner order form must be completed and made available by the medical professional to the social services district or any MMCOs as appropriate after the medical examination and independent assessment.

(i) The practitioner order is subject to the provisions of Parts 515, 516, 517 and 518 of this title. These Parts permit the Department of Health or other agencies or organizations duly authorized or delegated by the Department of Health, including but not limited to MMCOs or the Office of the Medicaid Inspector General, to impose monetary penalties on, or sanction and recover overpayments from, providers or prescribers of medical care, services, or supplies when medical care, services, or supplies that are unnecessary, improper or exceed individuals' documented medical needs are provided or ordered.

[(iv)] (iii) [Assessment of other services] Social services district or MMCO responsibilities.

(a) Before developing a plan of care or authorizing [or reauthorizing] personal care services, a social [service] services district [must assess each patient] or MMCO shall review the individual's most recent independent assessment and practitioner order, and may directly evaluate the individual, to determine the following:

(1) whether personal care services can be provided according to [the patient's] a plan of care, whether such services are medically necessary and whether the social services district or MMCO reasonably expects that such services can maintain the [patient's] individual's health and safety in his or her home, as determined in accordance with the regulations of the Department of Health;

(2) the frequency with which nursing supervision would be required to support services if authorized;

(3) the individual's preferences and social and cultural considerations for the receipt of care;

[(2)] (4) whether the [patient] individual can be served appropriately and more cost-effectively by personal care services provided under a consumer directed personal assistance program authorized in accordance with section 365-f of the Social Services Law;

[(3)] (5) whether the functional needs, living arrangements and working arrangements of [a patient] an individual who receives personal care services solely for monitoring the [patient's] individual's medical condition and well-being can be monitored appropriately and more cost-effectively by personal emergency response services provided in accordance with section 505.33 of this Part;

[(4)] (6) whether the functional needs, living arrangements and working arrangements of the [patient] individual can be maintained appropriately and more cost-effectively by personal care services provided by shared aides in accordance with subdivision (k) of this section;

[(5)] (7) whether [a patient] an individual who requires, as a part of a routine plan of care, part-time or intermittent nursing or other therapeutic services or nursing services provided to a medically stable [patient] individual, can be served appropriately and more cost-effectively through the provision of home health services in accordance with section 505.23 of this Part;

[(6)] (8) whether the [patient] individual can be served appropriately and more cost-effectively by other long-term care services and supports, including, but not limited to, [services provided under the long-term home health care program (LTHHCP),] the assisted living program or the enriched housing program;

[(7)] whether the patient can be served appropriately and more cost-effectively by using adaptive or specialized medical equipment or supplies covered by the MA program including, but not limited to, bedside commodes, urinals, walkers, wheelchairs and insulin pens; and

(8)] (9) whether personal care services can be provided appropriately and more cost-effectively by the personal care services provider in cooperation with an adult day health or social adult day care program[.];

(10) whether the individual's needs can be met through the use of telehealth services that can be demonstrated and documented to reduce the amount of services needed and where such services are readily available and can be reliably accessed;

(11) whether the individual can be served appropriately and more cost-effectively by using adaptive or specialized medical equipment or supplies covered by the MA program including, but not limited to, bedside commodes, urinals, walkers, wheelchairs and insulin pens;

(12) whether the individual's needs can be met through the provision of formal services provided or funded by an entity, agency or program other than the medical assistance program; and

(13) whether the individual's needs can be met through the voluntary assistance available from informal caregivers including, but not limited to, the individual's family, friends or other responsible adult, and whether such assistance is available.

(b) The social services district or MMCO must first determine whether the individual, because of the individual's medical condition, would be otherwise eligible for personal care services, including continuous personal care services or live-in 24-hour personal care services. For individuals who would be otherwise eligible for personal care services, the social services district must then determine whether, and the extent to which, the individual can be served through the provision of services described in clauses (a)(4) through (a)(13) of this subparagraph.

[(b)] (1) If a social services district or MMCO determines that [a patient] an individual can be served appropriately and more cost-effectively through the provision of services described in [subclauses (a)(2)] clauses (a)(4) through [(8)] (a)(10) of this subparagraph, and the social services

district or MMCO determines that such services are available in the district, the social services district or MMCO must [first] consider the use of such services in accordance with department guidance as well as the individual's identified preferences and social and cultural considerations described in clause (a)(3) of this subparagraph in developing the [patient's] individual's plan of care. [The patient must use such services rather than personal care services to achieve the maximum reduction in his or her need for home health services or other long-term care services].

(2) If a social services district or MMCO determines that other formal services are available or the individual's needs can be met using available adaptive or specialized medical equipment or supplies or voluntary assistance from informal caregivers, as described in clauses (a)(11) through (a)(13) of this subparagraph, the social services district or MMCO must include these in the individual's plan of care. To ensure availability of voluntary informal supports, the social services

district or MMCO must confirm the caregiver's willingness to meet the identified needs in the plan of care for which they will provide assistance.

[(c) A social services district may determine that the assessments required by subclauses (a)(1) through (6) and (8) of this subparagraph may be included in the social assessment or the nursing assessment.

(d) A social services district must have an agreement with each hospice that is available in the district. The agreement must specify the procedures for notifying patients who the social services district reasonably expects would be appropriate for hospice services of the availability of hospice services and for referring patients to hospice services. A social services district must not refer a patient to hospice services if the patient's physician has determined that hospice services are medically contra-indicated for the patient or the patient does not choose to receive hospice services.

(v) An authorization for services shall be prepared by staff of the local social services department.

(4) The initial authorization process shall include additional requirements for authorization of services in certain case situations:

(i) An independent medical review shall be completed by the local professional director, a physician designated by the local professional director or a physician under contract with the local social services department to review personal care services cases when:

(a) there is disagreement between the physician's order and the social, nursing and other required assessments; or

(b) there is question about the level and amount of services to be provided; or

(c) the case involves the provision of continuous personal care services as defined in paragraphs (a)(2) and (4), respectively, of this section. Documentation for such cases is subject to the following requirements:]

[(1)] (c) [The social assessment shall demonstrate that all alternative arrangements for meeting the patient's medical needs have been explored and are infeasible including, but

not limited to, the provision of personal care services in combination with other formal services or in combination with voluntary contributions of informal caregivers. In cases involving live-in 24-hour personal care services, the social assessment shall also] For cases involving live-in 24-hour personal care services, the social services district or MMCO shall evaluate whether the [patient's] individual's home has sleeping accommodations for a personal care aide. When the [patient's] individual's home has no sleeping accommodations for a personal care aide, continuous personal care services must be authorized for the [patient] individual; however, should the [patient's] individual's circumstances change and sleeping accommodations for a personal care aide become available in the [patient's] individual's home, the district or MMCO must promptly review the case. If a reduction of the [patient's] individual's continuous personal care services to live-in 24-hour personal care services is appropriate, the district or MMCO must send the [patient] individual a timely and adequate notice of the proposed reduction.

[(2)] (d) [The nursing assessment] For cases involving continuous personal care services or live-in 24-hour

personal care services, the social services district or MMCO shall assess and document in the plan of care the following:

[(i)] (1) whether the [physician's] practitioner order [has documented] indicated a medical condition that causes the [patient] individual to need frequent assistance during a calendar day with toileting, walking, transferring, turning and positioning, or feeding;

[(ii)] (2) the specific personal care functions with which the [patient] individual needs frequent assistance during a calendar day;

[(iii)] (3) the frequency at which the [patient] individual needs assistance with these personal care functions during a calendar day;

[(iv)] (4) whether the [patient] individual needs similar assistance with these personal care functions during the [patient's] individual's waking and sleeping hours and, if not, why not; and

[(v)] (5) whether, were live-in 24-hour personal care services to be authorized, the personal care aide would be likely to obtain, on a regular basis, five hours daily of uninterrupted sleep during the aide's eight hour period of sleep.

[(ii) The local professional director, or designee, must review the physician's order and the social and nursing assessments in accordance with the standards for services set forth in subdivision (a) of this section, and is responsible for the final determination of the amount and duration of services to be authorized.

(iii) When determining whether continuous personal care services or live-in 24-hour personal care services should be authorized, the local professional director, or designee, must consider the information in the social and nursing assessments.

(iv) The local professional director or designee may consult with the patient's treating physician and may conduct an additional assessment of the patient in the home. The final determination must be made with reasonable promptness, generally not to exceed seven business days after receipt of the physician's order and the completed social and nursing assessments, except in unusual

circumstances including, but not limited to, the need to resolve any outstanding questions regarding the amount or duration of services to be authorized.]

(e) The social services district or MMCO is responsible for developing a plan of care in collaboration with the individual or, if applicable, the individual's representative that reflects the assessments and practitioner order described in this paragraph. In the plan of care, the social services district or MMCO must identify:

(1) the personal care service functions or tasks with which the individual needs assistance;

(2) the amount, frequency and duration of services to be authorized to meet these needs;

(3) how needs are met, if not met through the authorization of services; and

(4) any other descriptions and documentation provided for in this section.

(f) Upon the development of a plan of care, the social services district or MMCO shall refer high needs cases described in subparagraph (v) of this paragraph to the independent review panel; provided, however, that an MMCO should not refer a case unless and until the individual is enrolled or scheduled for enrollment in the MMCO. When a case is referred to the independent review panel:

(1) the social services district or MMCO shall provide the individual's plan of care and any clinical records or other documentation used to develop the plan of care, such as records from treating providers and the results of any review or evaluation performed pursuant to this paragraph to the panel;

(2) the social services district or MMCO shall cooperate with the panel as appropriate to ensure an expedient review of each high needs case; and

(3) the social services district or MMCO shall consider the panel's recommendation in finalizing

the plan of care and authorization. However, the social services district or MMCO is not required to adopt the recommendation, either in full or in part, and retains responsibility for determining the amount and type of services medically necessary.

(iv) Coordinating the independent assessment, practitioner order and LDSS or MMCO responsibilities.

(a) The social services district or MMCO must coordinate with the entity or entities providing independent assessment and practitioner services to minimize the disruption to the individual and in-home visits.

(b) The social services district or MMCO must inform the entity or entities providing independent assessment and practitioner services when a new assessment or practitioner order is needed pursuant paragraphs (4)(xii) and (4)(xiii) of this subdivision, in accordance with department guidance, using forms as may be required by the department.

(1) When the social services district or MMCO receives an initial or new request for services it

shall refer the individual to the entity providing independent assessment services and provide assistance to the individual in making contact in accordance with department guidance; provided however that the social services district or MMCO may not pressure or induce the individual to request an assessment unwillingly.

(2) If needed, the MMCO shall also refer the individual to the social services district to determine the individual's eligibility for medical assistance, including community based long term care services.

(c) The entity or entities providing independent assessment or practitioner services may request that the social services district or MMCO confirm or update an individual's record in the assessment database designated by the Department. The social services district or MMCO shall respond within one business day and confirm or update the relevant record within three business days after receipt of request.

(d) Resolving mistakes and clinical disagreements in the assessment process.

(1) If the social services district or MMCO identifies a material mistake in the independent assessment that can be confirmed by the submission of evidence, the social services district or MMCO shall advise the independent assessor. A mistake is an error of fact or observation that occurred when the assessment was performed that is not subject to the assessor's clinical judgment. A mistake is material when it would affect the amount, type, or duration of services authorized. When identifying the mistake, the social services district or MMCO must provide evidence of the mistake to the independent assessor. The independent assessor shall promptly issue a corrected assessment or schedule a new assessment in accordance with subclause (3) of this clause as appropriate.

(2) After reviewing the independent assessment, practitioner order and the result of any social service district or MMCO assessment or evaluation, if the social services district or MMCO has a material disagreement regarding the outcome of the independent assessment, the social services district

or MMCO may advise the independent assessor. A disagreement occurs when the social services district or MMCO disputes a finding or conclusion in the independent assessment that is subject to the independent assessor's clinical judgment. A disagreement is material when it would affect the amount, type, or duration of services authorized. When submitting a disagreement to the independent assessor, the social services district or MMCO must provide the clinical rationale that forms the basis for the disagreement.

(3) Upon submission of a material disagreement, an independent assessor shall schedule and complete a new assessment within 10 days from the date it receives notice from the social services district or MMCO. This shall not pend or otherwise affect the timeframes within which the social services district or MMCO is required to make a determination, provide notice, or authorize services.

(e) Sanctions for failure to cooperate and abuse of the resolution process.

(1) The Department of Health may impose monetary penalties pursuant to Public Health Law section 12 for failure to coordinate with the entity or entities providing independent assessment and practitioner services in accordance with the provisions of clauses (a) through (c) of this subparagraph or engaging in abusive behavior that affects the coordination of the assessment process. In determining whether to impose a monetary penalty and the amount imposed, the Department shall consider, where applicable, the following:

(i) The frequency and numerosity of violations, both in absolute terms and relative to other MMCOs;

(ii) The responsiveness of the MMCO to requests for coordination;

(iii) The history of coordination between the MMCO and the entity or entities;

(iv) The good faith demonstrated by the MMCO in attempting to coordinate;

(v) Whether the MMCO provides a justification for the violation and whether it has merit, as determined by the Department;

(vi) Whether the violation resulted or could have resulted in injury or other harm to the individual; and

(vii) Other relevant facts or circumstances.

(2) The Department of Health may revoke, or impose other restrictions on, a social services district's or MMCO's privilege to request reassessments on the basis of a material disagreement where the Department determines that the social services district has abused this privilege, including the use of mistake process for issues subject to clinical judgment or pressuring or inducing individuals to request a new assessment. In determining whether a social services district or

MMCO has abused this privilege, the Department shall consider, where applicable, the following:

(i) The frequency and numerosity of disagreements, mistakes, and reassessment requests submitted to the independent assessor, both in absolute terms and relative to other social services districts and MMCOs;

(ii) Whether the clinical rationale provided for the disagreement has merit, as determined by the Department;

(iii) Whether the disagreement, mistake, and reassessment requests are made as a matter of course, instead of upon review of the clinical record;

(iv) The outcome of the reassessment as compared to the assessment it replaces; and

(v) Other facts or circumstances that tend to provide evidence for or against abuse.

(3) Nothing in this section shall be construed to limit the authority of the Department or other agencies to seek other remedies, sanctions or penalties, including other monetary penalties.

(v) Independent medical review of high needs cases.

An independent medical review of a proposed plan of care shall be obtained before a social services district or MMCO may authorize more than 12 hours of personal care services or consumer directed personal assistance separately or in combination per day on average, except as otherwise provided in paragraph (4) of this subdivision (“high needs cases”). The review shall result in a recommendation made to the social services district or MMCO, as described in this subparagraph.

(a) The independent medical review must be performed by an independent panel of medical professionals, or other clinicians, employed by or under contract with an entity designated by the Department of Health (the “independent

review panel”) and shall be coordinated by a physician (the “lead physician”) who shall be selected from the independent review panel. The lead physician may not be the same person who performed the initial medical examination and signed the individual’s practitioner order.

(b) The lead physician must review the independent assessment, the practitioner order, any other assessment or review conducted by the social services district or MMCO, including any plan of care created.

(c) The lead physician may evaluate the individual, or review an evaluation performed by another medical professional on the independent review panel. The medical professional may not have performed the initial medical examination or signed the individual’s practitioner order.

(d) The lead physician and panel members may consult with or interview other members of the independent review panel, the ordering practitioner, the individual’s treating or primary care physician, and other individuals who the lead physician deems important and who are available to assist the panel’s review and recommendation.

(e) The lead physician and panel members may request additional information or documentation, including medical records, case notes, and any other material the lead physician deems important to assist the panel's review and recommendation.

(f) After review, the independent review panel shall produce a report, signed by the lead physician, providing a recommendation on the reasonableness and appropriateness of the proposed plan of care to maintain the individual's health and safety in his or her own home, in accordance with the standards and scope of services set forth in this section. The report may suggest modifications to the plan of care, including the level, frequency, and duration of services and whether additional, alternative, or fewer services would facilitate the provision of medically necessary care. The report may not, however, recommend a specific amount or change in amount of services.

(3) Timeframes for the assessment and authorization of services

(i) The independent assessment and practitioner order processes shall be completed at least annually and in sufficient time such that

social services districts and MMCOs may have an opportunity when needed to comply with all applicable federal and state timeframes for notice and determination of services, including but not limited to immediate needs.

(ii) A social services district must make a determination and provide notice with reasonable promptness, not to exceed seven business days after receipt of both the independent assessment and practitioner order, or the independent review panel recommendation if applicable, except in unusual circumstances including, but not limited to, the need to resolve any outstanding questions regarding the amount or duration of services to be authorized, or as provided in paragraphs (6) and (7) of this subdivision.

(iii) An MMCO must make a determination and provide notice to current enrollees within the timeframes provided in the contract between the Department of Health and the MMCO, or as otherwise required by Federal or state statute or regulation.

Paragraphs (5) and (6) of subdivision (b) of section 505.14 are renumbered paragraphs (4) and (5), and renumbered paragraph (4) is amended to read as follows:

[(5)] (4) [The authorization for personal care services shall be completed prior to the initiation of services] Authorization and reauthorization criteria.

(i) An individual's eligibility for medical assistance and services, including the individual's financial eligibility and eligibility for personal care services provided for in this section, shall be established prior to the authorization for services. The entity designated by the Department of Health to provide independent assessment services shall be responsible for determining whether individuals meet minimum needs requirements for services.

(ii) The authorization for personal care services shall be completed by the social services district or MMCO prior to the initiation of services. In the case of the social services district, the authorization of services shall be prepared by staff of the social services district and such responsibility may not be delegated to another person or entity.

(iii) The authorization and reauthorization of personal care services, including the level, amount, frequency and duration of services, by the social services district or MMCO must be based on and reflect the outcome of the assessment process outlined in paragraph (2) of this subdivision except as otherwise provided for in subparagraphs (xii) and (xiii) of this paragraph.

~~[(i)]~~ (iv) The social services district [shall] or MMCO may authorize only the hours or frequency of services actually required by the [patient] individual.

~~[(ii)]~~ (v) The duration of the authorization period shall be based on the [patient's] individual's needs as reflected in the required assessments and documented in the plan of care. In determining the duration of the authorization period, the following shall be considered:

(a) the [patient's] individual's prognosis and/or potential for recovery; and

(b) the expected length of any informal caregivers' participation in caregiving; and

(c) the projected length of time alternative services will be available to meet a part of the [patient's] individual's needs.

(vi) The social services district or MMCO may not authorize more than 12 hours of personal care services per day on average prior to considering the recommendation of the independent review panel in accordance with procedures outlined in paragraphs (2)(iii) and (2)(v) of this subdivision, unless such authorization is ordered pursuant to a fair hearing decision or

by another court of competent jurisdiction. Pending review of the independent review panel's recommendation and if necessary to comply with federal or state timeliness requirements, including immediate needs cases, the social services district or MMCO may authorize and implement services based on a temporary plan of care which provides for more than 12 hours of personal care services per day on average.

[(iii)] (vii) No authorization for personal care services shall exceed [six] 12 months from the date of the most recent independent assessment or practitioner order, whichever is earlier. [The local social services department may request approval for an exception to allow for authorization periods up to 12 months. The request must be accompanied by the following:

(a) a description of the patients who will be considered for an expanded authorization period; and

(b) a description of the local social services department's process to assure that the delivery of services is responsive to changes in the patient's condition and allows immediate access to services by the patient, patient's physician, assessing nurse and provider agency if the need for services changes during the expanded authorization period.]

[(iv)] (viii) Requirements for the continuation, denial, or discontinuance of services.

(a) The social services district or MMCO must deny or discontinue personal care services when such services are not medically necessary or are no longer medically necessary or when the social services district or MMCO reasonably expects that such services cannot maintain or continue to maintain the client's health and safety in his or her home.

(b) The social services district or MMCO must notify the client in writing of its decision to authorize, reauthorize, increase, decrease, discontinue or deny personal care services [on forms required by the department. The client is entitled to a fair hearing and to have such services continued unchanged until the fair hearing decision is issued (aid-continuing) in accordance with the requirements of this Title]. The Department of Health may require the use of forms it develops or approves when providing such notice.

(c) The social services district's or MMCO's reasons for its determination to deny, reduce or discontinue personal care services must be stated in the client notice.

(1) Social services districts and MMCOs that deny, reduce or discontinue services based on medical necessity in accordance with clause (a) of this subparagraph must identify and document in the notice and in the client's plan of care the factors that demonstrate such services are not medically necessary or are no longer medically necessary. Any such denial or reduction in services must clearly indicate a clinical rationale that shows review of the client's specific clinical data and medical condition; the basis on which the client's needs do not meet specific benefit coverage criteria, if applicable; and be sufficient to enable judgment for possible appeal.

[(1)] (2) Appropriate reasons and notice language to be used when denying personal care services include but are not limited to the following:

(i) the client's health and safety cannot be reasonably assured with the provision of personal care services. The notice must identify the reason or reasons that the client's health and safety cannot be reasonably assured with the provision of personal care services;

* * *

(vi) the client's needs may be met, in whole or part, by a technological development, which the notice must identify, renders certain services unnecessary or less time-consuming, including the use of readily available telehealth services or assistive devices that are accessible to the individual and that can be demonstrated and documented to reduce the amount of services that are medically necessary;

(vii) the client resides in a facility or participates in another program or receives other services, which the notice must identify, which are responsible for the provision of needed personal care services, and either the client is not seeking to transition into a less restrictive setting or whose health and safety cannot be reasonably assured in a less restrictive setting; [and]

(viii) the client can be more appropriately and cost-effectively served through other Medicaid programs or services, which the notice must identify[.]; and

(ix) the client's need(s) can be met either without services or with the current level of services by fully utilizing any available informal supports, or other supports and services, that are documented in the plan of care and identified in the notice.

[(2)] (3) Appropriate reasons and notice language to be used when reducing or discontinuing personal care services include but are not limited to the following:

(i) the client's medical or mental condition or economic or social circumstances have changed and the district or MMCO determines that the personal care services provided under the last authorization or reauthorization are no longer appropriate or can be provided in fewer hours. [For proposed discontinuances, this] This includes but is not limited to cases in which: the client's health and safety can no longer be reasonably assured with the

provision of personal care services; the client's medical condition is no longer stable; the client is no longer self-directing and has no one to assume those responsibilities; [or] the services the client needs exceed the personal care aide's scope of practice; or voluntary informal supports that are acceptable to the client have become available to meet some or all of the client's needs. The notice must identify the specific change in the client's medical or mental condition or economic or social circumstances from the last authorization or reauthorization and state why the services should be reduced or discontinued as a result of the change;

* * * *

(iv) the client's needs may be met, in whole or part, by a technological development, which the notice must identify, that renders certain services unnecessary or less time-consuming including the use of telehealth services or assistive devices that can be demonstrated and documented to reduce the amount of services that are medically necessary;

(v) the client resides in a facility or participates in another program or receives other services, which the notice must identify, which are responsible for the provision of needed personal care services, and either the client is not seeking to transition into a less restrictive setting or whose health and safety cannot be reasonably assured in a less restrictive setting; [and]

(vi) the client can be more appropriately and cost-effectively served through other Medicaid programs and services, which the notice must identify[.];

(vii) an assessment of the client's needs demonstrates that the immediately preceding social services district or MMCO authorized more services than are medically necessary following any applicable continuity of care period required by the Department of Health.

(d) The social services district or MMCO may not authorize or reauthorize personal care services based upon a task-based

assessment when the applicant or recipient of personal care services has been determined by the social services district [or], the State or MMCO to be in need of 24-hour personal care, including continuous personal care services, live-in 24-hour personal care services or the equivalent provided by formal services or informal caregivers.

[(v)] (ix) When services are authorized, the local social services department or MMCO shall provide the agency or person providing services, the [patient] individual receiving the services, and the agency or individual supervising the services, with written information about the services authorized, including the functions and tasks required and the frequency and duration of the services. The individual shall be given a copy of the plan of care.

[(vi)] (x) All services provided shall be in accordance with the authorization. No change in functions or tasks or hours of services delivered shall be made without notification to, and approval of, the social services district or MMCO.

[(vii)] The local social services department shall notify the patient in writing when a change in the amount of services authorized is being

considered. Notification shall be provided in accordance with the requirements specified in subparagraph (b)(5)(v) of this section.]

[(viii)] (xi) Reauthorization for personal care services shall follow the procedures outlined in [paragraphs (2) through (4)] paragraph 2 of this subdivision, with the following exceptions:

(a) [Reauthorization of Level I services shall not require a nursing assessment if the physician's order indicates that the patient's medical condition is unchanged.

(b)] Reauthorization of Level II services shall include an evaluation of the services provided during the previous authorization period. The evaluation shall include a review of the nursing supervisory reports to assure that the [patient's] individual's needs have been adequately met during the initial authorization period.

(b)Where an independent review panel previously reviewed a high need case, reauthorization of services shall not require another panel review for as long as the case remains a high needs. If service levels are reduced below the high needs threshold and

subsequently increased to become a high needs case again, another review by the independent review panel is required.

(c) Neither an independent assessment nor a practitioner order shall be required to reauthorize or continue an authorization of services, except:

(1) prior to or in conjunction with a discharge from an institutional or in-patient setting, provided that this provision shall not be construed to prohibit a safe discharge from occurring;

(2) as provided in subparagraph (xii) of this paragraph;

(3) that an individual in receipt of services may request a new independent assessment; and

(4) an individual in receipt of services must receive an independent assessment and practitioner order at least annually to maintain authorization.

[(ix)] (xii) [When] Upon becoming aware of an unexpected change in the [patient's] individual's social circumstances, mental status or medical

condition occurs which would affect the type, amount or frequency of personal care services being provided during the authorization period, the social services district [is responsible for making] or MMCO shall make necessary changes in the authorization on a timely basis in accordance with the following procedures:

(a) When the change in the [patient's] individual's services needs results solely from a change in [his/her] the individual's social circumstances including, but not limited to, loss or withdrawal of support provided by informal caregivers, the local social services department or MMCO shall review the [social] independent assessment, document the [patient's] individual's social circumstances and make changes in the authorization as indicated. A new [physician's] practitioner order and [nursing] independent assessment shall not be required.

(b) When the change in the [patient's] individual's services needs results from a change in [his/her] the individual's mental status including, but not limited to, loss of his/her ability to make judgments, or from a change in his/her medical condition, the local social services department or MMCO shall [review the social assessment, document the changes in the patient's mental status and take appropriate action as indicated] obtain a new independent

assessment, practitioner order and, if required, refer the case to the independent review panel.

[(c) When the change in the patient's services needs results from a change in his/her medical condition, the local social services department shall obtain a new physician's order and a new nursing assessment and shall complete a new social assessment.]

(xiii) When there is any change in the individual's service needs, a social services district or MMCO shall consider such changes and document them in the plan of care, and shall consider and make any necessary changes to the authorization.

Paragraph (7) of subdivision (b) of section 505.14 is renumbered paragraph (6) and amended to read as follows:

[(7)] (6) This paragraph sets forth expedited procedures for social services districts' determinations of medical assistance (Medicaid) eligibility and personal care services eligibility for Medicaid applicants with an immediate need for personal care services.

(i) The following definitions apply to this paragraph:

(a) *A Medicaid applicant with an immediate need for personal care services* means an individual seeking Medicaid coverage who:

* * *

(2) provides to the social services district:

(i) a [physician's order] statement of need for personal care services from a physician with direct knowledge of the applicant's condition on a form required by the Department of Health; and

(ii) a signed attestation on a form required by the [department] Department of Health that the applicant has an immediate need for personal care services (attestation of immediate need) and that:

* * *

(b) *A complete Medicaid application* means a signed Medicaid application and all documentation necessary for the social services district to determine the applicant's Medicaid eligibility for Medicaid coverage of community-based long term care services.

For purposes of this paragraph, an applicant who would otherwise be required to document accumulated resources may attest to the current value of any real property and to the current dollar amount of any bank accounts. After the determination of Medicaid eligibility, if the commissioner or the district has information indicating an inconsistency between the value or dollar amount of such resources and the value or dollar amount to which the applicant had attested prior to being determined eligible for Medicaid, and the inconsistency is material to the individual's Medicaid eligibility, the district must request documentation adequate to verify such resources.

(ii) The social services district must determine whether the applicant has submitted a complete Medicaid application. If [the] an applicant has not submitted a complete Medicaid application, the district must notify the applicant of the additional documentation that the applicant must provide and the date by which the applicant must provide such documentation.

(a) When [the] an applicant submits [the] an incomplete Medicaid application together with the physician's [order] statement and the signed attestation of immediate need, the district must provide such notice as soon as possible and no later than four calendar days after receipt of these documents.

(b) When [the] an applicant submits [the] an incomplete Medicaid application and subsequently submits the physician's [order] statement, the signed attestation of immediate need, or both such documents, the district must provide such notice as soon as possible and no later than four calendar days after receipt of both the physician's [order] statement and the signed attestation of immediate need.

(iii) * * *

(iv) As soon as possible after receipt of a complete Medicaid application from a Medicaid applicant with an immediate need for personal care services, but no later than 12 calendar days after receipt of a complete Medicaid application from such an applicant, the social services district must:

(a) [obtain or complete a social assessment, nursing assessment, and an assessment of other services] refer the applicant for an independent assessment and medical exam and evaluate his or her need for other services pursuant to [subparagraphs (3)(ii) through (3)(iv)] paragraphs (2)(i) through (2)(v) of this subdivision; and

(b) determine whether the applicant, if determined eligible for Medicaid, would be eligible for personal care services and, if so, the amount and duration of the personal care services that would be authorized should the applicant be determined eligible for Medicaid, including Medicaid coverage of community-based long-term care services; provided, however, that personal care services shall be authorized only for applicants who are determined to be eligible for Medicaid, including Medicaid coverage of community-based long-term care services. In no event shall personal care services be authorized for a Medicaid applicant unless the applicant has been determined eligible for Medicaid, including Medicaid coverage of community-based long-term care services.

(v) * * *

Paragraph (8) of subdivision (b) of section 505.14 is renumbered paragraph (7) and subparagraph (i) of renumbered paragraph (7) of subdivision (b) is amended to read as follows:

(i) *A Medicaid recipient with an immediate need for personal care services* means an individual seeking personal care services who:

(a) * * *

(b)

(1) was a Medicaid applicant with an immediate need for personal care services pursuant to paragraph [(7)] (6) of this subdivision who was determined, pursuant to such paragraph, to be eligible for Medicaid, including Medicaid coverage of community-based long-term care services, and who was also determined pursuant to such paragraph to be eligible for personal care services; or

(2) is a Medicaid recipient who has been determined to be eligible for Medicaid, including Medicaid coverage of community-based long-term care services, and who provides to the social services district:

(i) a [physician's order] statement of need for personal care services from a physician with direct knowledge of the recipient's condition on a form required by the Department of Health; and

(ii) a signed attestation on a form required by the [department] Department of Health that the recipient has an immediate need for personal care services (attestation of immediate need) and that:

* * *

Clause (a) of subparagraph (iii) of renumbered paragraph (7) of subdivision (b) of section 505.14 is amended to read as follows:

(a) With regard to a Medicaid recipient with an immediate need for personal care services who is described in subclause (i)(b)(2) of this paragraph, the social services district, as soon as possible after receipt of the physician's [order] statement and signed attestation of immediate need, but no later than 12 calendar days after receipt of such documentation, must:

(1) [obtain or complete a social assessment, nursing assessment, and an assessment of other services] refer the applicant for an independent assessment and medical exam and evaluate his or her need for other services pursuant to [subparagraphs (3)(ii) through (3)(iv)] paragraphs (2)(i) through (2)(v) of this subdivision; and

(2) determine whether the recipient is eligible for personal care services and, if so, the amount and duration of the personal care services to be authorized.

A new paragraph (8) is added to subdivision (b) of section 505.14 to read as follows:

(8) Prior to October 1, 2022, and notwithstanding provisions of this section to the contrary, where the Department of Health has not contracted with or designated an entity or entities to provide independent assessment or practitioner services, or where there is limited access to timely assessments and medical exams in accordance with this subdivision, as determined by the Department of Health, then, in accordance with written direction from the Department of Health, assessments may be performed by the social services district or MMCO in accordance with the provisions of this section in effect as of January 1, 2021. The Department may limit such directive to a particular geographic region or regions based on the need for timely assessment and medical exams and may require that social services districts and MMCOs first attempt assessment and authorization pursuant to the provisions of this subdivision currently in effect. Notwithstanding the forgoing, upon becoming effective, the provisions of subparagraph (viii) of paragraph (4) of this subdivision shall remain in effect, and may not be pended pursuant to this paragraph.

Paragraph (1) of subdivision (c) of section 505.14 is amended to read as follows:

(1) Each social services district must have contracts or other written agreements with all agencies or persons providing personal care services or any support functions for the delivery of personal care services. As used in this subdivision, support functions for the delivery of personal care services include, but are not

necessarily limited to, [nursing assessments,] nursing supervision and case management, when provided according to subdivisions (b), (f) and (g) of this section, respectively.

Subparagraphs (i) and (ii) of paragraph (5) of subdivision (c) of section 505.14 is amended to read as follows:

(i) The social services district must use a contract or other written agreement for support functions for the delivery of personal care services, including case management[, nursing assessments] and nursing supervision, that the department approves to be used.

(ii) The social services district must not implement any contract or agreement for case management, [nursing assessments,] nursing supervision, or any other support function until the department approves such contract or agreement.

Subparagraph (vi) of paragraph (3) of subdivision (f) of section 505.14 is amended to read as follows:

(vi) The nurse who completes the nursing assessment, as specified in subparagraph [(b)(3)(iii)] (b)(2)(iii) of this section, must recommend the frequency of nursing supervisory visits for a personal care services patient and must specify the recommended frequency in the patient's plan of care.

Paragraphs (3) and (4) of subdivision (g) of section 505.14 are amended to read as follows:

(3) Case management includes the following activities:

(i) receiving referrals for personal care services, providing information about such services and determining, when appropriate, that the patient is financially eligible for [medical assistance] Medicaid, including community-based long term care services;

(ii) informing the patient or the patient's representative that an independent assessment and a [physician's] practitioner's order is needed, [making copies of the physician's order form available to hospital discharge planners, physicians, and other appropriate persons or entities,]referring the individual for assessment, and assisting the [patient to obtain a physician's order when the patient or the patient's representative is unable to obtain the order] individual to connect with the independent assessment entity;

(iii) [completing the social assessment according to subdivision (b) of this section, including an evaluation of:

(a) the potential contribution of informal caregivers to the patient's plan of care, as specified in subparagraph (b)(3)(ii) of this section;

(b) the patient's physical environment, as determined by a visit to the patient's home; and

(c) the patient's mental status;

(iv) obtaining or completing the nursing assessment according to subparagraph (b)(3)(iii) of this section] coordinating with the entity or entities designated to provide independent assessment and independent practitioner services as may be needed to ensure that individuals are assessed in accordance with subdivision (b) of this section;

[(v)] (iv) [assessing the patient's eligibility for hospice services and assessing the appropriateness and cost-effectiveness of the services specified in subparagraph [(b)(3)(iv)] (b)(2)(iii) of this section;

[(vi)] (v) forwarding [the physician's order; the social and nursing assessments; the assessments] the independent assessment, practitioner order, plan of care, and materials used in determining the plan of care and authorization required by subparagraph [(b)(3)(iv)] (b)(2)(iii) of this section[;] and any other information as may be required by the Department

of Health for an independent medical review according to subparagraph [(b)(4)(i)] (b)(2)(v) of this section;

[(vii)] (vi) negotiating with informal caregivers to encourage or maintain their involvement in the patient's care;

(vii) developing and maintaining the individual's plan of care;

(viii) determining the level, amount, frequency and duration of personal care services to be authorized or reauthorized according to subdivisions (a) and (b) of this section, or, if the case involves an independent medical review, obtaining the independent review [determination] panel recommendation;

* * *

(x) assuring that the patient is provided written notification of personal care services initially authorized, reauthorized, denied, increased, reduced, discontinued, or suspended and his or her right to a fair hearing, as specified in Part 358 of this Title [and subparagraph (b)(5)(iv) of this section];

(xi) arranging for the delivery of personal care services according to subdivision (c) of this section;

(xii) forwarding, prior to the initiation of personal care services, a copy of the patient's plan of care [developed by the nurse responsible for completion of the nursing assessment], as specified in subdivision (a) of this section, to the following persons or agencies:

* * *

(xv) allowing access by the patient to his or her written records, including [physicians'] practitioners' orders and [nursing] assessments and, pursuant to 10 NYCRR 766.2(e), by the State Department of Health and licensed provider agencies;

* * *

(xvii) promptly initiating and complying with the procedures specified in subparagraph [(b)(5)(ix)] (b)(4)(xii) of this section when the patient's social circumstances, mental status or medical condition unexpectedly change during the authorization period;

* * *

(4) The case management agency must maintain current case records on each patient receiving personal care services. Such records must include, at a minimum, a copy of the following documents:

(i) the [physician's] practitioner orders;

(ii) the [nursing and social assessments] independent assessment in subparagraph (b)(2)(i) of this section;

(iii) [the assessment of the patient's eligibility for hospice services and] the assessments of the appropriateness and cost-effectiveness of the services specified in subparagraph [(b)(3)(iv)] (b)(2)(iii) of this section;

(iv) for a patient whose case must be referred to the [local professional director or designee] independent review panel in accordance with subparagraph [(b)(4)(i)] (b)(2)(v) of this section, a record that the [physician's] practitioner order, the [social and nursing assessments] independent assessment, and the assessments required by subparagraph [(b)(3)(iv)] (b)(2)(iii) of this section were forwarded to the [local professional director or designee] independent review panel;

(v) for a patient whose case must be referred to the [local professional director or designee] independent review panel in accordance with

subparagraph [(b)(4)(i)] (b)(2)(v) of this section, a copy of the [local professional director's or designee's determination] panel's recommendation;

* * *

Clause (ii) of paragraph (5) subdivision (g) of section 505.14 is amended to read as follows:

(ii) Professional staff responsible for adult protective services have primary responsibility for case management for a patient who:

* * *

(b) receives or requires personal care services as part of an adult protective services plan; and

* * *

(2) is self-directing, as defined in subparagraph (a)(3)(ii) of this section, but refuses to accept personal care services in accordance

with the plan of care developed by the [nurse who completed the nursing assessment] social services district or MMCO.

Subdivision (b) of section 505.28 is amended to read as follows:

(b) Definitions. The following definitions apply to this section:

(1) Activity of daily living means those activities recognized as activities of daily living by the evidence based validated assessment tool in accordance with section 2-a of part MM of chapter 56 of the laws of 2020.

[(1)] (2) *consumer* means a medical assistance recipient who a social services district or MMCO has determined eligible to participate in the consumer directed personal assistance program.

[(2)] (3) *consumer directed personal assistance* means the provision of assistance with personal care services, home health aide services and skilled nursing tasks by a consumer directed personal assistant under the instruction, supervision and direction of a consumer or the consumer's designated representative.

[(3)] (4) *consumer directed personal assistant* means an adult who provides consumer directed personal assistance to a consumer under the consumer's

instruction, supervision and direction or under the instruction, supervision and direction of the consumer's designated representative. A person legally responsible for the consumer's care and support, a consumer's spouse, [parent] or the consumer's designated representative may not be the consumer directed personal assistant for that consumer; however, a consumer directed personal assistant may include any other adult relative of the consumer [who does not reside with the consumer or any other adult relative who resides with the consumer because the amount of care the consumer requires makes such relative's presence necessary] provided that the district or MMCO determines that the services provided by such relative are consistent with the consumer's plan of care and that the aggregate cost for such services does not exceed the aggregate costs for equivalent services provided by a non-relative personal assistant.

(5) consumer directed personal assistance program or consumer directed program or the program means the program provided for under section 356-f of title 11 of article 5 of the Social Services Law.

[(4)] (6) continuous consumer directed personal assistance means the provision of uninterrupted care, by more than one consumer directed personal assistant, for more than 16 hours in a calendar day for a consumer who, because of the consumer's medical condition, needs assistance during such calendar day with toileting, walking, transferring, turning and positioning, feeding, home health aide services, or skilled nursing tasks, and needs assistance with such frequency that a

live-in 24-hour consumer directed personal assistant would be unlikely to obtain, on a regular basis, five hours daily of uninterrupted sleep during the aide's eight hour period of sleep.

[(5)] (7) *designated representative* means an adult to whom a self-directing consumer has delegated authority to instruct, supervise and direct the consumer directed personal assistant and to perform the consumer's responsibilities specified in subdivision [(g)] (h) of this section and who is willing and able to perform these responsibilities. With respect to a non self-directing consumer, a *designated representative* means the consumer's parent, legal guardian or, subject to the social services district's approval, a responsible adult surrogate who is willing and able to perform such responsibilities on the consumer's behalf. The designated representative may not be the consumer directed personal assistant or a fiscal intermediary employee, representative or affiliated person.

[(6)] (8) *fiscal intermediary* means an entity that has a contract with [a social services district] the New York State Department of Health to provide wage and benefit processing for consumer directed personal assistants and other fiscal intermediary responsibilities specified in subdivision [(i)] (j) of this section.

[(7)] (9) *fiscal intermediary administrative costs* means the allowable costs incurred by a fiscal intermediary for performance of fiscal intermediary services

under section 365-f(4-a) of the Social Services Law and fiscal intermediary responsibilities under subdivision (i) of this section.

[(8)] (10) *home health aide services* means services within the scope of practice of a home health aide pursuant to article 36 of the Public Health Law including simple health care tasks, personal hygiene services, housekeeping tasks essential to the consumer's health and other related supportive services. Such services may include, but are not necessarily limited to, the following: preparation of meals in accordance with modified diets or complex modified diets; administration of medications; provision of special skin care; use of medical equipment, supplies and devices; change of dressing to stable surface wounds; performance of simple measurements and tests to routinely monitor the consumer's medical condition; performance of a maintenance exercise program; and care of an ostomy after the ostomy has achieved its normal function.

(11) *live-in 24-hour consumer directed personal assistance* means the provision of care by one consumer directed personal assistant for a consumer who, because of the consumer's medical condition, needs assistance during a calendar day with toileting, walking, transferring, turning and positioning, feeding, home health aide services, or skilled nursing tasks and whose need for assistance is sufficiently infrequent that a live-in 24-hour consumer directed personal assistant would be likely to obtain, on a regular basis, five hours daily of uninterrupted sleep during the aide's eight hour period of sleep.

(12) Medicaid Managed Care Organization or MMCO means an entity, other than an entity approved to operate a Program of All-inclusive Care for the Elderly (PACE) plan, that is approved to provide medical assistance services, pursuant to a contract between the entity and the Department of Health, and that is: (i) certified under article forty-four of the Public Health Law, or (ii) licensed under article forty-three of the Insurance Law.

(13) Medical assistance or Medicaid means the program to provide services and benefits under title 11 or article 5 of the Social Services Law.

(14) minimum needs requirements means, for individuals with a diagnosis by a physician of dementia or Alzheimer's, being assessed in accordance with subdivision (d) of this section as needing at least supervision with more than one activity of daily living, and for all other individuals, being assessed in accordance with subdivision (d) of this section as needing at least limited assistance with physical maneuvering with more than two activities of daily living.

[(8)] (15) *personal care services* means the nutritional and environmental support functions, personal care functions, or both such functions, that are specified in section 505.14(a)(5) of this Part except that, for individuals whose needs are limited to nutritional and environmental support functions, personal care services shall not exceed eight hours per week.

[(10)] (16) a *self-directing consumer* means a consumer who is capable of making choices regarding the consumer's activities of daily living and the type, quality and management of his or her consumer directed personal assistance; understands the impact of these choices; [and] assumes responsibility for the results of these choices; and is capable of instructing, supervising, managing and directing consumer directed personal assistants and performing all other consumer responsibilities identified in this section.

[(11)] (17) *skilled nursing tasks* means those skilled nursing tasks that are within the scope of practice of a registered professional nurse or a licensed practical nurse and that a consumer directed personal assistant may perform pursuant to section 6908 of the Education Law.

[(12)] (18) *stable medical condition* means a condition that is not expected to exhibit sudden deterioration or improvement and does not require frequent medical or nursing evaluation or judgment to determine changes in the consumer's plan of care.

[(13)] *live-in 24-hour consumer directed personal assistance* means the provision of care by one consumer directed personal assistant for a consumer who, because of the consumer's medical condition, needs assistance during a calendar day with toileting, walking, transferring, turning and positioning, feeding, home health aide services, or skilled nursing tasks and whose need for assistance is sufficiently

infrequent that a live-in 24-hour consumer directed personal assistant would be likely to obtain, on a regular basis, five hours daily of uninterrupted sleep during the aide's eight hour period of sleep.]

Subdivision (c) of section 505.28 is amended to read as follows:

(c) Eligibility requirements.

To participate in the consumer directed personal assistance program, an individual must meet the following eligibility requirements:

* * *

(2) be eligible for long term care and services provided by a certified home health agency, [long term home health care program] or an AIDS home care program authorized pursuant to article 36 of the Public Health Law; or for personal care services or private duty nursing services;

* * *

(6) be willing and able to fulfill the consumer's responsibilities specified in subdivision (h) of this section or have a designated representative who is willing and able to fulfill such responsibilities; [and]

(7) participate as needed, or have a designated representative who so participates, in the required assessment and reassessment processes specified in subdivisions (d) and (f) of this section[.]; and

(8) meet minimum needs requirements in accordance with state statute.

Subdivision (d) of section 505.28 is amended to read as follows:

(d) Assessment process. [When the social services district receives a request to participate in the consumer directed personal assistance program, the social service district must assess whether the individual is eligible for the program. The assessment process includes physician's order, a social assessment and a nursing assessment and, when required under paragraph (5) of this subdivision, a referral to the local professional director or designee.] The assessment process includes an independent assessment, a medical examination and practitioner order, an evaluation of the need and cost-effectiveness of services, the development of the plan of care, and, when required under paragraph (5) of this subdivision, a referral to an independent review panel. The independent assessment, medical exam and independent review panel may utilize telehealth modalities for all or a portion of such assessments provided that the individual is given an opportunity for an in-person assessment and receives any necessary support during the telehealth assessment, which may include the participation of an on-site representative or

support-staff. The initial assessment process shall include the following procedures:

(1) Independent assessment. An assessment shall be completed by an independent assessor employed or contracted by an entity designated by the Department of Health to provide independent assessment services on forms approved by the Department of Health in accordance with the following:

(i) The independent assessment must be performed by a nurse with the following minimum qualifications:

(a) a license and current registration to practice as a registered professional nurse in New York State; and

(b) at least two years of satisfactory recent experience in home health care.

(ii) The independent assessment shall include the following:

(a) an assessment of the functions and tasks required by the individual, including an assessment of whether the individual meets minimum needs requirements;

(b) a discussion with the individual or, if applicable, the individual's designated representative to determine the individual's perception of his or her circumstances and preferences; and

(c) an assessment of the potential contribution of informal supports, such as family members or friends, to the individual's care, which must consider:

(1) the number and kind of informal supports available to the individual;

(2) the ability and motivation of informal supports to assist in care;

(3) the extent of informal supports' potential involvement;

(4) the availability of informal supports for future assistance; and

(5) the acceptability to the individual of the informal supports' involvement in his or her care;

(iii) The independent assessment must assess the consumer where the consumer is located including the consumer's home, a nursing facility, rehabilitation facility or hospital, provided that the consumer's home or residence shall be evaluated as well if necessary to support the proposed plan of care and authorization or to ensure a safe discharge. This provision shall not be construed to prevent or limit the use of telehealth in the assessment of a consumer.

[(1)] (2) [Physician's] Independent medical exam and practitioner order.

(i) Each individual seeking to participate in the consumer directed program must have an examination by a medical professional employed or contracted by an entity designated by the Department of Health to provide independent practitioner services.

[(i) A] (ii) The medical professional who examines the individual must be a physician licensed in accordance with article 131 of the Education Law, a physician assistant or a specialist assistant registered in accordance with article 131-B of the Education Law or a nurse practitioner certified in accordance with article 139 of the Education Law [must conduct a medical examination of the

individual and complete the physician's order within 30 calendar days after conducting the medical examination].

(iii) The medical professional must be independent with respect to the individual, meaning that medical professional that conducts the exam must not have established a provider-patient relationship with the individual prior to the clinical encounter from which the practitioner order is completed.

[(ii) (iv) [The physician's order must be completed on a form that the department requires or approves. The physician or other medical professional who conducted the examination must complete the order form by] The medical professional must examine the individual and accurately [describing] describe the individual's medical condition and regimens, including any medication regimens[;], and the individual's need for assistance with personal care services, home health aide services and skilled nursing tasks[; and provide only such other information as the physician's order form requires. The physician or other medical professional who completes the order form must not recommend the number of hours of services that the individual should be authorized to receive].

(v) The medical professional must review the independent assessment and may review other medical records and consult with the individual's providers and others involved with the individual's care if available to and determined necessary by the medical professional.

(vi) The medical professional must complete a form required or approved by the Department of Health (the "practitioner order form").

[(iii)] (vii) [A physician] The medical professional must sign the [physician's] practitioner order form, [and] certify that [the individual can be safely cared for at home and that] the information provided in the [physician's order] form accurately describes the individual's medical condition and regimens[, including any medication regimens, and the individual's need for assistance at the time of the medical examination] at the time of the medical examination, and indicate whether the individual is self-directing, consistent with the definition of self-directing in this section, and whether the individual is medically stable.

[(iv)] (viii) The [physician's] practitioner's order form must be [submitted] completed and made available by the medical

professional to the social services district [within 30 calendar days] or any MMCOs as appropriate after the medical examination and independent assessment. [The form may be submitted by the physician, other medical professional or by the individual or the individual's representative.]

[(v)] ~~(ix)~~ The [physician's] practitioner order [form] is subject to the provisions of Parts 515, 516, 517 and 518 of this Title[, which]. These Parts permit the [department] Department of Health or other agencies or organizations duly authorized or delegated by the Department of Health, including but not limited to MMCOs or the Office of the Medicaid Inspector General, to impose monetary penalties on, or sanction and recover overpayments from, providers [and] or prescribers of medical care, services or supplies when medical care, services or supplies that are unnecessary, improper or exceed [recipients'] individuals' documented needs are provided or ordered.

[(2) Social assessment. Upon receipt of a completed and signed physician's order, social services district professional staff must conduct a social assessment. The social assessment must include the following:

(i) a discussion with the individual or, if applicable, the individual's designated representative to determine the individual's perception of his or her circumstances and preferences;

(ii) an evaluation of the individual's ability and willingness to fulfill the consumer's responsibilities specified in subdivision (g) of this section and, if applicable, the ability and willingness of the individual's designated representative to assume these responsibilities;

(iii) an evaluation of the potential contribution of informal supports, such as family members or friends, to the individual's care, which must consider the number and kind of informal supports available to the individual; the ability and motivation of informal supports to assist in care; the extent of informal supports' potential involvement; the availability of informal supports for future assistance; and the acceptability to the individual of the informal supports' involvement in his or her care;

(iv) for cases involving continuous consumer directed personal assistance or live-in 24-hour consumer directed personal assistance, the social assessment shall demonstrate that all alternative arrangements for meeting the individual's medical needs have been explored and are infeasible including, but not limited to, the provision of consumer directed personal

assistance in combination with other formal services or in combination with voluntary contributions of informal caregivers; and

(v) for cases involving live-in 24-hour consumer directed personal assistance, an evaluation whether the consumer's home has sleeping accommodations for a consumer directed personal assistant. When the consumer's home has no sleeping accommodations for a consumer directed personal assistant, continuous consumer directed personal assistance must be authorized for the consumer; however, should the consumer's circumstances change and sleeping accommodations for a consumer directed personal assistant become available in the consumer's home, the district must promptly review the case. If a reduction of the consumer's continuous consumer directed personal assistance to live-in 24-hour consumer directed personal assistance is appropriate, the district must send the consumer a timely and adequate notice of the proposed reduction.

(3) Nursing assessment. Upon receipt of a completed and signed physician's order, the social services district must conduct or obtain a nursing assessment.

(i) The nursing assessment must be completed by a registered professional nurse who is employed by, or under contract with, the social services

district or by a licensed or certified home care services agency or voluntary or proprietary agency under contract with the district.

(ii) The nursing assessment must include the following:

(a) a review and interpretation of the physician's order;

(b) the primary diagnosis code from the ICD-9-CM;

(c) an evaluation whether the individual's medical condition, as described in the physician's order, would require frequent nursing evaluation or judgment;

(d) an evaluation of the personal care services, home health aide services and skilled nursing tasks that the individual requires;

(e) an evaluation, made in conjunction with the social assessment and physician's order, whether the individual or, if applicable, the individual's designated representative, is self-directing and willing and able to instruct, supervise and direct the consumer directed personal assistant in performing any needed skilled nursing tasks, home health aide services and personal care services;

(f) an evaluation whether the individual's need for assistance can be totally or partially met through the use of adaptive or specialized medical equipment or supplies including, but not limited to, commodes, urinals, adult diapers, walkers or wheelchairs and whether the individual would be appropriate for personal emergency response services provided in accordance with section 505.33 of this Part;

(g) for continuous consumer directed personal assistance and live-in 24-hour consumer directed personal assistance cases, documentation of the following:

(1) whether the physician's order has documented a medical condition that causes the consumer to need frequent assistance during a calendar day with toileting, walking, transferring, turning and positioning, feeding, home health aide services, or skilled nursing tasks;

(2) the specific functions or tasks with which the consumer requires frequent assistance during a calendar day;

(3) the frequency at which the consumer requires assistance with these functions or tasks during a calendar day;

(4) whether the consumer requires similar assistance with these functions or tasks during the consumer's waking and sleeping hours and, if not, why not; and

(5) whether, were live-in 24-hour consumer directed personal assistance to be authorized, the consumer directed personal assistant would be likely to obtain, on a regular basis, five hours daily of uninterrupted sleep during the aide's eight hour period of sleep.

(h) development of a plan of care in collaboration with the individual or, if applicable, the individual's designated representative, that identifies the personal care services, home health aide services and skilled nursing tasks with which the individual needs assistance in the home and a recommendation for the number of hours or frequency of such assistance; and

(i) recommendations for authorization of services.

(4) Guidelines for completion of social and nursing assessment. The social services district must conduct the social assessment and conduct or obtain a nursing assessment with reasonable promptness, generally not to exceed

30 calendar days after receiving a completed and signed physician's order, except in unusual circumstances including, but not limited to, when the individual or, if applicable, the individual's designated representative has failed to participate as needed in the assessment process.

(5) Local professional director review.

(i) If there is a disagreement among the physician's order, the nursing assessment and the social assessment, or a question regarding the amount or duration of services to be authorized, or if the case involves continuous consumer directed personal assistance or live-in 24-hour consumer directed personal assistance, an independent medical review of the case must be completed by the local professional director, a physician designated by the local professional director or a physician under contract with the social services district.

(ii) The local professional director or designee must review the physician's order and the nursing and social assessments. When determining whether continuous consumer directed personal assistance or live-in 24-hour consumer directed personal assistance should be authorized, the local professional director or designee must consider the information in the social and nursing

assessments. The local professional director or designee may consult with the consumer's treating physician and may conduct an additional assessment of the consumer in the home.

(iii) The local professional director or designee is responsible for the final determination regarding the amount and duration of services to be authorized. The final determination must be made with reasonable promptness, generally not to exceed seven business days after receipt of the physician's order and the completed social and nursing assessments, except in unusual circumstances including, but not limited to, the need to resolve any outstanding questions regarding the amount or duration of services to be authorized.]

(3) Social services district or MMCO responsibilities.

(i) Before developing a plan of care or authorizing services, a social services district or MMCO shall review the individual's most recent independent assessment and practitioner order, and may directly evaluate the individual, to determine the following:

(a) whether services can be provided according to the individual's plan of care, whether such services are

medically necessary and whether the social services district or MMCO reasonably expects that such services can maintain the individual's health and safety in his or her home, as determined in accordance with the regulations of the Department of Health;

(b) the individual's ability and willingness to fulfill the consumer's responsibilities specified in subdivision (h) of this section and, if applicable, the ability and willingness of the individual's designated representative to assume these responsibilities;

(c) the individual's preferences and social and cultural considerations for the receipt of care;

(d) whether the functional needs, living and working arrangements of an individual who receives services solely for monitoring the individual's medical condition and well-being can be monitored appropriately and more cost-effectively by personal emergency response services provided in accordance with section 505.33 of this Part;

(e) whether the individual can be served appropriately and more cost-effectively by other long-term care services and

supports, including, but not limited to the assisted living program or the enriched housing program;

(f) whether services can be provided appropriately and more cost-effectively in cooperation with an adult day health or social adult day care program;

(g) whether the individual's needs can be met through the use of telehealth services that can be demonstrated and documented to reduce the amount of services needed and where such services are readily available and can be reliably accessed;

(h) whether the individual can be served appropriately and more cost-effectively by using adaptive or specialized medical equipment or supplies covered by the medical assistance program including, but not limited to, bedside commodes, urinals, walkers, wheelchairs and insulin pens;

(i) whether the consumer's needs can be met through the provision of formal services provided or funded by an entity, agency or program other than the medical assistance program; and

(j) whether the consumer's needs can be met through the voluntary assistance available from informal caregivers including, but not limited to, the consumer's family, friends or other responsible adult, and whether such assistance is available.

(ii) The social services district or MMCO must first determine whether the individual, because of the individuals' medical condition, would be otherwise eligible for personal care services, including continuous personal care services or live-in 24-hour personal care services. For individuals who would be otherwise eligible for personal care services, the district must then determine whether, and the extent to which, the individual can be served through the provision of services described in subparagraphs (i)(d) through (i)(j) of this paragraph.

(a) If a social services district or MMCO determines that an individual can be served appropriately and more cost-effectively through the provision of services described in subparagraphs (i)(d) through (i)(g) of this paragraph, and the social services district or MMCO determines that such services are available in the district to the individual, the

social services district or MMCO must consider the use of such services as well the individuals identified preferences and social and cultural considerations described in subparagraph (i)(c) of this paragraph in developing the individual's plan of care.

(b) If a social services district or MMCO determines that other formal services are available or the individual's needs can be met using available adaptive or specialized medical equipment or supplies or voluntary assistance from informal caregivers, as described in subparagraphs (i)(h) through (i)(j) of this paragraph, the social services district or MMCO must include these in the individual's plan of care. To ensure availability of voluntary informal supports, the social services district or MMCO must confirm the caregiver's willingness to meet the identified needs in the plan of care for which they will provide assistance.

(iii) For cases involving live-in 24-hour consumer directed personal assistance, the social services district or MMCO shall evaluate whether the consumer's home has sleeping accommodations for a consumer directed personal assistant. When the consumer's home has no sleeping accommodations for a

consumer directed personal assistant, continuous consumer directed personal assistance must be authorized for the consumer; however, should the consumer's circumstances change and sleeping accommodations for a consumer directed personal assistant become available in the consumer's home, the district or MMCO must promptly review the case. If a reduction of the consumer's continuous consumer directed personal assistance to live-in 24-hour consumer directed personal assistance is appropriate, the district must send the consumer a timely and adequate notice of the proposed reduction.

(iv) For cases involving continuous consumer directed personal assistance and live-in 24-hour consumer directed personal assistance cases, the social services district or MMCO shall assess and document in the plan of care the following:

(a) whether the practitioner order indicated a medical condition that causes the consumer to need frequent assistance during a calendar day with toileting, walking, transferring, turning and positioning, feeding, home health aide services, or skilled nursing tasks;

(b) the specific functions or tasks with which the consumer requires frequent assistance during a calendar day;

(c) the frequency at which the consumer requires assistance with these functions or tasks during a calendar day;

(d) whether the consumer requires similar assistance with these functions or tasks during the consumer's waking and sleeping hours and, if not, why not; and

(e) whether, were live-in 24-hour consumer directed personal assistance to be authorized, the consumer directed personal assistant would be likely to obtain, on a regular basis, five hours daily of uninterrupted sleep during the aide's eight hour period of sleep.

(v) The social services district or MMCO is responsible for developing a plan of care in collaboration with the consumer or, if applicable, the consumer's designated representative that reflects the assessments and practitioner order described in this subdivision. In the plan of care, the social services district or MMCO must identify:

(a) the personal care services, home health aide services and skilled nursing functions or tasks with which the consumer needs assistance;

(b) the amount, frequency and duration of services to be authorized to meet these needs;

(c) how needs are met, if not met through the authorization of services; and

(d) any other descriptions and documentation provided for in this section.

(vi) Upon the development of a plan of care, the social services district or MMCO shall refer high needs cases described in paragraph (5) of this subdivision to the independent review panel; provided, however, that an MMCO should not refer a case unless and until the individual is enrolled or scheduled for enrollment in the MMCO. When a case is referred to the independent review panel:

(a) the social services district or MMCO shall provide the individual's plan of care and any clinical records or other

documentation used to develop the plan of care, such as records from treating providers and the results of any review or evaluation performed pursuant to this paragraph to the panel;

(b) the social services district or MMCO shall cooperate with the panel as appropriate to ensure an expedient review of each high needs case; and

(c) the social services district or MMCO shall consider the panel's recommendation in finalizing the plan of care and authorization. However, The social services district or MMCO is not required to adopt the recommendation, either in full or in part, and remains responsible for determining the amount and type of services medically necessary.

(4) Coordinating the independent assessment, practitioner order and LDSS or MMCO responsibilities.

(i) The social services district or MMCO must coordinate with the entity or entities providing independent assessment and practitioner services to minimize disruption to the consumer and in-home visits.

(ii) The social services district or MMCO must inform the entity or entities providing independent assessment and practitioner services when a new assessment or practitioner order is needed pursuant to subdivision (f)(1)(ii) and subdivision (f)(2) of this section, in accordance with department guidance, using forms as may be required by the department.

(a) When the social services district or MMCO receives an initial or new request to participate in the consumer directed personal assistance program, it shall refer the individual to the entity providing independent assessment services and provide assistance to the individual in making contact in accordance with department guidance; provided however that the social services district or MMCO may not pressure or induce the consumer to request an assessment unwillingly.

(b) If needed, the MMCO shall also refer the individual to the social services district to determine the individual's eligibility for medical assistance, including community-based long term care services.

(iii) The entity or entities providing independent assessment or practitioner services may request that the social services district or MMCO confirm or update a consumer's record in the assessment database designated by the Department. The social service district or MMCO shall respond within one business day and confirm or update the relevant record within three business days after receipt of request.

(iv) Resolving mistakes and clinical disagreements in the assessment process.

(a) If the social services district or MMCO identifies a material mistake in the independent assessment that can be confirmed by the submission of evidence, the social services district or MMCO shall advise the independent assessor. A mistake is an error of fact or observation that occurred when the assessment was performed that is not subject to the independent assessor's clinical judgment. A mistake is material when it would affect the amount, type, or duration of services authorized. When identifying the mistake, the social services district or MMCO must provide evidence of the mistake to the independent assessor. The independent assessor shall promptly issue a corrected

assessment or schedule a new assessment in accordance with clause (c) of this subparagraph as appropriate.

(b) After reviewing the independent assessment, practitioner order and the result of any social service district or MMCO assessment or evaluation, if the social services district or MMCO has a material disagreement regarding the outcome of the independent assessment, the social services district or MMCO may advise the independent assessor. A disagreement occurs when the social services district or MMCO disputes a finding or conclusion in the independent assessment that is subject to the independent assessor's clinical judgment. A disagreement is material when it would affect the amount, type, or duration of services authorized. When submitting a disagreement to the independent assessor, the social services district or MMCO must provide the clinical rationale that forms the basis for the disagreement.

(c) Upon submission of a material disagreement, an independent assessor shall schedule and complete a new assessment within 10 days from the date it receives notice from the social services district or MMCO. This shall not

pend or otherwise affect the timeframes within which the social services district or MMCO is required to make a determination, provide notice, or authorize services.

(v) Sanctions for failure to cooperate and abuse of the resolution process.

(a) The Department of Health may impose monetary penalties pursuant to Public Health Law section 12 for failure to coordinate with the entity or entities providing independent assessment and practitioner services in accordance with the provisions of clauses (a) through (c) of this subparagraph or engaging in abusive behavior that affects the coordination of the assessment process. In determining whether to impose a monetary penalty and the amount imposed, the Department shall consider, where applicable, the following:

(1) The frequency and numerosity of violations, both in absolute terms and relative to other MMCOs;

(2) The responsiveness of the MMCO to requests for coordination;

(3) The history of coordination between the MMCO and the entity or entities;

(4) The good faith demonstrated by the MMCO in attempting to coordinate;

(5) Whether the MMCO provides a justification for the violation and whether it has merit, as determined by the Department;

(6) Whether the violation resulted or could have resulted in injury or other harm to the consumer;
and

(7) Other relevant facts or circumstances.

(b) The Department of Health may revoke, or impose other restrictions on a social services district's or MMCO's privilege to request reassessments on the basis of a material disagreement where the Department determines that the social services district has abused this privilege, including

the use of the mistake process for issues subject to clinical judgment or improperly pressuring consumers to request a new assessment. In determining whether a social services district or MMCO has abused this privilege, the Department shall consider, where applicable, the following:

(1) The frequency and numerosity of disagreements, mistakes, and reassessment requests submitted to the independent assessor, both in absolute terms and relative to other social services districts and MMCOs;

(2) Whether the clinical rationale provided for the disagreement has merit, as determined by the Department;

(3) Whether the disagreement, mistake, and reassessment requests are made as a matter of course, instead of upon review of the clinical record;

(4) The outcome of the reassessment as compared to the assessment it replaces; and

(5) Other facts or circumstances that tend to provide evidence for or against abuse.

(c) Nothing in this section shall be construed to limit the authority of the Department or other agencies to seek other remedies, sanctions or penalties, including other monetary penalties.

(5) Independent medical review of high needs cases.

An independent medical review of a proposed plan of care shall be obtained before a social services district or MMCO may authorize more than 12 hours of personal care services or consumer directed personal assistance, separately or in combination, per day on average (“high needs cases”). The review shall result in a recommendation made to the social services district or MMCO, as described in this paragraph.

(i) The independent medical review must be performed by an independent panel of medical professionals, or other clinicians, employed by or under contract with an entity designated by the Department of Health (the “independent review panel”).

(ii) The case review shall be coordinated by a physician (the “lead physician”) who shall be selected from the independent review panel. The lead physician may not be the same person who performed the initial medical examination or signed the individual’s practitioner order.

(iii) The lead physician must review the independent assessment, practitioner order, any other assessment or review conducted by the social services district or MMCO, including any plan of care created.

(iv) The lead physician may evaluate the individual, or review an evaluation performed by another medical professional on the independent review panel. The medical professional may not have performed the initial medical examination or signed the individual’s practitioner order.

(v) The lead physician and panel members may consult with or interview other members of the independent review panel, the ordering practitioner, the individual’s treating or primary care physician, and other individuals that the lead physician deems important and who are available to assist with the panel’s review.

(vi) The lead physician and panel members may request such additional information or documentation, including medical records, case notes, and any other material the lead physician deems important to assist the panel's review and recommendation.

(vi) After review, the independent review panel shall produce a report, signed by the lead physician, providing a recommendation on the reasonableness and appropriateness of the proposed plan of care to maintain the individual's health and safety in his or her own home, in accordance with the standards and scope of services set forth in this section. The report may suggest modifications to the plan of care, including the level, frequency, and duration of services and whether additional, alternative, or fewer services would facilitate the provision of medically necessary care. The report may not, however, recommend a specific amount or change in amount of services.

Subdivision (e) of section 505.28 is amended to read as follows:

(e) Authorization process.

(1)

(i) An individual's eligibility for medical assistance and services, including the individual's financial eligibility and eligibility for the consumer directed program and services thereunder as provided for in this section, shall be established prior to authorization for services. The entity designated by the Department of Health to provide independent assessment services shall be responsible for determining whether individuals meet minimum needs requirements for services.

(ii) The authorization must be completed by the social services district or MMCO prior to the initiation of services. In the case of the social services district, the authorization of services shall be prepared by staff of the social services district and such responsibility may not be delegated to another person or entity.

(iii) The authorization and reauthorization of services, including the level, amount, frequency and duration of services, by the social services district or MMCO must be based on and reflect the outcome of the assessment process outlined in subdivision (d) of this section except as otherwise provided in subdivision (f) of this section.

[i] (iv) When the social services district or MMCO determines pursuant to the assessment process that the individual is eligible to participate in the consumer directed personal assistance program, the district or MMCO must authorize consumer directed personal assistance according to the consumer's plan of care. The district or MMCO must not authorize consumer directed personal assistance unless it reasonably expects that such assistance can maintain the individual's health and safety in the home or other setting in which consumer directed personal assistance may be provided.

(v) The social service district or MMCO shall not authorize services provided through more than one fiscal intermediary per consumer.

[ii] (vi) Consumer directed personal assistance, including continuous consumer directed personal assistance and live-in 24-hour consumer directed personal assistance, shall not be authorized to the extent that the [consumer's need for assistance can be met by the following:] social services district or MMCO determines that any of the services or supports identified in clauses (h) through (i) of subdivision (d)(3)(j) of this section are available and appropriate to meet the consumer's needs and are cost-effective if provided instead of consumer directed personal assistance.

[(a) voluntary assistance available from informal caregivers including, but not limited to, the consumer's family, friends or other responsible adult;

(b) formal services provided or funded by an entity, agency or program other than the medical assistance program; or

(c) adaptive or specialized equipment or supplies including, but not limited to, bedside commodes, urinals, walkers, and wheelchairs, when such equipment or supplies can be provided safely and cost-effectively.

(iii) The social services district must first determine whether the consumer, because of the consumer's medical condition, would be otherwise eligible for consumer directed personal assistance, including continuous consumer directed personal assistance or live-in 24-hour consumer directed personal assistance. For consumers who would be otherwise eligible for consumer directed personal assistance, the district must then determine whether, and the extent to which, the consumer's need for assistance can be met by voluntary assistance from informal caregivers, by formal services, or by adaptive or specialized equipment or supplies, as specified in clauses (ii)(a) through (c) of this paragraph.]

(2) The district or MMCO may authorize only the hours or frequency of services that the consumer actually requires to maintain his or her health and safety in the home. [The authorization must be completed prior to the initiation of services.]

(3) The duration of the authorization period must be based upon the consumer's needs as reflected in the required assessments and plan of care. In determining the authorization period, the social services district must consider the consumer's prognosis and potential for recovery and the expected duration and availability of any informal supports or alternative services identified in the plan of care.

(4) The social services district or MMCO may not authorize more than 12 hours of personal care services per day on average prior to considering the recommendation of the independent review panel in accordance with procedures outlined in paragraphs (3) and (5) of subdivision (d), unless such authorization is ordered pursuant to a fair hearing decision or by another court of competent jurisdiction. Pending review of the independent review panel's recommendation and if necessary to comply with federal or state timeliness requirements, including immediate needs cases, the social services district or MMCO may authorize and implement services based on a temporary plan of care which provides for more than 12 hours of personal care services per day on average.

(5) No authorization may exceed [six] 12 months from the date of the most recent independent assessment or practitioner order, whichever is earlier. [unless the social services district has requested, and the department has approved, authorization periods of up to 12 months. The department may approve district requests for authorization periods of up to 12 months provided that professional staff of the social services district or its designee conduct a home visit with the consumer and, if applicable, the consumer's designated representative every six months and evaluate whether:

(i) the plan of care continues to meet the consumer's needs;

(ii) the consumer or, if applicable, the consumer's designated representative continues to be willing and able to perform the consumer's responsibilities specified in subdivision (g) of this section; and

(iii) the fiscal intermediary is fulfilling its responsibilities specified in subdivision (i) of this section.]

[~~(5)~~ (6) The social services district or MMCO must provide the consumer with a copy of the plan of care that specifies the consumer directed personal assistance that the district or MMCO has authorized the

consumer to receive and the number of hours per day or week of such assistance.

[(6)] (7) Nothing in this subdivision precludes the provision of the consumer directed personal assistance program in combination with other services when a combination of services can appropriately and adequately meet the consumer's needs; provided, however, that no duplication of Medicaid-funded services would result.

Subdivision (f) of section 505.28 is amended to read as follows:

(f) Reassessment and reauthorization processes.

(1) Prior to the end of the authorization period, the social services district or MMCO must [reassess] determine the consumer's continued eligibility for the consumer directed personal assistance program in accordance with the assessment process set forth in subdivision (d) of this section, except as otherwise provided for in this subdivision.

(i) The [reassessment] social services district or MMCO must evaluate whether the consumer or, if applicable, the consumer's designated representative satisfactorily fulfilled the consumer's responsibilities under the consumer directed personal assistance program. The social services district or MMCO must consider

whether the consumer or, if applicable, the consumer's designated representative has failed to satisfactorily fulfill the consumer's responsibilities when determining whether the consumer should be reauthorized for the consumer directed personal assistance program.

(ii) Neither an independent assessment nor a practitioner order shall be required to reauthorize or continue an authorization of services, except:

(a) prior to or in conjunction with a discharge from an institutional or in-patient setting, provided that this provision shall not be construed to prohibit a safe discharge from occurring;

(b) as provided in paragraph (2) of this subdivision;

(c) that an individual in receipt of services may request a new independent assessment; and

(d) an individual in receipt of services must receive an independent assessment and practitioner order at least annually to maintain authorization.

[(ii)] (iii) When the social services district or MMCO determines, pursuant to the reassessment process, that the consumer is eligible to continue to participate in the consumer directed personal assistance program, the district or MMCO must reauthorize consumer directed personal assistance in accordance with the authorization process specified in subdivision (e) of this section. When the district or MMCO determines that the consumer is no longer eligible to continue to participate in the consumer directed personal assistance program, the district or MMCO must send the consumer, and such consumer's designated representative, if any, a timely and adequate notice under Part 358 and Subpart 360-10 of this Title of the district's or MMCO's intent to discontinue consumer directed personal assistance on forms required by the department.

(2) The social services district or MMCO must reassess the consumer when an unexpected change in the consumer's social circumstances, mental status or medical condition occurs during the authorization [or reauthorization] period that would affect the type, amount or frequency of consumer directed personal assistance provided during such period. The district or MMCO is responsible for making necessary changes in the

authorization or reauthorization on a timely basis in accordance with the following procedures:

(i) when the change in the consumer's service needs results solely from an unexpected change in the consumer's social circumstances including, but not limited to, loss or withdrawal of informal supports or a designated representative, the social services district or MMCO must review the [social] independent assessment, document the consumer's changed social circumstances and make changes in the authorization or reauthorization as needed. A new [physician's] practitioner order and [nursing] independent assessment are not required; or

(ii) when the change in the consumer's service needs results from a change in the consumer's mental status or medical condition, including loss of the consumer's ability to make judgments or to instruct, supervise or direct the consumer directed personal assistant, the social services district or MMCO must obtain a new [physician's] independent assessment and practitioner order[, social assessment and nursing assessment].

(3) When there is any change in the individual's service needs, a social services district or MMCO shall consider such changes and document

them in the plan of care, and shall consider and make any necessary changes to the authorization.

A new subdivision (g) is added to section 505.28 to read as follows:

(g) Timeframes for the assessment and authorization of services

(1) The independent assessment and practitioner order processes shall be completed at least annually and in sufficient time such that social services districts and MMCOs may have an opportunity when needed to comply with all applicable federal and state timeframes for notice and determination of services, including but not limited to immediate needs.

(2) A social services district must make a determination and provide notice with reasonable promptness, not to exceed seven business days after receipt of both the independent assessment and practitioner order, or the independent review panel recommendation if applicable, except in unusual circumstances including, but not limited to, the need to resolve any outstanding questions regarding the amount or duration of services to be authorized, or as provided in subdivision (1) of this section.

(3) An MMCO must make a determination and provide notice to current enrollees within the timeframes provided in the contract between the

Department of Health and the MMCO, or as otherwise required by Federal or state statute or regulation.

Subdivision (g) of section 505.28 is redesignated as subdivision (h) and amended to read as follows:

[(g)] (h) Consumer and designated representative responsibilities.

(1) A consumer or, if applicable, the consumer's designated representative has the following responsibilities under the consumer directed personal assistance program:

[(1)] (i) managing the plan of care including recruiting and hiring a sufficient number of individuals who meet the definition of consumer directed personal assistant, as set forth in subdivision (b) of this section, to provide authorized services that are included on the consumer's plan of care; training, supervising and scheduling each assistant; terminating the assistant's employment; and assuring that each consumer directed personal assistant competently and safely performs the personal care services, home health aide services and skilled nursing tasks that are included on the consumer's plan of care;

[(2)] (ii) timely notifying the social services district or MMCO of any changes in the consumer's medical condition or social circumstances including, but not limited to, any hospitalization of the consumer or change in the consumer's address, telephone number or employment;

[(3)] (iii) timely notifying the fiscal intermediary of any changes in the employment status of each consumer directed personal assistant;

[(4)] (iv) attesting to the accuracy of each consumer directed personal assistant's time sheets;

[(5)] (v) transmitting the consumer directed personal assistant's time sheets to the fiscal intermediary according to its procedures;

[(6)] (vi) timely distributing each consumer directed personal assistant's paycheck, if needed;

[(7)] (vii) arranging and scheduling substitute coverage when a consumer directed personal assistant is temporarily unavailable for any reason; and

[(8)] (viii) entering into a department approved memorandum of understanding with the fiscal intermediary and with the social services district or MMCO that describes the parties' responsibilities under the consumer directed personal assistance program.

(2) the designated representative must make themselves available to ensure that the consumer responsibilities are carried out without delay. In addition, designated representatives for nonself-directing consumers must make themselves available and be present for any scheduled assessment or visit by the independent assessor, examining medical professional, social services district staff or MMCO staff.

(3) A consumer, or if applicable the consumer's designated representative, may not work with more than one fiscal intermediary at a time. Where more than one fiscal intermediary is serving the same consumer at a given time, the consumer is required to select a single fiscal intermediary to work with in accordance with guidance provided by the Department.

Subdivision (h) of section 505.28 is redesignated as subdivision (i) and amended to read as follows:

[(h)] (i) Social services district and MMCO responsibilities. Social services districts or MMCOs have the following responsibilities with respect to the consumer directed personal assistance program:

[(1) annually notifying recipients of personal care services, long term home health care program services, AIDS home care program services or private duty nursing services of the availability of the consumer directed personal assistance program and affording them the opportunity to apply for the program;]

[(2)] (1) complying with the assessment, authorization, reassessment and reauthorization procedures specified in subdivisions (d) through (f) of this section;

[(3)] (2) receiving and promptly reviewing, the fiscal intermediary's notification to the district or MMCO pursuant to subparagraph [(i)(1)(v)] (j)(1)(v) of this section of any circumstances that may affect the consumer's or, if applicable, the consumer's designated representative's ability to fulfill the consumer's responsibilities under the program and making changes in the consumer's authorization or reauthorization as needed;

[(4)] (3) discontinuing, after timely and adequate notice in accordance with Part 358 and Subpart 360-10 of this Title, the consumer's participation in the consumer directed personal assistance program and making referrals to other services that the consumer may require when the district or MMCO determines that the consumer or, if applicable, the consumer's designated representative is no longer able to fulfill the consumer's responsibilities under the program or no longer desires to continue in the program;

[(5)] (4) notifying consumers[, on forms required by the department,] of the district's or MMCO's decision to authorize, reauthorize, increase, reduce, discontinue or deny services under the consumer directed personal assistance program[, and of the consumer's right to request a fair hearing pursuant to Part 358 of this Title the social services district's decision to deny, reduce or discontinue consumer directed personal assistance must be stated in the notice]. The Department of Health may require the use of forms it develops or approves when providing such notice;

(i) Social services districts or MMCOs that deny, reduce or discontinue services based on medical necessity must identify and document in the notice and in the consumer's plan of care the factors that demonstrate such services are not medically necessary or are no longer medically necessary. Any such denial or reduction

in services must clearly indicate a clinical rationale that shows review of the consumer's specific clinical data and medical condition; the basis on which the consumer's needs do not meet specific benefit coverage criteria, if applicable; and be sufficient to enable judgment for possible appeal.

[(i)] (ii) Appropriate reasons and notice language to be used when denying consumer directed personal assistance include but are not limited to the following:

(a) the consumer's health and safety cannot be reasonably assured with the provision of consumer directed personal assistance. The notice must identify the reason or reasons that the consumer's health and safety cannot be reasonably assured with the provision of such assistance;

* * *

(e) the consumer's needs may be met, in whole or part, by a technological development, which the notice must identify, that renders certain services unnecessary or less time-consuming, including the use of telehealth services or assistive devices that can be demonstrated and documented

to reduce the amount of services that are medically necessary;

(f) [the consumer resides in a facility or participates in another program or receives other services, which the notice must identify, which are responsible for the provision of needed assistance; and

(g)] the consumer or, if applicable, the consumer's designated representative is unable or unwilling to fulfill the consumer's responsibilities under the program[.];

[(h)] (g) the consumer can be more appropriately and cost-effectively served through other Medicaid programs or services, which the notice must identify; and

[(i)] (h) the consumer's need(s) can be met either without services or with the current level of services by fully utilizing any available informal supports, or other supports and services, that are documented in the plan of care and identified in the notice.

[(ii)] (iii) Appropriate reasons and notice language to be used when reducing or discontinuing consumer directed personal assistance include but are not limited to the following:

(a) the consumer's medical or mental condition or economic or social circumstances have changed and the district determines that the consumer directed personal assistance provided under the last authorization or reauthorization are no longer appropriate or can be provided in fewer hours. [For proposed discontinuances, this] This includes but is not limited to cases in which: the consumer's health and safety can no longer be reasonably assured with the provision of consumer directed personal assistance; the consumer's medical condition is no longer stable; [or] the consumer is no longer self-directing and has no designated representative to assume those responsibilities; or voluntary informal supports that are acceptable to the client have become available to meet some or all of the client's needs. The notice must identify the specific change in the consumer's medical or mental condition or economic or social circumstances from the last authorization or reauthorization and state why the

assistance should be reduced or discontinued as a result of the change;

* * *

(d) the consumer's needs may be met, in whole or part, by a technological development, which the notice must identify, that renders certain assistance unnecessary or less time-consuming, including the use of readily available telehealth services or assistive devices that are accessible to the individual and that can be demonstrated and documented to reduce the amount of services that are medically necessary;

(e) the consumer resides in a facility or participates in another program or receives other services, which the notice must identify, which are responsible for the provision of needed assistance; [and]

(f) the consumer or, if applicable, the consumer's designated representative is no longer able or willing to fulfill the consumer's responsibilities under the program or the consumer no longer desires to continue in the program[.];

(g) the consumer can be more appropriately and cost-effectively served through other Medicaid programs or services, which the notice must identify;

(h) an assessment of the consumer's needs demonstrates that the immediately preceding social services district or MMCO authorized more services than are medically necessary following any applicable continuity of care period required by the Department of Health.

[(6)] (5) maintaining current case records on each consumer and making such records available, upon request, to the department or the department's designee;

[(7)] entering into contracts with each fiscal intermediary for the provision of fiscal intermediary responsibilities specified in subdivision (i) of this section and monitoring the fiscal intermediary's performance under the contract, including reviewing the fiscal intermediary's administrative and personnel policies and recordkeeping relating to the provision of consumer directed personal assistance program services and evaluating the quality of services that the fiscal intermediary provides; and

(8)] (6) entering into a [department] Department of Health approved memorandum of understanding with the consumer that describes the parties' responsibilities under the consumer directed personal assistance program.

Subdivision (i) of section 505.28 is redesignated as subdivision (j) and amended to read as follows:

[(i)] (j) Fiscal intermediary responsibilities.

(1) Fiscal intermediaries have the following responsibilities with respect to the consumer directed personal assistance program:

* * *

(iv) maintaining records for each consumer including copies of the social services district's or MMCOs authorization or reauthorization;

(v) monitoring the consumer's or, if applicable, the consumer's designated representative's continuing ability to fulfill the consumer's responsibilities under the program and promptly notifying the social services district or MMCOs of any

circumstance that may affect the consumer's or, if applicable, the consumer's designated representative's ability to fulfill such responsibilities;

* * *

(vii) entering into a contract with the [social services district] Department of Health and entering into administrative agreements with MMCOs for the provision of fiscal intermediary services; and

* * *

Subdivision (j) of section 505.28 is redesignated as subdivision (k), subdivisions (k) and (l) of section 505.28 are REPEALED and a new subdivision (l) is added to read as follows:

(l) Immediate need.

The process for determining whether an individual may obtain consumer directed personal assistance on an immediate need basis shall be the same as such process used for the determination of whether an individual may obtain personal care services on an immediate need basis, as described in subdivision (b)(6) and (7) of section 505.14 of this part, provided that in determining eligibility for services the

social services district and MMCO shall consider the eligibility and authorization requirements in this section.

A new subdivision (m) is added to section 505.28 to read as follows:

(m) Prior to October 1, 2022, and notwithstanding provisions of this section to the contrary, where the Department of Health has not contracted with or designated an entity or entities to provide independent assessment and practitioner services, or where there is limited access to timely assessments and medical exams in accordance with this subdivision, as determined by and the Department of Health, then, in accordance with written direction from the Department of Health, assessments may be performed by the social services district or MMCO in accordance with the provisions of this section in effect as of January 1, 2021. The Department may limit such directive to a particular geographic region or regions based on the need for timely assessment and medical exams and may require that social service districts and MMCOs first attempt assessment and authorization pursuant to the provisions of this section currently in effect. Notwithstanding the forgoing, upon becoming effective, the provisions of paragraph (4) of subdivision (i) shall remain in effect, and may not be pended pursuant to this paragraph.

REGULATORY IMPACT STATEMENT

Statutory Authority:

Social Services Law (“SSL”) § 363-a and Public Health Law (“PHL”) §§ 201(1)(v) and 206(1)(f) provide that the Department of Health (“Department”) is the single state agency responsible for supervising the administration of the State’s medical assistance (“Medicaid”) program and for adopting such regulations, not inconsistent with law, as may be necessary to implement and enforce the standards of the Medicaid program. SSL § 365-a(2) authorizes Medicaid coverage for specified medical care, services and supplies, together with such medical care, services and supplies as authorized in the regulations of the Department. Under SSL § 365-a(2)(e) and § 365-f, respectively, the Medicaid program includes personal care services (“PCS”) and consumer directed personal assistance services (“CDPAS”). Finally, under SSL § 364-j and PHL Article 44, the Department may contract with Medicaid Managed Care Organizations (“MMCOs”) to provide Medicaid services to enrollees, which the Department has done for PCS and CDPAS.

Legislative Objectives:

SSL § 365-a(2) authorizes Medicaid coverage for specified medical care, services and supplies, together with such medical care, services and supplies as authorized in the regulations of the Department. Under SSL § 365-a(2)(e) and § 365-f, respectively, the Medicaid program includes PCS and CDPAS. Based upon recommendations of the Medicaid Redesign Team II (“MRT II”), the 2020-21 budget (Chapter 56 of the Laws of 2020, Part MM) amended SSL § 365-a, § 365-f and PHL Article 44 to improve the

provision of Medicaid funded PCS and CDPAS. As amended, these provisions link the eligibility criteria for CDPAP and PCS to the performance of activities of daily living (“ADLs”) so services are authorized for those that need them the most, require the establishment of an independent assessor to take over the performance of assessments and reassessments required for determining individuals’ needs for such services, require an independent practitioner’s order to access PCS, ensure that such services are furnished to the extent medically necessary to maintain a member’s health and safety in his or her home, require that the standards established for the provision, management or assessment of such services meet that standards set forth in *Olmstead v. LC by Zimring*, 527 US 581 (1999), and provide relief for members who need access to such services by modifying the frequency in which assessments and authorizations for services are conducted.

Needs and Benefits:

The Department has promulgated regulations governing PCS at 18 NYCRR § 505.14 and CDPAS at 18 NYCRR § 505.28. Amendments to these regulations are essential to implementing requirements of the State Fiscal Year 2020-21 Enacted Budget (Chapter 56 of the Laws of 2020, Part MM) and MRT II long term care reform proposals, which include instituting new eligibility requirements, establishing an independent assessor, reducing the frequency of assessment from semi-annual to annual, centralizing practitioner orders and establishing an independent clinical review for high need cases to ensure that recipients receive the care they need to remain safely in the community. These amendments will help ensure Medicaid beneficiaries receive PCS and CDPAS that

are required to appropriately meet their clinical needs as determined by the updated assessment and authorization process and documented in the plan of care.

By centralizing many of the functions of the assessment process and making them independent of the LDSS or MMCO responsible for authorizing services, the changes will bring efficiencies and consistency to the approval of PCS and CDPAS, and promote clinically appropriate outcomes. In particular, the review of high needs cases by an independent panel of medical professionals will help ensure that plans of care are reasonable and appropriate to safely service individuals in the community. Accordingly, this proposal will better facilitate access to PCS and CDPAS for people with disabilities who with the provision of such services are capable of safely remaining in the community in accordance with the standards set forth in *Olmstead v. L.C.*, 527 U.S. 581 (1999).

The proposed regulations will further align the PCS and CDPAS regulations, which share many of the same or similar requirements, but historically have diverged in their drafting. This alignment will help to clarify the requirements for these benefits, which should lead to greater consistency in the assessment, authorization, and provision of services.

Proposed amendments to modernize the language are also included. Over the last decade, with the transition to mandatory enrollment into MMCOs, the majority of medical assistance recipients now receive most of their benefits through MMCOs, including community based long term care services. Although regulations in 18 NYCRR Part 505 are currently cast as requirements on LDSSs, contracts between the Department and MMCOs provide that services covered by MMCOs must comply with the terms of the New York State Medicaid Plan, established pursuant to SSL § 363-a, the

Department's regulations, and other applicable requirements. This contractual integration has meant that medical assistance service requirements, as outlined in 18 NYCRR Part 505 and throughout the Department's regulations, generally apply to MMCOs even when MMCOs are not specifically referenced in the regulation.

By introducing references to MMCOs directly in 18 NYCRR §§ 505.14 and 505.28, the Department is dictating more directly how these regulatory provisions apply to MMCOs, and where there may be differences in application of the rules between LDSSs and MMCOs. However, nothing in these amendments necessitates a change in the nature of MMCOs' contractual obligations under the model contracts. Requirements for the provision of covered services in 18 NYCRR Part 505 and throughout the Department's regulations still apply to MMCOs through the model contracts, even when they are not specifically referenced.

The Department is also proposing to clarify and reinforce documentation requirements, to ensure that authorizations, and any proposed changes to such authorizations, are well documented and can be supported in the care plan and medical record. The Department also proposes to clarify and add appropriate reasons and notice language to be used when a LDSS or MMCO denies, reduces or discontinues PCS or CDPAS. Together, these proposed regulations should assist LDSSs and MMCOs, as well as Administrative Law Judges, evaluate the appropriateness of PCS and CDPAS authorizations and changes thereto. This proposal should increase consistency of authorizations as well as the outcomes of an appeal or fair hearing process.

COSTS

Costs to Private Regulated Parties:

These regulatory amendments governing PCS at 18 NYCRR § 505.14 and CDPAS at 18 NYCRR § 505.28 do not impose any additional costs to regulated parties. In fact, in centralizing the assessment and practitioners' order process of authorizing PCS/CDPAS and reducing the assessment period to once a year absent any change in condition, the costs to private regulated parties is reduced. Furthermore, LDSS and MMCOs are already required to maintain and update plans of care and MMCOs are required to have an internal appeals process.

Costs to Local Government:

The proposed regulations require that social services districts refer Medicaid eligible individuals who may be eligible for long term care services and supports, including PCS and CDPAS, to the State's contracted independent assessor to complete the long term care assessment tool and, if necessary, obtain a practitioner's order for PCS or CDPAS. This relieves the LDSS from having to conduct initial and periodic reassessments and obtain a practitioners' order from the potential recipients' treating physician or other clinician. The proposed regulations do not impose any costs on local government.

Costs to the Department of Health:

The proposed regulations may result in minimal additional costs to the Department, which will be managed within existing resources.

Costs to Other State Agencies:

The proposed regulations will not result in any costs to other state agencies.

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 regulatory amendments include clarifying changes to existing forms, but regulated parties are familiar with and already use such forms. The amendments do not impose any new forms, paperwork or reporting requirements.

Duplication:

These regulatory amendments do not duplicate existing State or Federal requirements.

Alternatives:

Based on public comments received, many alternatives have been considered by the Department. A few of those follow, and the complete list of alternatives considered is included in the Assessment of Public Comment, which is located on the Department's website.

The Department reviewed and rejected several proposed alternatives that would fail to implement the requirements of Chapter 56 of the Laws of 2020, Part MM, which establishes new minimum needs criteria for PCS and CDPAP and requires assessments to be performed by an independent assessor using an evidenced-based, validated assessment tool. Such suggestions included removal or modification to the minimum needs criteria and the maintenance of the assessment role with LDSS or MMCOs.

Many commenters suggested in various ways that the care planning process should reflect or include consumer preference. The Department agreed with these comments generally, and revised the LDSS and MMCO responsibilities to provide that consumer preferences must continue to be considered when developing the plan of care. However, the Department declined to duplicate the provisions of the federal regulations, as doing so is unnecessary because such requirements apply in their own right and because doing so may lead to unnecessary conflict and additional State administrative burden if and when federal requirements change.

The Department also considered and adopted suggestions to incorporate more specific procedures for coordination between the IA and the LDSS or MMCOs. The comments received on this point were many and varied. Some commenters were concerned that too much influence from LDSS or MMCOs would compromise the IA process, while others were concerned that a lack of feedback from the LDSS or MMCO could result in plans of care being developed that do not reflect the individual's needs. The Department believes that there was validity to both of these concerns, and strived to balance them in the revised regulations. The addition of set procedures for coordination

and sanction provisions for abuse of these procedures reflects the best balance for addressing these concerns in the Department's view.

Another area of focus from commenters were the timeframes for the revised assessments and care planning processes. Comments were made about each step of the process, from the IA to the IRP. Some suggested that each step have its own specific timeframe, while others suggested that particular steps be waived in order to make timely service determinations. The Department has instead opted to require that the IA and Practitioner Order occur within sufficient time to allow the LDSS or MMCO to meet federal or State decision and notice timeframes. In addition, the Department has provided an exception to the prohibition on authorizing services for high needs cases prior to the IRP review and recommendation, to allow LDSS or MMCOs to meet federal and State timeframes, such as those for immediate need by providing a provisional authorization pending completion of the IRP report and final review by the LDSS or MMCO.

Federal Standards:

The proposed regulations do not duplicate or conflict with any Federal regulations.

Compliance Schedule:

The regulations will become effective on the 60th day following publication of a Notice of Adoption in the New York State Register.

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REGULATORY FLEXIBILITY ANALYSIS
FOR SMALL BUSINESSES AND LOCAL GOVERNMENTS

Effect of Rule:

The proposed regulations change the assessment and authorization process for personal care services and consumer directed personal assistance services through the State's medical assistance plan. Specifically, the frequency of assessments will change from semi-annually to annually; all assessments to determine individuals' needs for assistance with personal care and environmental and nutritional support functions will be conducted by an independent assessor; orders for services will now be obtained based on a medical examination performed by a qualified independent medical professional; and high needs cases will be subject to an additional independent medical review to assure that proposed plans of care are reasonable and appropriate to maintain the individual safely in his or her home.

These changes move many of the responsibilities from the Local Departments of Social Services (LDSS) or Medicaid Managed Care Organizations (MMCOs) and to an independent entity or entities. While these changes provide administrative relief to LDSS and MMCOs, they may impact Certified Home Health Agencies (CHHAs) and Licensed Home Care Services Agencies (LHCSAs) under contract with LDSSs and MMCOs to perform assessments that will no longer be a LDSS or MMCO responsibility. There are approximately 115 CHHAs and 1,400 LHCSAs certified or licensed to operate in New York State, a subset of which are contracted with MMCOs and LDSSs to perform these assessments.

Any changes that occur to the overall scope and number of contracts between LDSSs or MMCOs and CHHAs or LHCSAs are primarily attributable to the State Fiscal Year 2020-21 Enacted Budget, requiring the establishment of an independent assessor to determine individuals functional needs for PCS and CDPAS. The proposed regulations do not propose any further restrictions on the ability of CHHAs or LHCSAs to perform any of these functions, and include no restriction on the ability of the independent assessor to subcontract with CHHAs or LHCSAs.

Compliance Requirements:

These proposed regulations do not impose any new compliance requirements on LHCSA, CHHA, MMCO or LDSS.

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 a party subject to enforcement when developing a regulation or explain in the Regulatory Flexibility Analysis why one is not included. This revised proposed rulemaking includes the addition of new sanctions or penalties. To ensure that regulated entities are given time to come into compliance with new processes without threat of sanction or penalty, the Department will stay the imposition of penalties for non-compliance that occurs during the six month period immediately following the effective date of these amended regulations. As a general matter, the Department’s internal procedures for imposition of penalties and sanctions under Public Health Law section 12 and other authorities will

apply as applicable. Under these procedures, initial incidence of non-compliance would result in a “statement of deficiency” to be followed by a corrective action plan submitted by the party, which the Department must approve.

The corrective action plan procedures provide a reasonable cure period. If the party fails to provide or follow a corrective action plan, remains non-compliant, or later commits the same or similar violations, the Department may proceed with sanctions or penalties. However, the Department also reserves the right to impose sanctions or penalties on initial incidence of non-compliance when warranted, including but not limited to when a pattern of non-compliance is discovered without any good faith explanation or where sanctions or penalties may limit harm to or preserve the health of individuals.

Professional Services:

No new or additional professional services are required in order to comply with the proposed regulations.

Compliance Costs:

No capital costs would be imposed as a result of the proposed regulations. Nor would there be annual costs of compliance.

Economic and Technological Feasibility:

There are no additional economic costs or technology requirements associated with the proposed regulations.

Minimizing Adverse Impact:

As indicated above, the requirement for an independent assessor is mandated by statute, specifically Sections 2 and 11 of Part MM of chapter 56 of the Laws of 2020. The law prohibits CHHAs and LHCSAs from being selected as contractors to provide independent assessor services. The proposed regulations do not propose any further restrictions on the ability of CHHAs or LHCSAs to perform any of these functions, and include no restriction on the ability of the independent assessor to subcontract with CHHAs or LHCSAs.

Additionally, the Department has preserved certain LDSS and MMCO responsibilities in the proposed regulations at 505.14(b)(2)(iii) and 505.28(d)(3), such as the requirement to determine frequency of need for 24-hour cases, which are currently a source of contract work for CHHAs and LHCSAs. As such, under the proposed rule, CHHAs and LHCSAs could continue to perform this work. The Department has also elected to not prohibit the independent assessor from making arrangements with CHHAs and LHCSAs to perform assessment services. Together, these potentially mitigate much the impact that may occur from the centralization of the functional assessment responsibilities.

The proposed regulations should not have an adverse economic impact on social services districts.

Small Business and Local Government Participation:

These proposed regulations arise from a change in State law pursuant to Chapter 56 of the Laws of 2020, Part MM. The initiatives were recommended by the MRT II following a series of public meetings where stakeholders had the opportunity to comment and collaborate on ideas to address the efficacy of these services. In addition, the MRT II was comprised of representatives of LDSS and MMCOs, among others.

Comments were received from nine LDSS and a number of entities representing assessment agencies or individual CHHAs and LHCSAs. These comments ranged across many topics and across the full scope of these regulations. Based on these comments, the Department made various revisions to the rule package. Many of these revisions were to clarify provisions to reduce confusion among regulated or affected parties. Other amendments addressed more substantive issues, such as the nature of how LDSS will coordinate with the IA, for which the Department provided additional elaboration. The full scope of the changes made in response to comments is addressed in the Assessment of Public Comment, which is located on the Department's website.

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

A Rural Area Flexibility Analysis for these amendments is not being submitted because the amendments will not impose any adverse impact or significant reporting, record keeping or other compliance requirements on public or private entities in rural areas. There are no professional services, capital, or other compliance costs imposed on public or private entities in rural areas as a result of the proposed amendments.

JOB IMPACT STATEMENT

Sections 2 and 11 of Part MM of Chapter 56 of the Laws of 2020 require the Department to establish or procure the services of an independent assessor to take over, from LDSSs and MMCOs, the performance of assessments and reassessments required for determining individuals needs for personal care services. Under the proposed regulations, nurse assessors will continue to evaluate individuals to determine their functional need for long term care across the State.

Currently LDSS and MMCOs hire nurses directly or contract with LHCSAs and CHHAs to complete these assessments. Under the new structure, as a result of the statute, an independent assessor will now hire nurses or contract for nursing services to complete the assessments. However, these changes are not expected to affect the overall volume or distribution of individuals needing nurses to perform functional assessments for community based long term care services. Additionally, LDSSs and MMCOs remain responsible for certain evaluation requirements and developing the plan of care, roles which are currently by LDSS and MMCO employed or contracted nurse assessors. As such, the Department does not expect there to be a negative impact, regionally or overall, on nursing jobs in the State, and has reason to believe there may be a slight increase to the number of nursing jobs.

SUMMARY OF ASSESSMENT OF PUBLIC COMMENT

A Notice of Proposed Rule Making was initially published in the State Register on July 15, 2020. A Notice of Revised Proposed Rule Making was later published in the *State Register* on January 27, 2021. During the public comment period for the Notice of Revised Proposed Rule Making, the Department of Health (the “Department”) received comments from consumers of and individual advocates for personal care services (“PCS”) or consumer directed personal assistance services (“CDPAS”); the Consumer Directed Personal Assistance Association of New York State; Center for Elder Law & Justice; Downstate New York ADAPT; Gurwin Certified Home Health Agency; the Home Care Association of New York State; LeadingAge New York; the Legal Aid Society; New York City Human Resources Administration; the New York Health Plan Association; New York Legal Assistance Group; New York State Association of Health Care Providers; New York State Bar Association; The Nurse Practitioner Association New York State; Onondaga County; Paraprofessional Healthcare Institute, Inc.; and Vesta Healthcare.

All comments received were reviewed and evaluated.

No substantive changes have been made to the regulations in light of the comments received. Other clarifications and technical, non-substantive changes have been made:

Section 505.14(a)(5)(iii) was amended to clarify that the language should not be construed as prohibiting the authorization of services for times between intermittent

unpredictable tasks, such as may be needed and practical to ensure assistance with night-time toileting.

Sections 505.14(b)(2)(iv)(d)(1) and 505.28(d)(4)(iv)(a) are amended to clarify that LDSS and MMCOs are only required to notify the independent assessor when mistakes identified in the assessment are material such that they would affect the amount, type, or duration of services authorized. Amendments to these sections also clarify that the new assessment performed shall be performed in the same manner as new assessments performed as a result of a material disagreement.

Sections 505.14(b)(2)(iv)(d)(3) and 505.28(d)(4)(iv)(c) are amended to clarify that the requirements to schedule a new assessment as a result of a disagreement is only invoked when the disagreement is material.

Sections 505.14(b)(4)(viii)(c)(1) and 505.28(i)(4)(i) are amended to more clearly align with existing provisions at 505.14(b)(4)(viii)(a). The changes clarify that the requirement to identify and document factors that demonstrate when services are not medical necessity applies to denials and is not limited to reductions or discontinuances.

Sections 505.14(b)(4)(viii)(c)(2)(i), (c)(2)(vii), (c)(3)(i), (c)(3)(v) and 505.28(i)(4)(ii)(a) are amended to align and clarify existing provisions in light of Department guidance. *See Guidelines for the Provision of Personal Care Services in Medicaid Managed Care, May 31, 2013, at p. 7 (denial appropriate if “health and safety cannot be reasonably assured”)*,

available at

https://www.health.ny.gov/health_care/medicaid/redesign/docs/final_personal_care_guidelines.pdf.

Sections 505.14(b)(4)(viii)(c)(3)(i) and 505.28(i)(4)(iii)(a) are amended to align the reduction reason language related to the identification of informal supports to clarify that such supports must be acceptable to the client, in line with existing requirements under 505.14(b)(2)(i)(b)(3)(v) and 505.28(d)(1)(ii)(c)(5).

Sections 505.14(b)(8) and 505.28(m) are amended to align with each other and to clarify that other subdivisions of such sections could be read as they were as of 1/1/21, such as those needed to reimburse LDSS for case management.

Section 505.28(i)(2) is amended to clarify that the language applies to MMCOs as well as LDSS.

ASSESSMENT OF PUBLIC COMMENT

Comment: Similar to the prior Assessment of Public Comments for this proposed rulemaking, commenters expressed opposition to these regulatory changes based on their belief that these changes will not save money and instead increase costs to the Medicaid program. A majority of the commenters compared the per diem cost of skilled nursing facility (SNF) to cost of hiring a caretaker through Consumer Directed Personal Assistant Program (CDPAP). Commenters also expressed belief that the Consumer Directed Personal Assistance Services (CDPAS) program is a more cost-effective way to aid individuals with ADL needs, than nursing home placement, as nursing home placements have generally poorer outcome and enrich operators.

Response: The Department appreciates this perspective by these commenters and will monitor whether these changes help contribute to the financial sustainability of the Medicaid program. The Department notes that the fiscal impact from these proposals is not based on comparing the costs of CDPAS or Personal Care Service (PCS) with SNF care, but through achieving a more streamlined and standardized process for assessment and authorization of services and improving the independence of the assessment and medical order processes from the entity authorizing services, as well as decreasing the frequency of routine assessments, which commenters have largely supported.

Comment: One Local Department of Social Services (LDSS) commenter raised concerns about issuing temporary authorizations before the independent review panel (IRP) has completed its review in cases of immediate need.

Response: For purposes of clarity, the Department has only permitted temporary authorizations in cases that require IRP review, but such IRP review would not be possible for cases involving immediate need or expedited assessments. Regardless of whether the case requires IRP review, the independent assessor (IA) must complete its assessment and practitioner order process in sufficient time to allow the LDSS to meet state and federal timeframes, such as immediate needs. Accordingly, the LDSS should have the assessment in a reasonable time to ensure the completion of care planning activities. Where the care planning activities shows that an IRP review is needed for authorization, then the LDSS may issue a temporary authorization subject to further IRP review.

As stated in the prior Assessment of Public Comment, the statutory authorization in Section 2-a of the Part MM of Chapter 56 of the Laws of 2020 does not exclude immediate needs cases from the IA process. Accordingly, the Department believes that this version of the proposed regulations appropriately ensure that the needs of these consumers are addressed timely and best implements the intent of the statute. The Department has made no further changes to the regulations.

Comment: Health plan commenters requested a better understanding of the consequences should the IA not complete the Community Health Assessment (CHA) timely to meet service authorization timeframes.

Response: No changes to the regulations are necessary in response to this comment, but the Department will issue guidance and instructions to Medicaid Managed Care Organizations (MMCOs) and LDSS with regard to the channels necessary to ensure timely completion of the CHAs and practitioner orders that will inform the plan of care and service authorization process. Additionally, the Department will hold the IA accountable through its contact with the IA to ensure that timely completion occurs, given the importance of CHA and practitioner order completion on the development of the plan of care.

Comment: Many commenters once again indicated that the regulations did not include precise timeframes for completion of steps between referral of an individual for an assessment and completion of CHA by the IA, to issuance of a service authorization by LDSS or MMCO. These steps include: conducting the assessment, completion of the CHA, issuance of a medical order by the independent practitioner panel (IPP), issuance of an authorization of services by the LDSS or MMCO following development of a plan of care (POC), and making a recommendation by the IRP for high needs cases, if applicable. Without timeframes as to when each step of the above-process is required to be completed, commenters expressed concern that completion of the CHA by the IA, issuance of medical orders (also referred as “practitioner orders” or “POs”) by the IPP, and reviews conducted by the IRP would create barriers to consumer access of timely service authorizations and may result in “undue” and “harmful” delay, especially for those consumers with disabilities, who require expedited assessments or who have “immediate needs” under 18 NYCRR § 505.14(b)(6)(iv). Other comments expressed

concerns that failure to include specific timeframes may prevent MMCOs or LDSS from adhering to determination or authorization deadlines set forth in State regulations (e.g., “reasonable promptness”) or federal regulations, including 42 C.F.R. Part 438.

Response: The Department appreciates these comments, but has not further revised the regulations after it already added clarifying edits in the last rulemaking to provide that the IA and IPP processes shall be completed in sufficient time for LDSS and MMCOs to have an opportunity to comply with all federal and State timeframes for notice and determination and reviews, including but not limited to immediate needs. The Department reiterates that in implementing this regulatory requirement, it will impose and contractually enforce timeframes on the IA in connection with these processes but has declined to impose more specific timeframes in the regulation. This approach will provide the IA with the same flexibility that already exists in the processes for MMCOs and LDSS and preserves its ability to adjust or further solidify these timeframes through guidance and contractual requirements, as it works to accommodate the needs of LDSS, MMCOs, and consumers through this significant statutory change in the assessment process. However, the Department disagrees with the specific suggestion to assign timeframes to each of these steps in the regulations, even for Immediate Needs cases. While doing so would add specificity, it would do so at the cost of flexibility necessary to ensure adequate and thorough independent assessments, especially given the launch of this new assessment approach. Being overly specific regarding timeframes for any one element of the assessment process may limit parties’ ability to properly assess and authorize services in accordance with the consumer’s needs or other requirements,

potentially leading to worse outcomes for some consumers due to unnecessarily rushed assessments or unsupported concerns regarding compliance.

Comment: One commenter expressed concern that an automatic referral to the IRP for a review will cause delays in the authorization and delivery of services, especially without stated timeframes, which could increase utilization of institutional care in violation of *Olmstead v. LC by Zimring*, 527 U.S. 581 (1999) (hereinafter, “*Olmstead*”) and the Americans with Disabilities Act of 1990 (ADA).

Response: The Department appreciates the commenter’s request for additional clarity and certainty with respect to timeframes that apply to the assessment and authorization of PCS, especially for high hours cases that require IRP review. While the Department disagrees that the added IRP review itself would cause delays that lead to institutionalization, the Department once again points to several amendments to the proposed rule made in the prior round of rulemaking that address timing requirements and the timely provision of services. The revised regulations permit a “temporary” service authorization to be granted prior to receipt of the IRP report, which will ensure compliance by LDSS and MMCOs with federally and State-mandated timeframes, including immediate needs, and avoid the delays in authorization that the commenter sites that commenter’s claim might cause an increase in institutional care. Accordingly, the Department believes the concerns expressed by the commenters have been sufficiently addressed and no further changes to the regulations have been made.

Comment: One commenter requested a resource attestation process during the 30-month lookback period prior to initiation of community-based long-term services eligibility.

Response: The Department appreciates these comments but notes that the 30-month lookback period is not currently being implemented part of these regulations, but is undergoing federal review and approval. The Department will address these comments in connection with implementation of this initiative following federal approval.

Comment: Some commenters once again raised concern that Activities of Daily Living (ADL) definitions are missing key functions, such as toilet use, incontinence, medication administration, and transferring outside of toileting, or should be included in regulations, rather than the CHA tool.

Response: Although these ADLs or tasks are not specifically enumerated in the proposed regulations, they continue to be captured by the elements in the CHA tool and will be used to determine whether the consumer satisfies minimum needs criteria, as now referenced in the regulatory definition of ADL. For example, if an individual requires assistance transferring to the toilet, that individual also likely needs assistance transferring from a bed to a chair. Medication administration is not an ADL, but rather a Level II task, which someone with sufficient ADL needs would have covered in their POC if that question on the CHA so indicates. Accordingly, the Department has not revised the regulations in this response to this comment.

Comment: Commenters registered concerns about the proposed provision intended to codify existing Department policy regarding supervision and cueing, also sometimes referred to as “safety monitoring.” Several commenters also requested clarification on whether, and how, standalone supervising and cueing should relate to the ADL definitions and associated minimum needs determinations. In connection with these requests, these commenters requested that the regulations explicitly clarify that supervising and cueing are covered when expressly connected to a task and recommended that the language “separately from or in addition to the performance of nutritional and environmental support functions or personal care functions” be deleted and amended, to clarify that supervision and cueing must be authorized when needed for the assistance with the performance of ADLs or Instrumental Activities of Daily Living (IADLs) to ensure the safe completion of those tasks.

Response: The Department appreciates the concerns of commenters and agrees that the provision should align with Departmental policy regarding the requirement that supervision and cueing may be provided only when assisting with a task related to an identified personal care function. The Department believes the proposed regulatory language achieves this objective and made technical changes in the prior rulemaking in connection with these regulations. The Department is also making a further technical change to clarify that it should not be construed as prohibiting the authorization of services for times between intermittent unpredictable tasks, such as may be needed and practical to ensure assistance with night-time toileting. The Department also notes that the proposed provision would extend the use of supervision and cueing to assistance with

nutritional and environmental support functions, which had not previously been specified in Departmental guidance.

Comment: Commenters requested that DOH seek a new statutory authorization that utilizes a different standard than minimum needs requirements set forth in statute.

Response: The Department appreciates the suggestions of commenters regarding appropriate needs based medical necessity criteria for the provision of services. However, the requirements are specified in current State law, as enacted in Sections 2-a and 3 of Part MM of Chapter 56 of the Laws of 2020, which is authorizing this rulemaking. The Department has determined no changes to the regulation are needed.

Comment: Several commenters cited *Olmstead* and the ADA in that the eligibility standards for the provision, management or assessment of personal care services must consider whether an individual is capable of safely remaining in the community based on identifying actual risks, with their probability of occurrence, and considering whether reasonable modifications of policies, practices or procedures will mitigate or eliminate the risk. Similarly, comments expressed concern that institutionalization will increase for those with significant needs that fail to meet the new minimum requirements to be eligible for PCS or CDPAP.

Response: The Department appreciates these concerns of commenters regarding appropriate needs based on medical necessity criteria for the provision of services. As

specified in several of these comments, the criteria are specified in State law, as enacted in Sections 2-a, 2-b and 3 of Part MM of Chapter 56 of the Laws of 2020, and the Department has opted to align the regulations with the statutory medical necessity provisions. In so doing, the Department has also incorporated the requirement that any standards for the provision, management or assessment of services meet the standards set forth in *Olmstead* into the regulations, and the Department is establishing implementation standards accordingly to the IA, MMCOs, and LDSS. As a result, the Department has determined that no further changes to the regulation are needed.

Comment: One commenter suggested that by using the ADLs specified on the CHA tool gives the IA an improper level of discretion over which ADLs will be used to determine whether someone meets the applicable minimum needs criteria.

Response: The Department disagrees that using the ADLs specified on the CHA tool would provide any improper discretion to the assessor. This tool has been independently validated by experts in the field as providing the necessary information about consumer's condition and needs, and the ADLs it assesses are the same regardless of the assessor.

The Department has determined that no changes to the regulation are needed.

Comment: Commenters renewed previous comments that that implementing minimum needs standards that differentiate by diagnosis (e.g., Alzheimer's and dementia) violates federal discrimination requirements under the ADA, and that the Department has authority to override the language of the authorizing statute as a reasonable interpretation.

These commenters cite *City of New York v. New York State Department of Health*, 164 Misc. 2d 247, 623 N.Y.S.2d 491 (Sup. Ct. 1995) (holding “Department of Health’s (DOH) reasonable and rationale interpretation of N.Y. Pub. Health Law § 1104(1) deserved deference” and recognizing the agency’s complete autonomy under § 204 of the State Administrative Procedure Act to issue declaratory rulings based upon assumed or hypothetical facts, citing *Matter of Howard v Wyman*, 28 N.Y.2d 434, 438 (1971)(“It is well settled that the construction given statutes and regulations by the agency responsible for their administration, if not irrational or unreasonable, should be upheld”)).

Response: The Department appreciates these concerns of commenters regarding appropriate needs based on medical necessity criteria for the provision of services. As specified in several of these comments, the criteria are specified in State law, as enacted in Sections 2-a, 2-b and 3 of Part MM of Chapter 56 of the Laws of 2020, and the Department has aligned the regulations with the statutory medical necessity provisions. In so doing, the Department has also previously incorporated the requirement that any standards for the provision, management or assessment of services meet the standards set forth in *Olmstead* into the regulations, and the Department is establishing implementation standards accordingly to the IA, MMCOs, and LDSS. As a result, the Department has determined that no further changes to the regulation are needed.

Comment: Some comments raised concern that ADL are being deferred to the CHA or definitions are missing key functions, such as toilet use, incontinence, medication administration, and transferring outside of toileting.

Response: Although these ADLs or tasks are not specifically enumerated in the proposed regulations, they continue to be captured by the elements in the CHA tool and will be used to determine whether the consumer satisfies minimum needs criteria, as now referenced in the regulatory definition of ADL. For example, if an individual requires assistance transferring to the toilet, that individual also likely needs assistance transferring from a bed to a chair. Medication administration is not an ADL, but rather a Level II task, which someone with sufficient ADL needs would have covered in their POC if that question on the CHA so indicates. Accordingly, the Department determined that no changes to the regulations were necessary in response to this comment.

Comment: Several commenters requested clarification on whether, and how, standalone supervising and cueing should relate the ADL definitions and associated minimum needs determinations. In connection with these requests, commenters requested that the regulations explicitly clarify that supervising and cueing are covered when expressly connected to a task and recommended that the language “separately from or in addition to the performance of nutritional and environmental support functions or personal care functions” be further amended, to clarify that supervision and cueing must be authorized when needed for the assistance with the performance of ADLs or IADLs to ensure the safe completion of those tasks.

Response: The Department continues to appreciate the concerns of commenters and made technical corrections to the regulations already. The Department also notes that the proposed provision would extend the use of supervision and cueing to assistance with nutritional and environmental support functions, which had not previously been specified in Departmental guidance. Additionally, in response to these comments, the Department believes a further technical correction is necessary to mitigate any unintended and unfounded concerns that this regulatory provision could be used to prohibit authorization of services for times between intermittent and unpredictable tasks (e.g., authorization for time spent by the aide between assistance provided with toileting at night). Accordingly, the Department has proposed a technical and non-substantive clarifying change in this regard.

Comment: Commenters request clarification on who determines whether an individual meets the minimum needs criteria.

Response: As described in the regulations, this determination belongs with the IA.

Comment: Commenters expressed concerns that the IA may not appropriately account for the individual's needs when applying the new minimum needs criteria (e.g., ability to toilet).

Response: The Department reminds commenters that if an individual believes that the IA was incorrect in its determination of minimum needs, then it may appeal that determination through the fair hearing process. Moreover, the individual, MMCO, or LDSS has the right to request a new CHA be completed if they believe that the prior CHA was clinically inaccurate based on the dispute resolution process.

Comment: Commenters suggested an alternative standard for the minimum needs criteria, such that an individual would be assessed as requiring limited or greater assistance with more than one ADL in all instances, and then requiring extensive assistance with either an additional ADL or IADL.

Response: The Department appreciates these concerns of commenters regarding appropriate needs based on medical necessity criteria for the provision of services. As specified in several of these comments, the criteria are specified in State law, as enacted in Sections 2-a, 2-b and 3 of Part MM of Chapter 56 of the Laws of 2020, and the Department determined it is necessary to align the regulations with the statutory medical necessity provisions. In so doing, the Department has also incorporated the requirement that any standards for the provision, management or assessment of services meet the standards set forth in *Olmstead* into the regulations, and the Department is establishing implementation standards accordingly to the IA, MMCO, and LDSS. As a result, the Department has determined that no further changes to the regulation are needed.

Comment: Commenters asked whether the new IA and minimum needs requirements apply to 1915(c) waiver services.

Response: As described in the prior Assessment of Public Comments, the IA and minimum needs requirements do not apply to individuals with traumatic brain injury and people with intellectual and developmental disabilities may receive home and community based services, as well as other Medicaid benefits, under one or more 1915(c) waivers approved by CMS. The eligibility for these waiver services are not impacted by this rulemaking.

Comment: Commenters requested clarifying technical changes to reflect that MMCOs are subject to Fiscal Intermediary (FI) notification requirements.

Response: The Department made these technical clarifying revisions to the regulations.

Comment: Commenters expressed appreciation and support for requiring that consumers have only one FI.

Response: The Department appreciates this support.

Comment: Commenters asked the Department to reconsider the elimination to notice members of CDPAP.

Response: The Department notes that this change was enacted in the State Fiscal Year (SFY) 2020-21 budget and the Department does not have regulatory discretion to modify this statutory change through regulations.

Comment: MMCOs, LDSS, and other commenters requested confirmation that they cannot enroll or disenroll CDPAP consumers if the MMCO does not believe it is safe for the consumer to remain in the community without backup caregiver support. Similarly, LDSS wanted specific clarity as to their service authorization determinations when backup CDPAP personal assistants cannot be located.

Response: The Department does not believe changes to the regulation are required, as this determination is already part of the care planning process that are the responsibility of MMCOs and LDSS and, other than high hours cases, this determination remains within the purview of entities conducting these service authorizations. However, the Department notes failure to incorporate adequate backup into a plan of care as part of CDPAS is not a basis for plan disenrollment.

Comment: A few commenters expressed concerns regarding how the Department will implement the new IA, new minimum needs criteria, and related processes, given their substantial impact on CDPAP and Licensed Home Care Services Agency (LHCSA) services.

Response: The Department appreciates these concerns and, while no changes to the regulations are required, it notes that it has and will continue to work closely with plans, providers and LDSS to ensure a smooth transition.

Comment: Commenters re-raised due process concerns based on existing case law and federal requirements, including *Mayer v. Wing*, 922 F. Supp. 902 (SDNY 1992) and the special terms and conditions within New York State's 1115 Demonstration Waiver authorizing MMCO and Managed Long-Term Care (MLTC) coverage of these services. The commenters raised concerns regarding the reasons for which MMCOs and LDSS may consider reductions in the need for PCS, CDPAP, or other community based long-term care services (CBLTCS) when issuing an authorization from an individual's plan of care, including whether the LDSS or MMCO must specifically state the reasons for the reduction, whether an MMCO or LDSS may reduce services without identifying an underlying change in circumstances, and whether a plan or LDSS may reduce CBLTCS when the member transitions from one plan to another or between a plan and an LDSS.

Response: The Department appreciates these comments and their recitation of the Department's legal obligations to safeguard the due process rights of individuals when accessing PCS and CDPAS services from LDSS or MMCOs. In response to the comments, the Department notes that the rationales furnished by MMCOs and LDSS for denials, reductions, and discontinuances described in the regulations do not represent the total universe of appropriate reasons for LDSS or MMCOs to take such actions, and that LDSSs or MMCOs may validly take actions for other reasons, provided that notice is

appropriately provided. The purpose of the rationale list is to guide LDSS and MMCOs towards rationales that may be supported, which may at the same time discourage them from taking “unlisted” actions that may not be supportable. This approach is both consumer friendly, in that it clarifies a variety of appropriate valid rationales for taking action, which can help distinguish when a provided rationale is not valid. Further, this approach encourages the efficient use of resources by apprising LDSS and MMCOs in advance when an action could be considered as justifiable. Accordingly, the proposed new reasons in the regulations should not be viewed as newly valid reasons for reductions in service, rather they are newly listed examples and clarifications of historically valid reasons.

Comment: One commenter asked whether it was Department policy to allow combination cases when someone is eligible for both CDPAP and PCS.

Response: While the Department appreciates this comment, it is not relevant to the proposed rulemaking. Specifically, 505.28(e) Authorization process states: “(6) Nothing in this subdivision precludes the provision of the consumer directed personal assistance program in combination with other services when a combination of services can appropriately and adequately meet the consumer’s needs; provided, however, that no duplication of Medicaid-funded services would result.”

Comment: Commenters expressed strong opposition to changes to the regulations that permitted reductions in services when a prior assessment authorized more services than

are medically necessary or after a continuity of care period. In expressing this opposition, commenters once again cited constitutional and statutory due process rights of Medicaid recipients that have been repeatedly affirmed by the federal courts, including in *Mayer v. Wing*, *Strouchler v. Shah*, and *Caballero v. Senior Health Partners*, indicating that the impact of the holding from *Mayer v. Wing* is that there needed to be documentation of changes in the consumer's condition to avoid finding that such reductions were arbitrary. Considering these cases, commenters were concerned that the proposed regulation would establish a "catch-all" reason that would allow reductions in services without a documented change in the consumer's condition or specific documentation of an alleged identified mistake in a prior assessment.

Response: The Department responds to these important comments with the same response as it did in the prior Assessment of Public Comments. We strongly disagree that the regulatory changes implicate a consumer's due process rights, contravene legal requirements or preexisting MLTC Policies. These regulations support longstanding legal principles that an MMCO or LDSS may make supportable and appropriate changes in service authorization when such authorizations are based on medical necessity, use the assessed needs of the individual, and consistently apply clinical standards. Finding that an MMCO or LDSS cannot make changes when these circumstances are present would fundamentally undermine the ability of the Medicaid program to appropriately provide services in accordance with individuals' medical needs. This requirement has been explained and reinforced through guidance. Furthermore, with these regulations, the Department has ensured that there are the following sufficient controls and oversight over

the process to both discourage and to ameliorate the types of arbitrary action about which commenters express legal concerns:

- The newly added example rationale for reductions based on medical necessity refers only to specific circumstances where there has been a continuity of care period prescribed in law or policy and that period has ended. The Department added the new example to clarify that it is appropriate for an MMCO to be able to use its own medical necessity criteria after a continuity of care period has concluded, and that a change in condition is not required for the MMCO to amend the authorization, which may sometimes result in a reduction in care. As in any care planning process, the criteria must be fairly and consistently applied to all enrollees of the MMCO, and the service authorization must be sufficient to ensure that enrollee's health and safety can be maintained in the community.
- The Department has included new language clarifying the standard to which LDSS and MMCOs must achieve when denying, reducing, or discontinuing care based on medical necessity. This standard requires the LDSS and MMCO to specify the clinical rationale on which the determination is based both in the notice to the consumer and in their plan of care. In direct response to concerns regarding arbitrary authorization changes, LDSS and MMCOs must do more than simply record the clinical rationale, they must do so in a way that demonstrates that they have reviewed the particular consumer's clinical assessment and medical condition so that a reviewer of the case can understand how the clinical rationale is being applied in this case. The Department will endeavor to provide further

guidance to MMCOs and LDSS on these notices through MLTC Policies or other communications.

- Pursuant to Section 4403-f(11-b) of the Public Health Law (PHL) and MLTC Policy 17.02, the State requires that in cases of a MLTC plan merger, acquisition, or other similar arrangement, the MLTC plan that is a party to the arrangement and that received the enrollees, who would be subject to a continuity of care period as described in the example rationale, must report to the Department information about the enrollees' service authorization both before and after the transfer and continuity period. This reporting gives the Department direct and systematic insight into how MLTC plans are applying their medical necessity criteria to the authorization of services, including PCS and CDPAS. This requirement not only discourages plans that might be tempted to arbitrarily reduce care, but also enables the Department promptly to detect issues and take ameliorative actions if necessary. Further, the Department is required to summarize these reports and make them available to the public. This reporting provides an additional layer of transparency for the public to ensure that plans are authorizing services in accordance with appropriate medical necessity criteria. The Department also clarifies that it is adding the new example to clarify that it is appropriate for an MMCO to be able to use its own medical necessity criteria after a continuity of care period has concluded, and that a change in condition is not required for the MMCO to amend the authorization, which may sometimes result in a reduction in care. As always, the criteria must be fairly and consistently

applied to all enrollees of the MMCO, and the authorization must be sufficient to ensure that enrollee's health and safety can be maintained in the community.

Comment: One commenter objected to the definition of 24-hour live-in consumer directed personal assistance used in the regulations, as it potentially contravenes New York Court of Appeals case law in *Andryeyeva v. New York Health Care, Inc.*, and *Moreno et al., v. Future Care Health Services, Inc.*

Response: The definitions for continuous and 24-hour live-in PCS/CDPAS and the potential impact of recent case law is not within the scope of this rulemaking, which is intended to implement statutory changes to the medical necessity criteria for PCS and CDPAS and an IA process. We appreciate the concern and are taking the comments under advisement to determine whether additional regulatory action is needed.

Comment: Several commenters expressed concern that the regulations violate federal requirements under Community First Care Option (CFCO), 42 U.S.C. § 1915(k) and associated regulations, and jeopardize the enhanced Federal Medical Assistance Percentage (FMAP) furnished by CMS for these services by not including all tasks of daily living, including IADLs and health related tasks. Specifically, commenters believe that implementing eligibility standards that differentiate by diagnosis (e.g., Alzheimer's and dementia) violates federal discrimination requirements under the ADA.

Response: The Department has not revised the regulations, as having medical necessity criteria for services that accounts for diagnosis, where there is a nexus between the diagnosis and the varying need for services, is both rational and appropriate, and does not violate federal or State law. The Department is not proposing new eligibility categories for PCS or CDPAS services based on diagnosis nor has the amount, duration, or scope of the PCS/CDPAS benefit been changed.

Comment: One commenter expressed concern that the regulations violate federal requirements under CFCO, 42 U.S.C. § 1915(k) and associated regulations, and jeopardize the enhanced FMAP furnished by CMS for these services by not including all tasks of daily living, including IADLs and health related tasks. Specifically, commenters believe that implementing eligibility standards that differentiate by diagnosis (e.g., Alzheimer's and dementia) violates federal discrimination requirements under the ADA.

Response: The Department has not revised the regulations, as having medical necessity criteria for services that accounts for diagnosis, where there is a nexus between the diagnosis and the varying need for services, is both rational and appropriate, and does not violate federal or State law. In any case, these criteria are clearly established in State law, as enacted in Sections 2-a and 3 of Part MM of Chapter 56 of the Laws of 2020. Accordingly, the Department lacks discretion to amend this statutory enactment through regulation.

Comment: Commenters expressed concern that the regulations, including the process by which MMCOs or LDSS engage in care planning and the IRP determines whether the individual may remain safely in the community, do not comply with federal CFCO rules, *Olmstead* requirements, or the Medicaid Act requirements because the regulations do not specify the specific steps by which the MMCO, LDSS, or IRP will analyze health and safety and determine whether the individual will remain safely in the community.

Response: The Department appreciates this concern by commenters but notes at the outset the IRP is not making a determination of whether the individual may remain safely in the community. Rather, the role of the IRP is to make a recommendation that must be considered by the MMCO or LDSS in issuing its own service authorization. In effect, the IRP acts as a second opinion to help inform the proposed plans of care so that high needs cases receive an appropriately greater amount of review before the authorization is finalized. However, the care planning function and the resulting service authorization by the LDSS and MMCO are not changing by virtue of these regulations. Second, the IRP's review, much like the MMCO's and LDSS's, is based on the CHA tool that the Department currently requires LDSSs and MMCOs to use, and that will continue to be used to determine service needs. This tool has been independently validated by experts in the field as providing the necessary information about consumer's condition and needs. Accordingly, the CHA tool enables professionals, such as the independent providers on the IRP, or the LDSS's, or MMCO's professional staff or contractors, to make informed decisions or recommendations about services that might meet the consumer's needs, including whether an individual may need services and supports available in the

community and other settings. The Department has determined that no changes to the regulation are needed.

Comment: Similarly, several commenters cited *Olmstead* and the ADA in that the eligibility standards for the provision, management or assessment of personal care services must consider whether an individual is capable of safely remaining in the community based on identifying actual risks, with their probability of occurrence, and considering whether reasonable modifications of policies, practices or procedures will mitigate or eliminate the risk. Similarly, comments expressed concern that institutionalization will increase for those with significant needs that fail to meet the new minimum requirements to be eligible for PCS or CDPAP.

Response: The Department appreciates these concerns of commenters regarding appropriate needs based on medical necessity criteria for the provision of services and seeks to comply with standards set forth in *Olmstead*. As specified in several of these comments, the criteria are specified in State law, as enacted in Sections 2-a and 3 of Part MM of Chapter 56 of the Laws of 2020. Additionally, the determination of need is based on CHA tool that the Department currently requires LDSSs and MMCOs to use, and that will continue to be used to determine the service needs. This tool has been independently validated by experts in the field as providing the necessary information about consumer's condition and needs. Accordingly, the CHA tool enables professionals, such as the independent providers on the IRP, or the LDSS's, or MMCO's professional staff or contractors, to make informed decisions or recommendations (as applicable)

about services that might meet the consumer's needs, including whether an individual may need services and supports available in the community and other settings. The Department has determined that no changes to the regulation are needed.

Comment: One commenter requested that the Department provide additional information about how the CHA in the Uniform Assessment System – New York (UAS-NY) translates the assessment into the ADL assessment criteria.

Response: Information about the UAS-NY is found on the Department's website, which includes the information requested.

https://www.health.ny.gov/health_care/medicaid/redesign/uniform_assessment_system/archives/uasny_reporting02.htm

Comment: Commenters recommended that the proposed regulations expand the definition of medical necessity to be consistent with State law and federal regulations, including provisions of the Medicaid Act or ADA. These comments also noted that the definition and usage of the term in the proposed regulations utilize a narrower definition than what is written elsewhere in State law. Accordingly, the commenters seek to have the regulations define medical necessity to include services that are needed to assist individuals who are impaired from performing normal life activities.

Response: The Department did not revise the regulations based on these comments. Having medical necessity criteria for services that accounts for diagnosis, where there is a

nexus between the diagnosis and the varying need for services, is both rational and appropriate, and does not violate federal or State law. Additionally, these criteria are clearly established in State law, and as such the Department lacks discretion to amend them. Differences between the regulations' description of medically necessary services and generic definitions of "medical necessity" in State and federal law are expected, as the former is a specific instantiation of the latter. The Department believes that restating definitions from other authorities would not assist MMCOs or LDSS in the application of medical necessity to the particular services – i.e., PCS or CDPAS –that are the subject of these regulations.

Comment: One commenter asked whether the IA process was required for skilled nursing services furnished by Certified Home Health Agencies (CHHA), which are required by federal and state rules and regulations to conduct their own assessments.

Response: The Department did not revise the regulations based on this comment, as the regulations are already clear that the scope of the IA and the associated processes are limited to PCS and CDPAS, as authorized by MMCOs and LDSS. To the extent that a CHHA is furnishing skilled nursing services as part of a post-acute care episode, these regulations do not apply to such services. That said, the Department appreciates these comments and will consider the comments further to determine if further guidance or rulemaking would be helpful to clarify roles and reduce unnecessary duplication of responsibilities.

Comment: Commenters, including the NYS Office of Mental Health (OMH), sought additional clarity regarding the minimum needs criteria for individuals with diagnoses of severe mental illness (SMI), but not Alzheimer's and dementia.

Response: The Department has considered these comments, in particular those received from OMH, and determined that a reasonable accommodation is needed for those with SMI who, because of their condition, may need services to remain in a home or community based setting, even without a need for at least limited assistance with physical maneuvering with more than two ADLs. In particular, OMH indicated that those with serious functional impairments due to their SMI may not present with any physical function needs at all, yet due to their SMI if sufficiently serious, could be unable to perform ADLs such that they would be placed at risk of institutionalization. Accordingly, the Department will issue implementing guidance establishing a process whereby services may be determined medically necessary for those individuals identified as having SMI when they demonstrate a need for assistance with at least supervision and cueing with more than one ADL, which is consistent with the spirit of the authorizing legislation.

For other conditions mentioned by commenters, such as traumatic brain injury (TBI), intellectual and developmental disabilities (IDD), and blindness, the Department did not receive similar comments as those provided on SMI from OMH, either in substance or from other governmental agencies or commenters with particular subject matter expertise. Rather, most commenters who raised this issue simply provided a list of

conditions that they expressed should be excepted from the primary ADL criteria along with Alzheimer's and Dementia. Additionally, for those with TBI or IDD that may otherwise meet the eligibility criteria for 1915(c) waiver enrollment, these individuals have access to services within the respective waiver programs that are specifically aimed at maintaining individuals in their home or community setting. Consequently, the Department does not believe there is sufficient evidence at this time to indicate that further guidance is needed to help inform the primary ADL criteria, but will consider further feedback in developing future guidance as we are doing with SMI.

Comment: Several commenters once again requested that the assessment process require that the IA and IRP consult with an individual's treating provider, permit the treating provider to submit information to IA when completing the CHA and determining needs for PCS or CDPAS. In support of this recommendation, commenters noted that the individual's treating provider may have important information about that individual that the individual cannot provide directly to the IA, including medical diagnoses, functional impairments, and service needs that the IA or IPP may not be able to obtain from their assessments or examinations, respectively.

Response: The Department did not revise the regulations as the IA, IPP, and IRP is already permitted and encouraged to consult available medical records in completing the CHA, PO, and high needs recommendation. The regulations permit an individual to share their medical records with the IA nurse assessor or practitioner during the assessment or medical examination process, respectively. Moreover, the MMCO will

have access to this medical information to inform the development of the plan of care and issuing the authorization for PCS and CDPAS. If the MMCO discover, through examination of these records and completion of the plan of care, that the IA failed to identify an individual's appropriate medical diagnoses, functional impairments, or service needs, the regulations now provide for a mistake correction and resolution process to facilitate those revisions. Finally, it would be inappropriate for the IA to give undue weight to the opinion of the treating physician in completing the CHA, as this preference could be viewed as compromising the independence of the IA, in favor of the treating physician who has an established relationship with the individual.

Comment: Commenters reminded the Department that the process for requesting medical records by the IA from the treating physicians should require a consent for release of protected health information (PHI) under the Health Insurance Portability and Accountability Act (HIPAA).

Response: The Department agrees with this comment and can confirm that an appropriate consent form will be shared with consumers by the IA in connection with the receipt of medical information that is PHI from the consumers' treating providers. The Department believes that these federal requirements are not necessary to include in the regulations.

Comment: Commenters asked that the Department clarify in regulations that members do not have to accept institutional care.

Response: The Department does not believe that this requirement is necessary to include in regulations.

Comment: In connection with their support for the change in the frequency of reassessments from semi-annual to annual, commenters requested that the Department educate consumers on their rights to request assessments based on changes in condition.

Response: Although this comment does not necessitate a change in the regulations, the Department once again confirms that it will instruct MMCOs and LDSS to inform and remind consumers of their ability to request reassessments apart from the routine annual reassessment based upon changes in condition. The ability to request reassessments based on changes in condition has not been modified by these regulations and may be done presently.

Comment: Commenters indicated that the consumer preference in the plan of care does not equate to consumer preference with regard to authorization of care hours.

Response: The Department disagrees as these comments do not recognize that the plan of care development process by the MMCO or LDSS is what results in the number of home care hours on a plan of care. Accordingly, consumer preference is reflected in this service authorization and determination.

Comment: Commenters requested that an individual's representative should be able to attend the clinical examination by the nurse assessors working for the IA.

Response: The Department once again notes the regulations do not preclude an individual's representative from attending the IPP examination, subject to other legal requirements that may apply to this process, including consent to have a third-party present during a clinical examination.

Comment: Commenters suggested that the IRP should be informed of the consumer's preferences with regard to the service authorizations in the plan of care.

Response: The Department disagrees with the IRP's receipt of the consumer's desired service authorization, as the IRP makes recommendations with regard to whether the services are clinically appropriate for the individual to remain in the community, but not to adjudicate disputes between the consumer and their MMCO or the LDSS. The grievance, internal appeal and Fair Hearing process remains available for these services.

Comment: One commenter sought further clarification whether changes made to the proposed regulations in the last round of revisions were intended to distinguish between available alternative services when taking into account consumer preference.

Response: The Department disagrees that the regulations make a distinction in the consideration of available services when gauging consumer preference. The Department

once again notes that these requirements are not new to the regulations and the regulations have contemplated care planning to involve consideration of the use of supplies and equipment, informal supports, adult day and social adult day, and formal services outside of Medicaid, when they can meet the consumer's needs and are cost-effective and available. Consistent with the earlier comments and the last round of revisions, the consumer's preference must also be taken into account and be part of the care planning process, which the Department believes addresses the commenters' concerns.

Comment: Commenters asked how MMCOs should handle instances where the member seeks more hours than the CHA supports.

Response: In response to this inquiry, the Department notes that the same process applies as it does today in terms of the CHA supporting the plan of care. If the MMCO cannot support a service authorization through the care planning process and believes that the CHA is factually and clinically accurate, then it should issue the appropriate services authorization and the member may appeal that determination.

Comment: Many commenters either objected to or sought further clarity regarding cost effectiveness being a consideration for an MMCO or LDSS in making a determination for services under a plan of care. Notwithstanding certain clarifying changes made to the draft regulations in the earlier rulemaking, these commenters asked how cost effectiveness should be assessed, how the identification of comparative service to PCS

and CDPAS should be considered, and how cost effectiveness will impact service authorization as compared to other services such as Personal Emergency Response Systems (PERS), adult day health, or equipment and supplies. Other commenters noted that failure to specify clear processes may result in a violation of established legal principles in Olmstead and DeLuca.

Response: The Department once again notes that it has not amended any of the current regulatory provisions or definitions regarding the determination of cost-effectiveness as it relates to the authorization of services, except to the extent that the amendments re-designated and streamlined many provisions. In general, the requirements of what LDSSs and MMCOs must consider in reaching an authorization has not fundamentally changed, with the exception that some portions of the assessment are now conducted by the IA. Nonetheless, the Department is concerned with the indication by some commenters that portions of the regulations related to the determination of cost effectiveness are not being observed. To that end, the Department previously removed the requirement in the revised regulations that MMCOs and LDSS first consider cost effectiveness in developing the plan of care. Instead, MMCOs and LDSS must balance considerations of cost-effective with available alternatives, social and cultural consideration, and consumer preferences. Given this balancing, the Department does not feel it is appropriate or necessary to further specify a process for balancing these interests or provide a specific definition of “cost effectiveness,” as this consideration process will necessarily occur during the care planning process and based on the information available. Notwithstanding these changes, this regulatory revision still requires MMCOs and LDSS

to include other programs (e.g., Medicare when coverage is primary to Medicaid), willing and available informal supports, and adaptive or specialized equipment or supplies in the individual's plan of care and authorize services accordingly. Beyond these changes germane to the current rulemaking, the Department will further evaluate these comments to determine whether additional action, including additional rulemaking, is necessary to address the issues raised by commenters.

Comment: Several commenters stated their belief that the proposed changes will not save money and instead increase costs to the Medicaid program. A majority of the commenters compared the per diem cost of SNF to cost of hiring a caretaker through CDPAP. Commenters also expressed belief that CDPAP is a more cost-effective way to aid individuals with ADL needs, than nursing home placement.

Response: The Department appreciates this perspective by these commenters and will monitor whether these changes help contribute to the financial sustainability of the Medicaid program. The Department notes that the fiscal impact from these proposals is not based on comparing the costs of CDPAS or PCS with SNF care, but through achieving a more streamlined and standardized process for assessment and authorization of services and improving the independence of the assessment and medical order processes from the entity authorizing services, as well as decreasing the frequency of routine assessments, which commenters have largely supported.

Comment: Commenters asked whether members could refuse a plan of care that uses other support services (e.g., social adult day) instead of PCS or CDPAS hours, even if it is more cost effective. Commenters also question how this requirement impacts fair hearing.

Response: As indicated in our response to the prior version of the regulations, the proposed changes continue to indicate that the care planning process involves a balancing of cost-effective with consumer preferences, among other considerations, which is highlighted by this question. Accordingly, utilizing the most cost-effectiveness service is not an inflexible standard that MMCOs or LDSS must use in the course of developing a plan of care. However, should the consumer not agree with the authorization contained in the plan of care, then an appeal and fair hearing remains within the consumer's rights to pursue. Whether the MMCO or LDSS considered cost-effectiveness with member preference and other considerations would be relevant to the fair hearing process.

Comment: Commenters expressed concern with the costs to the State regarding the IA process due to the Department having to contract for a substantial volume of services related to IA implementation, along with the IPP and IRP.

Response: The Department appreciates the comment, but it is not germane to this rulemaking. The Department also notes that it currently contracts with MMCOs to perform many these functions under the current process or through other means, such as

reimbursement of evaluation and management services by physicians who order PCS or CDPAS. .

Comment: Commenters asked the Department whether consumers will be notified of differences in clinical judgment that may arise, even when a new assessment is not requested by the MMCO or LDSS.

Response: As the plans and LDSS are not conducting their own CHAs, there is no way to document each and every difference in clinical judgment that may arise in the care planning process. Rather, the LDSS or MMCO, consistent with their care planning function, will only request a new assessment when the potential differences in clinical judgment may result in a different service authorization. Requiring such reporting otherwise will not be operationally feasible for plans, LDSS or the IA.

Comment: Commenters requested that the Department consider the modality--telehealth vs. in-person--in determining whether an MCO or LDSS abused the dispute resolution process in terms of requesting a second assessment due to clinical inaccuracies.

Response: No change to the regulations are needed by virtue of this comment, but the Department notes that there should be no difference in the quality of assessment by virtue of whether it was conducted by telehealth or in-person; however, a determination of whether an MCO or LDSS abused the dispute resolution process can consider these factors.

Comment: Commenters interpreted the requirement that the IA and IPP complete a CHA upon discharge from an institutional or in-patient setting, as potentially contravening existing and longstanding DOH guidance regarding the provision of aid-continuing until a final service authorization is in place, such that reinstatement of previously authorized PCS and CDPAS would not be delayed pending a new service authorization.

Response: The Department disagrees with the commenters that the regulations are unclear as to the direction of when the IA must conduct an assessment and complete the CHA, as opposed to the impact of that CHA on the previously authorized services. The Department clarified herein that the longstanding requirements regarding aid-continuing in these situations remains unchanged by these regulations and does not view a conflict in this regard.

Comment: Health plan commenters asked that any incomplete questions on the CHA no count towards quality score or risk adjustment calculation.

Response: Consistent with the dispute resolution process set forth in the regulations, the MMCO or LDSS should inform the IA of any questions on the CHA that it believes are incomplete or inaccurately answered. The Department agrees that a complete and timely CHA is important for care planning and to ensure accurate MMCO quality scores and risk adjustment calculations, such that both the Department and MMCOs should ensure

completeness and accuracy of the CHA through the transition to this new process, but regulatory changes are not required.

Comment: Plan commenters sought more notice or warnings by the Department prior to application of plan sanctions for "abuse" of the dispute resolution outlined in the proposed regulations regarding inaccurate CHAs from the IA.

Response: The Department appreciates these comments and will address whether warnings or other carveouts from a determination of abuse is warranted as it implements the IA process and gains experience with any disputes that arise under this process. At this point, the Department does not believe that any additional revisions are necessary to the proposed regulations based on the process outlined.

Comment: Commenters requested clarification on the timing of the dispute resolution process, and whether the dispute will toll the requirements of MMCOs and LDSS to issue a service authorization for enrolled and non-enrolled individuals who are eligible for services.

Response: As reflected in the earlier Assessment of Public Comment, the dispute resolution set forth in the proposed regulations does not modify the required timeframes for issuing an authorization following the completion of the CHA by the IA. Accordingly, the processes established by the regulations must occur within these timeframes. When requesting a second assessment due to a clinical disagreement, the IA

have up to ten (10) days from the date it is notified by the LDSS or MMCO to schedule and complete a new assessment.

Comment: Commenters asked whether the regulatory processes established for clinical or factual disputes involving the CHA will extend to individual challenges with regard to the plan of care.

Response: The Department believes that the regulations are clear that the dispute resolution processes involving clinical or factual disputes involving the CHA are limited to the content of the CHA, rather than the plan of care.

Comment: One commenter asked for clarification regarding the provision that requires the LDSS or MMCO to confirm that the information in the individual's record is up to date upon request by the IA, and which obligation may apply. However, the Department has clarified that only *material* mistakes need to be reported to the IA. There is no requirement to inform the IA of mistakes that are not material, such that they would not impact completion of the CHA.

Response: The Department has established this process to ensure that the UAS-NY is up to date at all times, such that the IA can appropriately schedule reassessments when due. Accordingly, the Department believes that the regulations are clear in that this requirement applies generally.

Comment: Some commenters requested that the Department withdraw the proposal for the monetary penalties for abusing the clinical disagreement process.

Response: The Department declines to eliminate monetary penalties for plans that abuse the clinical disagreement process, as it believes it is important to ensure the integrity and independence of the assessment process. The Department will review data reported to ensure that any penalties assessed are warranted and measured in accordance with the factors outlined in the regulation.

Comment: Conversely, other comments argued that the dispute resolution process may be over-utilized by MMCOs and LDSS, which would result in delays in an individual's receipt of a service authorization. Consequently, these commenters recommended eliminating or streamlining any processes.

Response: The Department disagrees with these commenters that the dispute resolution will create delays, as an MMCOs or LDSS decision to request a second CHA due to clinical concerns regarding the accuracy of the completed CHA does not extend the time periods provided for issuing a service authorization.

Comment: In the event of a corrected CHA following a clinical or factual dispute by the MMCO or LDSS, commenters requested that the individual be afforded all copies of the CHAs (original and corrected) in connection with any internal appeals or fair hearing requests following the service authorization.

Response: The Department does not believe it is necessary to specify that individuals who receive all versions of a CHA and disagrees that the information would be relevant to the consumer in any appeal or Fair Hearing activities. The purpose of the dispute resolution process is to make necessary corrections to the CHA based on perceived inaccuracies by MMCOs and LDSS that rely on the CHA for purposes of developing the plan of care and issuing a service authorization. Consumers will have the ability to receive a copy of the CHA in connection with appeals related to service authorization to the extent that such CHA was used in developing the plan of care, to deny an initial request for services or enrollment in an MLTC plan. Other CHAs, not used in developing the plan of care, or rendering a medical necessity determination, are not relevant in connection with appeals or fair hearings because they were not used as the basis of the service authorization.

Comment: Commenters expressed concern regarding the sanction process that could be imposed by the Department if MMCOs and LDSS request unnecessary second assessments. These commenters view the sanction process as unnecessarily punitive and potentially chilling to valid clinical disputes.

Response: The Department appreciates this comment but recognizes that the IA process regarding completion of the CHA is new and MMCOs and LDSS may seek to have assessments conducted again without express and specific concerns as they adjust to this new process. While the Department anticipates that it not need to apply to the sanction

process established by these regulations, it seeks to reserve the rights in case it detects instances of abuse, which would contravene the intended purposes of the IA process and result in member inconvenience. Moreover, the Department believes that the regulations are clear that sanctions will not be imposed if the CHAs change as a result of clinical disputes being requested by MMCOs or LDSS.

Comment: Plan commenters requested that the second assessment, as requested by MMCOs or LDSS, will be performed by a different nurse assessor than the first that was viewed as clinically inaccurate.

Response: The Department disagrees that the second assessment needs to be completed by a different nurse assessors, as the clinical disagreement may be for reasons unrelated to the skill and competency of the nurse assessor who performed the first assessment, such as how the consumer was presented on the day on which the assessment was conducted. Accordingly, a second assessment being completed, along with information from the MMCO or LDSS on the nature of the clinical disagreement, should be sufficient to ensure that the second assessment addresses the perceived clinical inaccuracies noted in the first assessment.

Comment: In connection with the dispute resolution process, MMCOs sought clarification whether MMCOs are still required to enroll individuals while the second assessment was pending.

Response: The Department confirms that an MMCO should continue to enroll members based on the results of the first assessment, which will confirm MMCO and service availability based on application of the minimum needs criteria and new MLTC enrollment eligibility criteria. However, the Department recognizes that the service authorization may be contingent upon completion of the second assessment if it changes the determination regarding the needs of a consumer. The Department determined the no changes to the regulations are required in this regard.

Comment: Commenters raised concerns that MMCOs can issue denials or reductions in service authorizations based on their own arbitrary medical necessity criteria.

Response: In addition to the responses to similar comments on potential application of this criteria in which the Department notes that the rationales furnished by MMCOs and LDSS for denials, reductions, and discontinuances described in the regulations do not represent the total universe of appropriate reasons for LDSS or MMCOs to take such actions, and that LDSSs or MMCOs may validly take actions for other rationales, the Department notes that it is seeking implementation of a uniform tasking tool that will help guide LDSS and MMCOs in applying industry standards against service authorizations being issued, which will help with some of the speculative concerns noted by commenters.

Comment: Commenters continued to express concern and opposition to changes to the regulations that permitted reductions in services when a prior assessment authorized more

services than are medically necessary or after a continuity of care period. In expressing this opposition, commenters cited constitutional and statutory due process rights of Medicaid recipients that have been repeatedly affirmed by the federal courts, including in *Mayer v. Wing*, *Strouchler v. Shah*, and *Caballero v. Senior Health Partners*, indicating that the impact of the holding from *Mayer v. Wing* is that there needed to be documentation of changes in the consumer's condition to avoid finding that such reductions were arbitrary. Specifically, these commenters disagreed with the prior responses to the Department that cited Section 4403-f(11-b) of the PHL and MLTC Policy 17.02, which requires that, in cases of a MLTC plan merger, acquisition, or other similar arrangement, the MLTC plan that is a party to the arrangement and that received the enrollees, who would be subject to a continuity of care period as described in the example rationale, must report to the Department information about the enrollees' service authorization both before and after the transfer and continuity period. The Department previously noted that this reporting gives the Department direct and systematic insight into how MLTC plans are applying their medical necessity criteria to the authorization of services, including PCS and CDPAS.

Response: Since the establishment of the reporting requirement in Section 4403-f(11-b) there has been only one plan merger or similar transaction to which the statute applied. Although the rationale would also apply in contexts where a plan terminates operations or leaves a service area without a receiving plan, there have only been two such closures in the time since the statute became effective. The infrequency of these events strongly supports the Department's view that the proposed rationale is narrow in scope, and that

commenter's claims that the introduction of the rationale would lead to widespread abuse are simply unfounded. While the rationale is limited, the Department still believes this to be an important change to ensure the availability of plans willing to serve Medicaid recipients and offer them a plan of care, when their MMCO no longer serves their service area.

Comment: Several comments once again expressed strong opposition to changes to the regulations that permitted reductions in services when a prior assessment authorized more services than are medically necessary or after a continuity of care period. Considering these cases, commenters were concerned that the proposed regulation would establish a “catch-all” reason that would allow reductions in services without a documented change in the consumer’s condition or specific documentation of an alleged identified mistake in a prior assessment.

Response: The Department appreciates these comments, but strongly continues to disagree that the regulatory changes implicate a consumer’s due process rights, contravene legal requirements or preexisting MLTC Policies. These regulations support longstanding legal principles that an MMCO or LDSS may make supportable and appropriate changes in service authorization when such authorizations are based on medical necessity, use the assessed needs of the individual, and consistently apply clinical standards. Finding that an MMCO or LDSS cannot make changes when these circumstances are present would fundamentally undermine the ability of the Medicaid program to appropriately provide services in accordance with individuals’ medical needs.

This requirement has been explained and reinforced through guidance. Furthermore, with these regulations, the Department has ensured that there are sufficient controls and oversight over the process to both discourage and to ameliorate the types of arbitrary action about which commenters express legal concerns, including the example rationale for reductions based on medical necessity refers only to specific circumstances where there has been a continuity of care period prescribed in law or policy and that period has ended. The Department previously added an example as part of the prior Assessment of Public Comment to clarify that it is appropriate for an MMCO to be able to use its own medical necessity criteria after a continuity of care period has concluded, and that a change in condition is not required for the MMCO to amend the authorization, which may sometimes result in a reduction in care. As in any care planning process, the criteria must be fairly and consistently applied to all enrollees of the MMCO, and the service authorization must be sufficient to ensure that enrollee's health and safety can be maintained in the community.

Additionally, the Department previously clarified and strengthened the requirement that when making a determination based on medical necessity the MMCO or LDSS must provide in the notice the clinical rationale that forms the basis for the action and how it related to the individual's particular case, and that the rationale must be clear enough to allow review. The commenters' concerns that this would allow an MMCO or LDSS to base a decision on the "excessive authorization" of a previous MMCO or LDSS are unfounded, as such a rationale is clearly precluded under the proposed rules. This represents a reasonable constraint and imposes a framework on the MMCOs or LDSSs

decision making when authorizing a plan to ensure that medical necessity determinations relate back to the clinical criteria used by the MMCO or LDSS.

Comment: Commenters raised due process concerns based on ongoing litigation, existing case law, fair hearing decisions, and federal requirements and the special terms and conditions within New York State's 1115 Demonstration Waiver authorizing MMCO and MLTC coverage of these services. The commenters raised concerns regarding the reasons for which MMCOs and LDSS may consider reductions in the need for PCS, CDPAP, or other CBLTCS when issuing an authorization from an individual's plan of care, including whether the LDSS or MMCO must specifically state the reasons for the reduction, whether an MMCO or LDSS may reduce services without identifying an underlying change in circumstances, and whether a plan or LDSS may reduce CBLTCS when the member transitions from one plan to another or between a plan and an LDSS. Commenters also suggested that the Department repeal the requirement that services must be medically necessary to be authorized, are requiring all decisions to be based on the list of denial or reduction rationales.

Response: The Department appreciates these comments and their recitation of the Department's legal obligations to safeguard the due process rights of individuals when accessing PCS and CDPAS from LDSS or MMCOs. In response to the comments, the Department notes that the rationales furnished by MMCOs and LDSS for denials, reductions, and discontinuances described in the regulations do not represent the total universe of appropriate reasons for LDSS or MMCOs to take such actions, and that

LDSSs or MMCOs may validly take actions for other rationales, provided that notice is appropriately provided. Nor does it replace the requirement that for services to remain medically necessary. The purpose of the rationale list is to guide LDSS and MMCOs towards rationales that can be supported, which may at the same time discourage them from taking “unlisted” actions that may not be supportable. This approach is both consumer friendly, in that it clarifies a variety of appropriate valid rationales for taking action, which can help distinguish when a provided rationale is not valid. Further, this approach encourages the efficient use of resources by appraising LDSS and MMCOs in advance when an action is officially considered justifiable. Accordingly, the proposed new reasons in the regulations should not be viewed as newly valid reasons for reductions in service, rather they are newly listed examples and clarifications of historically valid reasons.

Nor is the list of rationales, either in its current version or with the addition of the new examples, able to stand in for the basic requirement of all Medicaid services that they are medically necessary. Instead the requirement that services be medically necessary and the list of valid actions complement and inform each other. Without either one, the regulation would not be the same, and both are needed to ensure due process and to protect scarce public resources. As such the Department also declines to remove the requirement that services must be medically necessary.

The Department has included new language clarifying the standard to which LDSS and MMCOs must achieve when denying, reducing, or discontinuing care based on medical

necessity. This standard requires the LDSS and MMCO to specify the clinical rationale on which the determination is based both in the notice to the consumer and in their plan of care. In direct response to concerns regarding arbitrary authorization changes, LDSS and MMCOs must do more than simply record the clinical rationale, they must do so in a way that demonstrates that they have reviewed the particular consumer's clinical assessment and medical condition so that a reviewer of the case can understand how the clinical rationale is being applied in this case. The Department will endeavor to provide further guidance to MMCOs and LDSS on these notices through MLTC Policies or other communications.

Comment: One commenter suggested that the Department expand the implementation provisions that allow the Department to rollout the new assessment and medical necessity criteria as capacity allows in different geographic regions to include also the changes to the action and notice requirements.

Response: The Department does not think it is necessary to tie the implementation of the IA or minimum needs criteria to the addition of examples for which a denial or reduction may be made. The Department also questions whether it would be permissible to stage the implementation of permissible denial and reduction rationales as proposed by the commenter, given that 505.14(b)(8) and 505.28(m) allow for implementation on a geographic and other basis.

However, as the rulemaking constitutes a significant change to the processes used for assessing the need for services, which will require time to implement, the Department agrees that it is important to allow sufficient time for stakeholders to learn and implement the various changes or to comply with federal limitations and Maintenance of Effort (MOE) requirements, including those apply under Section 9817 of the American Rescue Plan Act and Section 6008 of the Families First Coronavirus Response Act or any subsequent similar requirements. Accordingly, the Department will stage the effective date of these regulations to begin on the 60th day following publication of the Notice of Adoption in the New York State Register and will issue guidance as needed in accordance with 505.14(b)(8) and 505.28(m) to pend implementation of the IA or minimum needs criteria.

Comment: Commenters expressed a desire to remove the regulatory flexibility afforded in the revised regulations to implement the IA process in phases based on the needs of the Department and access to timely assessments.

Response: The Department continues to believe that flexibility in the effective date is necessary to ensure a smooth implementation of the IA process, as mandated by Part MM of Chapter 56 of the Laws of 2020, as access to timely assessments is paramount and should drive the ultimate effective date of each component of the assessment process.

Comment: Commenters want at least 60 days' notice prior to implementation.

Response: The Department appreciates the need for adequate notice prior to implementation and has set the effective date to be the 60th day following the publication of the Notice of Adoption in the New York State Register.

Comment: Many commenters recommended revising the minimum needs requirement for persons needing physical assistance to allow individuals to qualify for PCS if they need physical assistance with one ADL and two of either extensive assistance with an IADL or limited assistance with an ADL. Specifically, commenters expressed concern that the minimum needs requirements, which require people with dementia to need assistance with more than one ADL and other consumers to need assistance with more than two ADLs, need revisiting, because a quantification of the number of ADLs that a consumer needs assistance with does not always accurately capture an individual's true need.

Response: The Department appreciates the suggestions of commenters regarding appropriate needs based medical necessity criteria for the provision of services. However, the requirements are specified in State law, as enacted in Sections 2-a and 3 of Part MM of Chapter 56 of the Laws of 2020. The Department has determined no changes to the regulation are needed.

Comment: MMCO Commenters asked whether the change to the IA process impacts if and when individuals have to enroll in MMCOs.

Response: No changes to the regulations are required in response to this comment as the MMCO enrollment process is unchanged as a result of these regulations.

Comment: MMCO comments asked for further details on the mechanics on the transition of information to the IA regarding MMCO enrollment requests and completion of various steps in the service authorization process (e.g., IPP, etc.)

Response: No changes to the regulations are required in response to these comments, as this information will be provided in guidance to MMCOs and LDSS separate from the regulations.

Comment: MMCOs asked for more information on the time requirements for submission of enrollment requests.

Response: The IA process does not impact the plan enrollment submission requirements, as compared to the current Conflict Free Evaluation and Enrollment Center (CFEEC) process.

Comment: Commenters continue to seek additional guidance—although not necessarily as part of revised regulations—regarding how LDSS and MMCOs should address individuals who have functional needs that fall short of the new minimum needs criteria, including whether Level I or Level II PCS or CDPAS is still available to these individuals.

Response: Section 365-f of the Social Services Law grandfathers individual to the minimum needs criteria that existed prior to implementation of these regulations, so long as they have already been assessed and authorized for services prior to the effective date of the regulations. All other individuals will be subject to the new minimum needs criteria. Individuals who are not subject to the new minimum needs criteria will continue to be able to access Level I services, such as making beds and doing laundry, even if they do not meet the new criteria. Individuals who are subject to the new minimum needs criteria set forth in statute will need to meet the minimum needs criteria to access PCS or CDPAS. Individuals who only have need for Level I services do not meet the minimum needs criteria, and individuals who are subject to and who meet the criteria will have access to both Level I and Level II services. Note that the minimum needs criteria referred to in the proposed regulations describes the criteria needed to access PCS and CDPAS, but do not change the criteria needed for MLTC plan eligibility as established in Section 4403-f of the PHL. Although the same clinical standards are used, some individuals may be subject to the new criteria for services but not for plan eligibility and vice versa. This change in MLTC plan eligibility criteria is outside the scope of this rulemaking and will be subject to review and approval under an amendment to New York's 1115(a) research and demonstration waiver with the CMS. The Department may also issue additional guidance to further clarify how service and plan eligibility will interact. The Department has determined no changes to the regulation are needed.

Comment: Commenters asked whether a decrease in service authorization based on an IRP recommendation trigger an appeal and fair hearing right.

Response: The Department believes that the regulations are sufficiently clear in this regard, in that once an MMCO or LDSS issues a service authorization, whether based on the IRP's recommendation or not, that service authorization will trigger an individual's rights regarding internal appeals and fair hearing.

Comment: Commenters requested that the Department clarify in the regulations that review by the IRP will not occur when the MMCO or LDSS approves fewer than the threshold number of hours, but the consumer appeals (either an internal appeal or fair hearing) and receives greater than the threshold number of hours through a fair hearing.

Response: In the prior round of regulatory revisions, the Department already revised the regulations to reflect that the approval of hours through an internal appeal or fair hearing, even if the approval crosses the threshold as a high needs case, will not necessitate review by the IRP to confirm that the individual may remain safely in the home. The Department does not believe that further revisions are necessary to clarify how the plan of care development process relates to the work of the IRP, as the regulations make clear that: the IRP must review the plan of care to determine whether the PCS and other CBLTC services authorized therein are sufficient to keep the individual in the home

safely; and that the LDSS or MMCO must consider the IRP recommendation in finalizing the plan of care.

Comment: Certain commenters expressed support for regulatory changes around a determination of self-direction.

Response: The Department appreciates these comments and support for these changes.

Comment: Commenters requested clarification regarding whether a change in social circumstances alone would require that the IA conduct a new CHA or whether the MMCO or LDSS may adjust the service authorizations based on the previously completed CHA.

Response: As reported in the prior Assessment of Public Comment, other than routine reassessments, which will now occur annually, the IA will conduct reassessments for consumers upon a significant change in their physical or mental condition, a return to service, a discharge from inpatient care, and other applicable circumstances. MMCOs and LDSS, or other assigned care managers, will monitor these circumstances and work with the IA to schedule a reassessment, if required. A change of social circumstances alone will not trigger the need for a new independent assessment, and the LDSS or MMCO must only review the most recent CHA on file.

Comment: Health plan commenters sought additional regulatory clarity on the triggers for change in condition assessments.

Response: The Department declines to add further standards, criteria, or processes for the determination of whether change in condition assessments are warranted. The “triggers” for change in condition assessments are unaffected by this rulemaking or the transition to an IA. Because the assessment will not be conducted by the independent assessor, MMCOs and LDSSs will need to forward cases to the IA when they become aware of a need for a new assessment based on a change of condition.

Comment: Commenters objected to the regulations based on a view that the proposed changes will not save money and instead increase costs to the Medicaid program, as the per diem cost of SNF or Adult Living Facilities is higher than PCS and CDPAP. Accordingly, these commenters believe that the CDPAS program or PCS is a more cost-effective way to aid individuals with ADL needs, than nursing home placement.

Response: The Department appreciates this perspective by these commenters and will monitor whether these changes preserve and support an individual’s placement in the community and help contribute to the financial sustainability of the Medicaid program. As with the prior Assessment of Public Comment, the Department notes that the fiscal impact from these proposals is not based on comparing the costs of CDPAS or PCS with SNF care, but through achieving a more streamlined and standardized process for assessment and authorization of services and improving the independence of the

assessment and medical order processes from the entity authorizing services, as well as decreasing the frequency of routine assessments.

Comment: Other comments continued to express their lack of support for the proposed PCS and CDPAP changes due to concerns about increased institutionalization and decreased quality of life that may result from application of new minimum needs criteria.

Response: The Department continues to appreciate these comments and notes that the minimum needs criteria, including the minimum ADL requirements, are a function of legislative changes in the enacted SFY 2020-21 budget. See Section 2-a of Part MM of Chapter 56 of the Laws of 2020. In drafting these regulations to implement this legislative change, the Department has remained cognizant of these concerns raised by the commenters and has worked to preserve community-based care and quality of life for consumers impacted by these changes.

Comment: Commenters do not believe that these regulations improve the relationship between the care managers at MMCOs and LDSS and the individuals who are authorized to receive PCS and CDPAP, which ultimately may result in further reductions in authorized care.

Response: The Department appreciates the perspective of these commenters, but notes that the process by which LDSS and MMCOs conduct care planning and develop plans of care have not changed, such that the types of care being identified and the authorization

for these services remains as it does today, with all related review and appeal rights. Additionally, the Department highlights its view that these regulations do confer benefits on the process by seeking a more streamlined and standardized process for assessment and authorization of services, improving the independence of the assessment and medical order processes from the entity authorizing services, as well as decreasing the frequency of routine assessments, which commenters have largely supported.

Comment: Commenters raised concerns that the MMCOs, by retention of the care planning process, are still able to "exploit" members and pursue "financial considerations over health and safety" of members.

Response: The Department acknowledges these perspectives from commenters, but the proposed regulations do not speak to changes in the care planning process, but only to the assessment process. Moreover, by centralizing the assessment function in a single IA, the Department believes there will be more standardization and consistency in how assessments are completed, which will promote better care planning by MMCOs and LDSS.

Comment: Certain comments once again expressed opposition to the regulations based on the perception that these changes would create additional burden on individuals seeking PCS and CDPAS and, by extension, the workers who serve these individuals through the home care industry.

Response: The Department continues to believe that the processes contained in these regulations will not increase burdens on requesters for several reasons. First, the IA process centralizes the assessment, medical order, and IRP process within a single point of contact—that of the State-contracted IA. Additionally, the process by which LDSS and MMCOs conduct care planning and develop plans of care have not changed, such that the types of care being identified and the authorization for these services remains as it does today, with all related review and appeal rights. Finally, the Department will continue to implement the IA process in a way that ensures the IA and the clinicians that participate on the IPP and IRP have access to the medical records and information of consumers to avoid the consumer having to educate the assessor any more than they do under the current process.

Comment: Certain commenters sought to have the entire regulations "tabled and withdrawn" such that the authorization legislation could be reconsidered by the legislature.

Response: The Department expresses no opinion on whether the legislature will reconsider the statutory enactments in Part MM of Chapter 56 of the Laws of 2020 that give rise to this rulemaking.

Comment: Commenters continued to express concern about the ability of the IA to complete accurate reassessments without having an ongoing relationship, as MMCOs and LDSS do.

Response: The Department understands these ongoing concerns by commenters, but these regulations implement the statutory direction to transition to a single, statewide IA for these purposes. Accordingly, the Department lacks discretion to change the regulations in response to this comment.

Comment: One commenter expressed support for permitting nurse practitioners and physician assistants, in addition to physicians, to issue practitioner orders.

Response: The Department appreciates this comment in support of this regulatory change.

Comment: Commenters asked how the Department will identify individuals who are not subject to the new minimum needs or Plan enrollment eligibility criteria.

Response: The system that houses the CHA and is used by the IA will be able to identify individuals under the appropriate minimum needs criteria. No changes to the regulations are necessary in response to this comment.

Comment: Commenters asked the Department to clarify from which date the application of the legacy minimum needs requirements apply.

Response: No changes to the regulations are required, as they clearly specify that individuals who have been assessed and authorized for PCS or CDPAS prior to the effective date of these regulations will not be assessed under the new minimum needs criteria set forth in statute and these regulations for PCS and CDPAS. The regulations do not address enrollment eligibility criteria for MLTC plans, which are outside the scope of these regulations.

Comment: Commenters asked whether the current or new minimum needs requirements would apply if someone was disenrolled from Medicaid due to loss of eligibility and the person reapplies for services after they have been re-enrolled.

Response: No changes to the regulations are necessary, as the regulations are clear that these individuals would have been assessed and authorized for PCS or CDPAS prior to the effective date of these regulations, and thus will not be assessed under the new minimum needs criteria set forth in statute and these regulations for PCS and CDPAS, even if there is a temporary loss of Medicaid enrollment up to 45 days from the date of disenrollment, which will be established and subject to modification pursuant to guidance issued by the Department.

Comment: Commenters asked about application of the legacy MLTC enrollment eligibility criteria to individuals based on different circumstances, including when these individuals may be temporarily disenrolled from an MLTC.

Response: The regulations do not directly address MLTC enrollment eligibility criteria; however, the Department has requested a conforming amendment to the 1115 waiver demonstration Special Terms and Conditions to ensure alignment of MLTC enrollment eligibility criteria with the new minimum needs criteria for PCS and CDPAS, as community based long-term supports and services. As of the date of publication, this amendment request remains pending review and approval by the Centers for Medicare & Medicaid Services.

Comment: One LDSS requested additional clarification regarding how they may continue offering Level I PCS to grandfathered populations, including how such populations will be identified.

Response: As part of the implementation process, the Department will require that the IA identify and track populations subject to grandfathering requirements, such that these individuals are assessed under the current, rather than new, minimum needs criteria. LDSS and MMCOs will be informed by the IA of these individuals. Accordingly, the Department believes that no changes to the regulations are required.

Comment: Commenters asked the Department to apply the "grandfathering" criteria consistently across PCS and CDPAS minimum needs requirements and MLTC enrollment eligibility criteria.

Response: The regulations apply standard grandfathering criteria, such that individuals who have been assessed and authorized for PCS or CDPAS prior to the effective date of these regulations (or when specific components of these regulations are effective, if later than when the regulations are published) will not be assessed under the new minimum needs criteria set forth in statute and these regulations for PCS and CDPAS. This group includes those individuals who currently receive Level I PCS through the LDSS. Notwithstanding the application of the legacy minimum needs criteria to these individuals, the IA will conduct their assessments, rather than the MMCO or LDSS. MLTC enrollment eligibility is not dictated by the regulations and thus not addressed herein.

Comment: Commenters asked the Department to standardize the circumstances under which individuals may be treated under the historical minimum needs criteria, as opposed to the new minimum needs criteria, to ensure that individuals are assessed under the appropriate medically necessity standard for PCS and CDPAS.

Response: No changes to the regulations are required, as the Department believes that the regulations do achieve standardization in the process for applying the historical, rather than the new, minimum needs criteria, which is consistent with the statute authorizing this change. Under this approach, as set forth in the regulations, individuals who have been assessed and authorized for PCS or CDPAS prior to the effective date of these regulations will not be assessed under the new minimum needs criteria set forth in statute and these regulations for PCS and CDPAS. This group includes those individuals

who currently receive Level I PCS through the LDSS. Notwithstanding the application of the legacy minimum needs criteria to these individuals, the IA will conduct their assessments, rather than the MMCO or LDSS.

Comment: Commenters cautioned the Department about applying differential standards for Immediate Needs cases, depending on whether someone is leaving an institution or based in the community.

Response: The Department does not believe changes to the regulation are required as the Immediate Needs process, including whether someone qualifies for an Immediate Needs review based on a physician statement, is the same regardless of the location of the individual.

Comment: One commenter suggested that the Physician Statement of Need for Immediate Needs cases replace the IP process.

Response: The Department disagrees with this comment because the Physician Statement of Need and the IPP's practitioner order provide different information or serve different purposes. The Statement of Need needed to initiate the Immediate Needs process must be completed by a physician who has direct knowledge of the consumer's condition, such as the consumer's treating physician or primary care physician. Based on the authorizing statute for these regulations, the practitioner order must be issued by a practitioner does not have an established relationship with the individual. Accordingly,

the Department does not have the authority to substitute the IPP with the Physician Statement of Need and such a substitution would contravene the statutory direction to the Department.

Comment: One commenter requested that the Department allow an MMCO or LDSS to issue a temporary plan of care for Immediate Needs cases following issuance of the Physician Statement of Need.

Response: The Department does not agree that a temporary plan of care is needed for Immediate Needs cases, as the current process and timelines affords LDSS and MMCOs adequate time, consistent with federal and state requirements, to issue a timely service authorization. These regulations do not change the timing for issuance of the service authorizations for Immediate Needs cases.

Comment: Commenters requested that the Department provide copies of the IPP practitioner order to the individual.

Response: The Department does not believe a change to the regulations are required in response to this comment. The individual will have access to the practitioner order, including as part of the record pertinent to a challenge of a determination made by the IPP regarding the medical necessity of PCS or CDPAS. Notice will be provided by the IPP or the MMCO or LDSS as applicable when the independent medical review result in the denial or termination of services.

Comment: Commenters expressed support for the Department now permitting, with CMS approval, nurse practitioners and physician assistants being able to sign practitioner orders for PCS and CDPAS.

Response: The Department appreciates these commenters' support for this change, which the Department believes is appropriate under, and consistent with, federal and State law.

Comment: One LDSS requested further clarification on who completes the practitioner orders for PCS or CDPAP.

Response: The Department believes that the regulations are sufficiently clear that the IPP, inclusive of Doctors of Medicine (MD), Nurse Practitioners (NP), and Physician's Assistants (PA), independent of the consumers, will complete and sign the practitioner order. The IA, as part of its contract with the Department, will be responsible for managing the IPP.

Comment: Several commenters requested that the assessment process require that the IA consult with an individual's treating provider, permit the treating provider to submit information to IA when completing the CHA and determining needs for PCS or CDPAS, and that the IA give appropriate "weight" to the opinion of the treating provider. In support of this recommendation, commenters noted that the individual's treating provider may have important information about that individual that the individual cannot provide

directly to the IA, including medical diagnoses, functional impairments, and service needs that the IA or IPP may not be able to obtain from their assessments or examinations, respectively.

Response: The Department did not revise the regulations as the IA is already permitted and encouraged to consult available medical records in completing the CHA. The regulations do not prohibit an individual from sharing his or her medical records with the IA nurse assessor or practitioner during the assessment or medical examination process, respectively. Moreover, the LDSS or MMCO will have access to this medical information to inform the development of the plan of care and issuing the authorization for PCS and CDPAS. Additionally, as stated in the Assessment of Public Comment released by the Department in January 2021, it would be inappropriate for the IA to give undue weight to the opinion of the treating physician in completing the CHA, as this preference could be viewed as compromising the independence of the IA and the validity of the CHA, in favor of the treating physician who has an established relationship with the individual.

Comment: Commenters expressed a desire for specific credentials, in terms of training and experience, for NPs and Physician Assistants PAs to complete practitioner orders under the IPP process.

Response: As previously provided by the Department in the prior Assessment of Public Comment, the Department believes not requiring a physician signature on the order form

in these cases is consistent with recent changes in federal law that allows for NPs and PAs, rather than physicians, to order all manner of home care services; federal regulations that grant states discretion as to when to require physician signatures on orders for PCS and CDPAS (42 C.F.R. § 440.167(a)); and the general scope of expansion authority of PAs and NPs in New York State to engage in independent clinical practice without the direct supervision of, or collaboration with, a physician. The IPP requirements will indicate that NPs and PAs hold appropriate licensure and credentials under the State Education Law; to the extent that other requirements on NPs and PAs become necessary, the Department will address this comment in guidance or future rulemaking.

Comment: One commenter indicated that State Law does not permit substitution of an NP or PA for a physician when ordering PCS or CDPAS.

Response: The Department disagrees with this understanding by the commenter. As noted in the last Assessment of Public Comments, the Department believes not requiring a physician signature on the order form in these cases is consistent with recent changes in federal law that allows for NPs and PAs, rather than physicians, to order all manner of home care services; federal regulations that grant states discretion as to when to require physician signatures on orders for PCS and CDPAS (42 C.F.R. § 440.167(a)); and the general scope of expansion authority of PAs and NPs in New York State to engage in independent clinical practice without the direct supervision of or collaboration with a physician.

Comment: One commenter claimed that the imposition of the IRP was in violation of federal law, as it discriminates based on a person's needs, and was not authorized by State statute.

Response: The Department disagrees with these comments and does not believe any changes to the regulations are required. First, Section 2 of Part MM of Chapter 56 of the Laws of 2020 amends Section 365-a of the Social Services Law to authorize the Department to adopt standards regarding the review of individuals whose need "exceeds a specified level" of services, "determined by the commissioner" to determine whether these individuals are "capable of remaining safely in the community," consistent with federal law. Personal care services are delivered through CDPAP, and so it is not only appropriate but required that the standards that apply to personal care services described in Section 365-a would apply to those same services when delivered through CDPAP, unless otherwise provided in statute. Contrary to the commenters' unsupported statutory construction argument, Section 365-f provides no such override to the provisions in Section 365-a with regards to higher needs review. Second, the Department disagrees that subjecting only higher cases to the IRP is discriminatory, as this application is a reasonable review of cases based on the standards of remaining in the community and the legislative mandate. Under the commenter's construct, any utilization review of services could potentially violate federal law, which is certainly not the case based on the latitude afforded by federal law and CMS in a state's determination of medical necessity criteria to Medicaid services.

Comment: One commenter requested that an MMCO or LDSS "must" create a temporary plan of care prior to referring a case to the IRP.

Response: The Department declines to adopt this standard, as it remains within the MMCO's or LDSS's reasonable discretion to determine when a temporary plan of care is needed to ensure adherence to federal and state timeframes for issuance of a service authorization. Given that the IRP's recommendation is intended to help inform the service authorization, the Department wants to encourage the IRP to review the case prior to any service authorization, where possible.

Comment: Commenter objected to the delay in the IRP's review until an individual is enrolled or scheduled to be enrolled in an MMCO.

Response: The Department does not understand the basis of the commenter's concern. The purpose of requiring the MMCO to pend referral to the IRP until the individual is enrolled or scheduled to be enrolled in the MMCO is to prevent the unnecessary duplication of reviews by the IRP, where a potential member requesting proposed plans of care from multiple MMCOs prior to enrollment in any one of them.

Comment: Commenters requested confirmation that the MMCO or LDSS does not need to agree with the recommendation of the IRP, and adjust the plan of care accordingly.

Response: The Department confirms that the IRP's recommendation is just that -- a non-binding recommendation to the MMCO or LDSS as to whether the plan of care is appropriate to keep the individual safe in the community.

Comment: The Health Plan Association sought further instruction from the Department whether MMCOs must inform their members of the IRP's recommendations.

Response: The Department does not believe the regulations need to be clarified; however, it will consider providing additional guidance or outreach to assist MMCOs and LDSSs in incorporating the new IRP processes into their authorization procedures. Because the MMCO or LDSS is required to consider the IRP recommendation, it will automatically become of any decisions record. Accordingly, if a member challenges the determination, the MMCO or LDSS would need to provide the IRP recommendation to the individual as part of the case record.

Comment: Health plan commenters requested clarity whether an IRP referral should wait until a member elects to enroll in a particular plan.

Response: The Department believes that the regulations are sufficiently clear. The IRP process is not intended to occur until a consumer has selected an MMCO and is scheduled to be enrolled. The consumer must be enrolled or have selected the MMCO that they want to enroll in and the MMCO received confirmation that enrollment will be processed on a date certain by the enrollment broker. The Department previously revised

the proposed regulations to indicate the relationship between enrollment and the role of the IRP and will review whether additional guidance is needed.

Comment: Commenters sought further clarity on timeframes for IRP review, especially in the cases in change of condition assessments that required an expedited assessment.

Response: As stated in the current draft of the regulations, the IRP's review will be done expeditiously, and MMCOs or LDSSs may authorize up to 12 hours of services per day pending the IRP recommendation or, if needed to comply with federal and state timeliness requirements, may issue a temporary authorization pending review by the IRP in these instances, such that further changes to the regulations are not warranted.

Comment: Commenters requested that the Department issue further guidance to MMCOs and LDSS on the workflows and systems that govern IRP implementation.

Response: This comment requests guidance that extends beyond any changes to the regulations; however, the Department acknowledges that it will issue additional guidance on the IRP process and workflows to facilitate implementation of this component of the SFY 2020-21 budget initiative.

Comment: One commenter requested the Department allow authorization without an IRP recommendation where the mental status and physical condition is unchanged and there is no change in the service authorization.

Response: The Department received this comment in response to the original proposed rulemaking and agreed with it. Moreover, the rule was previously amended such that the IRP recommendation is not needed again for authorization as long as the individual remains a high needs case.

Comment: Commenters wanted temporary plans of care to be issued by MMCOs or LDSS prior to the IRP in all cases, as a requirement.

Response: The Department disagrees with the comment and did not make a revision to the regulations because temporary plans of care should be issued in those cases where the circumstances warrant, as ideally the service authorization should be informed by the recommendation of the IRP, where possible, consistent with legislative enactment from the SFY 2020-21 enacted budget.

Comment: Commenters recommended that the Department specify the number, qualifications, and type of clinicians who may serve on the IRP, beyond the lead physician, as a larger panel may create scheduling difficulties and create delays in authorization.

Response: Similar to the Department's response to the earlier rulemaking, it reasonably believes flexibility on the composition of the IRP is necessary to promote the requisite level of experience that will inform a robust and meaningful independent review of these

high needs cases. Accordingly, the Department does not believe that restricting the panel size achieves the intent of the legislative authorization for this review and has determined that no changes to the regulations are needed. That said, the Department previously made other changes to the regulations, including permitting MMCOs and LDSS to issue temporary plans of care, and to begin service, when IRP review is required to avoid delays when federal or State timeframes, including those for immediate needs cases, may otherwise be impacted. These previously changes address these comments.

Comment: One commenter once again asked whether an IRP occurs when hours have already been authorized above the high needs hours threshold, and the consumer has been reassessed and authorized to require the same level or more services. Given this question, the commenter requested that the regulations further clarify that IRP reviews are not required during these service reauthorizations.

Response: Previously, revisions to the proposed regulations clarified that an IRP does not occur under these circumstances. These clarifications noted that if the consumer is already above the high-hours threshold through an authorized plan of care, and then a subsequent plan of care renewal does not modify the authorized hours or retains hours that are above that threshold, then the IRP does not review the plan of care. However, if a consumer is above the threshold, then dips below the threshold as part of a subsequent reassessment, and then crosses the threshold again as part of another assessment and plan of care development, the IRP review would occur once the consumer crosses the threshold again.

Comment: A commenter requested further language clarity that IRP review is required after an individual's service authorization decreases below a service authorization and then increases above the threshold across multiple service authorizations.

Response: The Department believes that the proposed regulations are sufficiently clear in this regard, and declines to adopt further language clarifications, which are unnecessary to the rulemaking.

Comment: One commenter sought further clarification on when it is permissible to "close" a case upon reassessment if the IA is unable to complete the required reassessment in a timely manner, especially for vulnerable individuals who may be at risk

Response: The Department appreciates the commenter's concern about completing timely assessments for individuals who may be at risk; however, the regulations reflect that in certain instances, with the assistance of the LDSS or MMCO for outreach, the IA will be unable to complete a reassessment for that member. To the extent necessary, the Department or the IA will issue guidance to LDSS and MMCOs about these circumstances and how to ensure that reassessments are completed whenever possible.

Comment: Commenters asserted that Section 2 of Part MM of Chapter 56 of the Laws of 2020 did not authorize the IRP to apply to services authorized under CDPAP, and thus the IRP should not apply to this program, but PCS only.

Response: The Department disagrees and reads the legislative authority to establish assessment and approval processes for services as applicable to all Medicaid services, including PCS and CDPAS. Accordingly, the Department has determined that no changes to the regulation are needed.

Comment: Commenters once again argued that the IRP's review is duplicative and unnecessary, especially given that the IRP is making recommendations, rather than specific service authorizations.

Response: Consistent with Section 2 of Part MM of Chapter 56 of the Laws of 2020, the IRP is intended to act as an additional clinical review for cases that rise above a certain needs threshold, as measured by whether the LDSS or MMCO is prepared to authorize more than 12 hours per day on average. This additional clinical review differs from the IA because the reviews have special qualifications to ensure that the highest needs cases are reasonable and appropriate to maintain the consumer's health and safety in the home or community. The Department disagrees that the IRP does not serve as useful function in enhancing the LDSS's and MMCO's care planning process simply because the IRP does not draft a specific plan of care or recommend a specific number of hours. The recommendation alone that the plan of care is or is not reasonable and appropriate (or the recommendation of additional, alternative, or fewer services) will assist the LDSS or MMCO in confirming their own clinical assessment, or identifying high needs cases that

the LDSS or MMCO may need to review differently. The Department has determined that no changes to the regulation are needed in response to this comment.

Comment: One commenter sought clarification from the Department that would prohibit an MMCO or LDSS from identifying the number of hours required by an individual, but approving less, such that the individual or their family would have to cover the remaining hours.

Response: At the outset, the Department notes that the regulations do not change any requirements on MMCOs and LDSS with regard to what may be considered in the course of developing a plan of care and authorizing specific service hours based on informal supports, or otherwise. To the extent that the commenter is concerned about how an MMCO or LDSS accounts for informal supports, the Department draws the commenter attention to the parts of the regulations that have continuously required LDSS and MMCOs to consider informal supports where they are willingly provided and able to meet the individual's needs. LDSS and MMCOs responsibility to undertake this assessment and schedule informal supports where they are available, willing and accepted, remains unchanged. In the prior version of the regulations, the Department responded to past comments to add specific language that the LDSS or MMCO must “confirm the caregiver’s willingness” to meet the needs of the consumer in the plan of care. Accordingly, the Department does not believe that any further changes to the regulations are needed.

Comment: One LDSS commenter requested removal of the ability of the LDSS or MMCOs to issue provisional or temporary authorizations pending IRP review, as the LDSS believes it could increase fair hearing requests and it would be impactful to change its authorization once issued.

Response: The Department appreciates these concerns from the LDSS, but believes that preserving this flexibility is important to ensure that the IRP is provided an opportunity to review high hours cases in connection with the service authorization process, while at the same ensuring that a consumer can begin services within the federal and state required timeframes. The Department reminds the LDSS that the IRP's output is a recommendation, such that the LDSS may choose how to consider that recommendation in connection with current service authorization activities, if at all.

Comment: Commenters once again asked the Department to clarify whether the decisions of the IRP are, in fact, “recommendations” that are not appealable by the member. Relatedly, commenters asked the Department to confirm whether the IRP is able to recommend specific hours of PCS or other CBLTC services in connection with its review.

Response: With the clarifications previously provided, the Department believes it is sufficiently clear that the IRP is issuing “recommendations,” rather than authorizations and determinations, or binding in any way on the service authorizations issued by MMCOs or LDSS. The MMCO or LDSS must then review and consider this

recommendation to inform changes to the plan, especially if those changes will enable the member to remain in the community. The Department retained the language in the original regulations that the IRP cannot recommend specific care hours, as the process of determining care hours is best performed through the MMCO's or LDSS' care planning process, which may use a tasking tool (until a uniform tasking tool is implemented), or other techniques for determining care hours. The legislative intent behind the creation of the IRP, as set forth in Section 2 of Part MM of Chapter 56 of the Laws of 2020, was not to replace the care planning process, which remains within the authority of MMCOs or LDSS. Rather, the goal is to help inform this process appropriately through a qualified and independent clinical review that will ensure a member can remain safely in the community. Accordingly, the Department believes that any comments about having the IRP recommend specific care hours would exceed the intent of the legislative authorization for this proposal.

Comment: Commenters asked the Department to confirm whether the IRP is able to recommend specific hours of PCS or other CBLTC services in connection with its review and requested that specific hours be recommended.

Response: The Department retained the language in the original regulations that the IRP cannot recommend specific care hours, as the process of determining care hours is best performed through the MMCO's or LDSS' care planning process. The legislative intent behind the creation of the IRP, as set forth in Section 2 of Part MM of Chapter 56 of the Laws of 2020, was not to replace the care planning process, which remains within the

authority of MMCOs or LDSS. Rather, the goal is to help inform this process appropriately through a qualified and independent clinical review that will ensure a member can remain safely in the community. Accordingly, the Department believes that any comments about having the IRP recommend specific care hours would exceed the intent of the legislative authorization for this proposal.

Comment: One commenter requested that the Department clarify that an individual may request a fair hearing prior to the recommendation of the IRP.

Response: The Department does not believe a clarifying change to the regulations are required. The provisions in question do not condition an individual's ability to challenge a decision on the occurrence of the IRP review. Rather, they make clear that if a fair hearing or other proceeding results in an order that requires the provision of more than 12 hours of care on average per day, an IRP review will not be required to sustain the authorization. Additionally, the IRP is making a recommendation, rather than issuing an authorization. Accordingly, the appeal rights of an individual occur once a determination is made by the MMCO or LDSS, which may occur before or after the IRP's review in certain cases.

The Department also believes that the IRP process helps to inform any challenges made by individuals in a fair hearing process, especially if the independent recommendations of the IRP were not accepted in the services authorization. Accordingly, the Department

believes it will benefit individuals to wait until after the IRP's recommendation is issued before proceeding with a fair hearing, when applicable.

Comment: One commenter asked that the IRP be given the consumer's preference in connection with its review, such that the required number of hours may be taken into consideration.

Response: The Department appreciates this request but does not believe a change to the regulations is required. Specifically, the IRP is not designed to perform a dispute resolution function; rather, the function is to ensure that the plan of care approved by the MMCO or LDSS is sufficient to keep the member safe in the community. Consumer preference is already considered as part of the plan of care development process by the MMCO or LDSS.

Comment: One commenter sought certain technical changes to confirm that involuntary supports need to be "acceptable to the client" and "have become available to meet some or all of the client's needs."

Response: The Department made these technical requirements to the regulations.

Comment: Commenters expressed concern that the regulations are not sufficiently clear in requiring documentation by the MMCO or LDSS of the availability and acceptability of informal supports by both the caregiver and the consumer, such that there is no coercion by MMCOs or LDSS. Commenters proposed various technical language revisions to help further clarify this regulatory intent. Commenters further noted that it is

similarly important that the MMCO or LDSS be required to document when there has been a change in the availability of informal supports for an individual before reducing services.

Response: While the Department appreciates these comments, it believes that the regulations are sufficiently clear in the voluntary nature of informal supports by both caregiver and consumer. In the prior version of these regulations, the Department added specific language that the LDSS or MMCO must “confirm the caregiver’s willingness” to meet the needs of the consumer in the plan of care. Additionally, as noted in the previous version of this rulemaking, the CHA tool includes an assessment of the availability and interest of informal supports from both the recipient and the caregiver. The proposed regulation specifically identifies the need for the IA to ascertain both the availability and interest on the part of the caregiver and the willingness to accept help from that person on the part of the recipient. The plan of care development process already requires the MMCOs and LDSS to document days and times of available informal supports and ensure that the recipient is willing to have the caregiver serve in that role and that the caregiver is both willing and available to serve. Accordingly, the Department does not believe that additional regulatory clarification is warranted beyond what was already provided in the prior version of this rulemaking and as described in the prior comment.

Comment: A commenter objected to the implementation of the IA until the CHA tool can be updated to better reflect the assessment of an individual's needs, including nighttime needs, which, according to the commenter, is not sufficiently captured with the

current CHA tool. Relatedly, other commenters raised concerns that reliance on the CHA tool is insufficient to ensure compliance with *Olmstead*.

Response: The regulations maintain the requirement to assess and document the frequency of needs throughout a calendar day for cases that involve live-in or 24-hour continuous care, and MMCOs and LDSS may assess and document such needs for other cases as well. As described in current guidance from the Department, this would include identifying night-time needs. These requirements work in concert with the current CHA tool, which has been used for years by MMCOs and LDSS and will now be used by the IA as the evidence-based validated assessment tool for determining needs for assistance with ADLs and IADLs. The Department has maintained the responsibility to assess frequency of needs with the MMCOs and LDSS because the current CHA tool does not ask these questions, and the Department does not have another evidence-based validated assessment tool that can be used for this purpose, as is required under Section 365-a(2)(e)(v) of the Social Services Law. To the extent that changes to the CHA tool itself are proposed, the Department has taken them under advisement, but has determined that such changes are not immediately needed to implement the IA.

Comment: One commenter suggests that the IA document whether a home health aide or personal assistant will be able to get sufficient sleep and meal breaks, and that the regulation should specify the consequences should this fail to occur

Response: Please see the previous response.

Comment: Several commenters cited *Olmstead* and the ADA in that the eligibility standards for the provision, management, or assessment of personal care services must consider whether an individual is capable of safely remaining in the community based on identifying actual risks, with their probability of occurrence, and considering whether reasonable modifications of policies, practices or procedures will mitigate or eliminate the risk. Similarly, comments expressed concern that institutionalization will increase for those with significant needs that fail to meet the new minimum requirements to be eligible for PCS or CDPAP.

Response: The Department notes that the changes being made to the regulations through this rulemaking do not affect in any way the need to ensure that determinations of whether someone can be maintained safely in their home or community-based setting are appropriately made. Rather, the rule is simply assigning some of these functions to new entities, in particular the IA, IPP, and IRP. Previously, the responsibility for making these determinations, from the initial assessment of need to the development of a plan of care and service authorization (or a refusal to authorize services based on a determination that someone cannot be maintained safely in the community) was all within the scope of either the LDSS or MMCO with the exception of the physician order.

By breaking up the various elements of the process across a number of entities, allowing each to more clearly focus on their particular aspect of the process, and requiring independent clinical judgment to inform the needs assessment, PO, and the IRP

recommendation, the Department believes that this rulemaking will lead to significantly improved standardization in the assessment and authorization of PCS and CDPAS around independent clinical judgment of what is necessary to ensure individuals' health and safety in the community. In particular, the creation of the IRP ensures that the most vulnerable individuals will receive a more thorough review of the actual proposed plan of care, to evaluate whether the risks to the individuals' health and safety are being appropriately addressed. While the authorization determination remains with the LDSS or MMCO, the Department believes this additional review is a clear improvement on the existing structure for decisions by both the LDSS or MMCO, and helps the State maintain compliance with *Olmstead* and the ADA.

That notwithstanding, the Department has incorporated the requirements that the standards used to assess needs for services comply with *Olmstead* and is developing policies to ensure reasonable accommodations are made where the application of the State's medical necessity criteria may pose an unreasonable risk of being unable to remain in the home or community-based setting for an identifiable population.

Specifically, the Department is issuing guidance and materials to ensure that those with serious mental illness that significantly affects their abilities to perform major life activities can demonstrate a need for services when their assessment indicates a need for at least supervision and cueing with more than one activity of daily living.

Comment: Commenters sought further technical clarification in the regulations regarding how the MMCOs and LDSS should consider consumer preference when

engaging in person-centered service planning for individuals who are currently residing in an institution. Specifically, these commenters sought clarification on whether consumer preference should be expressly stated in the regulations as a criteria for returning to the community, whether the individual needs to be affirmatively seeking a transition into a less restrictive setting, whether a consumer's health and safety being maintained needs to be an express condition of this determination, and whether the standard for "health and safety" needs to reference existing Departmental guidance on the standard to be used by MMCOs. See DOH, *Guidelines for the Provision of Personal Care Services in Medicaid Managed Care*, May 31, 2013, at p. 7 (denial appropriate if “health and safety cannot be reasonably assured”), at https://www.health.ny.gov/health_care/medicaid/redesign/docs/final_personal_care_guidelines.pdf.

Response: The Department generally agrees with commenters that the act of being evaluated for the need for services is sufficient indication to imply that the individual was in fact seeking services. However, the Department must point out that this does not imply that they were seeking to transition into a less restrictive setting, where such services are available. In fact, the *Olmstead* court and the ADA expressly note this possibility. *Olmstead v. L. C. by Zimring*, 527 U.S. 581, 602, 119 S. Ct. 2176, 2188 (1999) (citing 28 CFR § 35.130(e)(1) (1998)); see also 42 C.F.R. § 12201(d). It is also the case that individuals may seek services and begin the authorization process and then change their minds before the LDSS or MMCO reaches a determination. Additionally, the Department is providing a technical amendment to the regulations to indicate that denials

based on health and safety must be "reasonably assured," which is consistent with longstanding application of existing guidance.

Comment: Commenter requested clarification on how a determination of appropriateness and cost-effectiveness will be done, given that the regulations did not change the Assisted Living Provider (ALP) and enriched housing assessments. These commenters pointed out that any requirement that consumers move from their homes to these alternative housing programs would violate person-centered service planning and *Olmstead*, notwithstanding the fact that many of these programs have limited availability even if a consumer agreed to transition to them.

Response: Consumer choice will always remain a priority in service authorization within available ALP and enriched housing options. These considerations are not new to the proposed regulations and continue to require MMCOs and LDSS to consider a range of services and supports, including ALPs and enriched housing, that may be appropriate in conjunction with consumer preferences. The Department has determined no changes to the regulation are needed.

Comment: Commenters requested that the regulations expressly state that an MMCO cannot reduce an existing service authorization upon enrollment because it would constitute a reduction in the scope of services available to Medicaid recipients.

Response: The Department has not made any changes in response to this comment as the commenter mistakenly conflates determinations based on medical necessity with determinations based on the scope of services available under the Medicaid program.

Comment: One commenter wanted further clarification in the regulations regarding the exemption of Programs of All-Inclusive Care for the Elderly (PACE) enrollees from the minimum needs criteria.

Response: As contained in the Assessment of Public Comment from the Department's prior revisions to these proposed regulations, the Department agrees that federal regulations govern eligibility for PACE Organization enrollment, but will consider whether PCS or CDPAS authorized by a PACE Organization is subject to different needs criteria through subsequent guidance informed by the Department's review of federal rules to this effect. Accordingly, no further changes to the regulations will be made as part of this rulemaking.

Comment: Commenters objected to perceived changes in the regulation that would no longer require an LDSS or MMCO to notify the individual of a change in amounts of services.

Response: The Department clarifies that the regulations do not change these notification obligations on MMCOs or LDSS.

Comment: Commenters sought further revisions to the regulation with regard to how strongly an MMCO or LDSS must consider consumer preference over the cost effectiveness of certain authorized services, proposing that a prioritization of consumer preference will prevent arbitrary reduction of services.

Response: The Department's response to this comment is similar to the prior version of these regulations in that these regulations do not amend any of the current regulatory provisions or definitions regarding the determination of cost-effectiveness as it relates to the authorization of services, except to the extent that the amendments re-designated and streamlined many provisions. In general, the requirements of what LDSSs and MMCOs must consider in reaching an authorization has not changed, with the exception that some portions of the assessment are now conducted by the IA. The Department remains concerned with the indication by some commenters that portions of the regulations related to the determination of cost effectiveness are not being observed in apparent attempt to comply with caselaw, which may appear to create arbitrary decisions by MMCOs or LDSS. However, other than removing the initially proposed requirement in the earlier revised regulations that MMCOs and LDSS first consider cost effectiveness in developing the plan of care, the Department believes that the regulations appropriately describe the person centered service planning responsibilities of MMCOs and LDSS, in that they must balance considerations of cost-effectiveness with available alternatives, social and cultural consideration, and consumer preferences. Given this balancing, the Department does not feel it is necessary to specify a further process for balancing these interests in these regulations.

Comment: One commenter queried why the regulations were revised to require review of only the "most recent" assessment.

Response: The Department used "most recent" in the regulations to indicate that it is this assessment, and the members conditions set forth in that assessment, that should inform the plan of care. MMCOs and LDSS are able to consider collateral information, including health records furnished by the individual being assessed, as well as past assessments in informing the plan of care, but it is required that the most recent assessment be considered, which is reflected in the regulations. Accordingly, the Department has not further revised the regulations in response to this comment.

Comment: Commenters recommend the designated representative language in CDPAP regulation (18 NYCRR § 505.28(g)(2)) also be included in the PCS regulation (18 NYCRR § 505.14).

Response: A designated representative under PCS does not have the same responsibilities as the designated representative does for CDPAP, such that this recommended change would create more confusion between these roles and the Department has declined to adopt it. The Department has determined that no changes to the regulation are needed.

Comment: Health plan commenters asked whether it would be appropriate for an MMCO to ask a prospective enrollee for additional information or medical record documentation in connection with developing the plan of care.

Response: This question is not germane to the current rulemaking, as the person-centered service planning requirements have not changed as a result of these regulations. Accordingly, MMCOs should follow federal and state rules on person-centered service planning, consumer outreach, and marketing with regard to the information or documentation sought in connection with this process. The regulations do not impact these requirements and thus no changes are required.

Comment: One commenter requested that the Medicaid premiums of MLTC plans should not be adjusted as MLTC plans are required to perform substantial functions, including notification, cooperation, and coordination among the IA, IPP, and IRP, which are resource intensive and require plan expenditures that should be reflected in the actuarially sound premium.

Response: The Department appreciates this comment. Consistent with federal rules requiring actuarial soundness of MMCO rates, the Department strives to ensure adequate reimbursement of required plan functions. The purpose of the IA process, consistent with Section 2-a of Part MM of Chapter 56 of the Laws of 2020 is to transition the entirety of the assessment function from MMCOs, including MLTC plans, to the IA. The Department's independent actuary will consider the retained plan functions in

determining the appropriate premium to certify to CMS, in accordance with actuarial soundness principles, but such consideration will not include conducting assessments that are now the responsibility of the IA.

Comment: Commenters asked whether the Department would ensure confidentiality and privacy of medical record information exchanged by the individual's treating physician.

Response: The Department is developing processes in connection with implementation to ensure that any medical information is securely transmitted and follows appropriate patient consent in accordance with federal and state laws, including Section 33.13 of the Mental Hygiene Law, 42 CFR Part 2 and Article 27F of the Public Health Law.

Comment: One commenter requested that agency staff be able to provide practitioner orders for PCS and CDPAP in addition to the IPP.

Response: The Department appreciates this comment but has been directed by virtue of Section 2 of Part MM of Chapter 56 of the Laws of 2020 to have practitioner orders written by "qualified independent" clinicians. Accordingly, the Department does not possess the ability to expand who can issue these orders beyond this group.

Comment: Health plan commenters asked for clarification as to whether "new to MLTC" members will be assigned to an MMCO or if they will be referred to the IA first.

Response: The Department appreciates this comment but notes that these topics can be addressed in guidance to MMCOs and LDSS regarding assignment and referrals.

Comment: Health plan commenters asked how complaints regarding past service authorizations will be documented by the IA during the course of reassessments.

Response: The Department appreciates this comment but notes that these topics can be addressed in guidance to MMCOs and LDSS regarding how this information can be most effectively conveyed to MMCOs and LDSS that are completing service authorizations.

Comment: Commenters raised concerns that providing the IA with an additional ten (10) days in the event that the MMCO or LDSS raise a clinical dispute with the IA will prevent the MMCO or LDSS from completing a timely service authorization under federal and State requirements.

Response: As previously provided by the Department in the prior Assessment of Public Comment, the dispute resolution set forth in the proposed regulations does not modify the required timeframes for issuing an authorization following the completion of the CHA by the IA. Accordingly, the processes established by the regulations must occur within these timeframes. When requesting a second assessment due to a clinical disagreement, the IA have up to ten (10) days from the date it is notified by the LDSS or MMCO to schedule and complete a new assessment. Based on the Department's review of the federal requirements, including those under 42 C.F.R. Part 438, regarding the timeframes

required to issue a service authorization, there will be adequate time in most instances for the MMCO to request a second assessment for consideration in the service authorization process; however, the ability to meet these timeframes will need to be a consideration for when an MMCO may make this request. Not extending the timeframe for issuing the service authorization if there is a clinical dispute was an important consumer protection that the Department did not change as part of these regulations.

Comment: Health plan commenters seek additional guidance regarding the file transmission process between the IA and MMCOs, including when files get transmitted in the course of the member enrollment process.

Response: The Department appreciates this comment but notes that these topics can be addressed in guidance to MMCOs regarding how and when MMCOs should be transmitting information and sending files to the IA for assessments to be conducted.

Comment: The Department received many comments on the proposed process by which the IA would resolve factual errors or clinical inaccuracies in the completed CHA, as identified by the MMCO, LDSS, or the consumer. One commenter sought to require the IA and the MMCO or LDSS, as applicable, to seek consumer input and documentation to help resolve the dispute.

Response: The Department did not change the regulations, as consumers are necessarily part of the assessment process, with consumer input being solicited as part of the CHA

tool. However, consumers do not usually have an additional role in review of the accuracy of the CHA, as that document is a technical assessment tool and used by the LDSS or MMCO to develop the plan of care, which is when the consumer has an opportunity to review their service authorization, including through a fair hearing, if necessary.

Comment: Commenters recommended that the consumer be permitted to have a representative present at their assessment in alignment with person-centered service planning requirements under federal regulations, as well as have access to a copy of the completed CHA.

Response: The Department agrees that person-centered planning requirements at the federal and State level require that an individual may request the participation of family members, caregivers, and professionals in their care plan development. The Department confirms that neither the current nor proposed regulations prohibit the participation of representatives in the assessment process. Accordingly, the Department has determined no changes to the regulation are needed. Departmental policy does not currently permit the consumer to receive a copy of their completed CHA in the normal course, as the plan of care (rather than the CHA) is the operative document to inform service authorizations and determinations by the LDSS and MMCOs and informs appeal and fair hearing rights. The Department does not intend to revisit this policy as part of the transition to the IA process.

Comment: Commenters requested the Department should require the presence of the designated representative for a non-self-directing consumer for any scheduled assessment or visit by the independent assessor, examining medical professional, social services district staff, or MMCO staff. The designated representative must be allowed to participate by other means such as telephone, telehealth, or video call.

Response: Consistent with past practice, the IA will schedule assessments based upon consumer and, if applicable, designated representative availability. As the designated representative is responsible for fulfilling the consumer's responsibilities under the consumer directed model and Section 365-f of the Social Services Law, it is imperative that they be involved in this process, including the IA, IPP, care planning, and IRP, if applicable. As reflected by the COVID-19 pandemic, the Department agrees that flexibility is critical in ensuring services remain available to those in need. This flexibility allows participation by designated representatives in assessments, IPP medical examinations, or the IRP examinations via telehealth methods. However, such participation must still comply with the roles and responsibilities of the designated representative, as set forth in other State statutes, regulations, and guidance. The Department has determined that no changes to the regulation are needed

Comment: Commenters sought further clarification as to the use of telehealth for assessments conducted by the IA after the end of the COVID-19 public health emergency, including information regarding consent to telehealth assessments and how that consent will be obtained.

Response: As stated in the prior Assessment of Public Comments, based on the Department's experience through the COVID-19 pandemic, consumers expressed positive experiences with the ease and convenience of using synchronous telehealth modalities to conduct an assessment or reassessment for that consumer, rather than conducting all assessments through an in-person, face-to-face visit. Accordingly, in operationalizing the IA process, the proposed regulations were previously amended to contemplate that the Department will encourage the IA to offer synchronous, audiovisual telehealth assessments to willing consumers as an alternative to in-person face-to-face, where appropriate, which can increase consumer convenience, especially in rural areas. This willingness will be gauged by the IA through an educational and informed consent process during the initial outreach between the IA and the consumer. The Department will consider whether such consent may be written or oral, but such record will be documented. Such requirements are not required to be incorporated in this rulemaking.

Comment: One commenter objected to the fact that the care planning process in the regulations did not change, believing that the IA should make the final determination regarding service authorization, consistent with its role of preserving independence in the needs assessment process.

Response: The Department appreciates this comment but has not updated the regulations because the legislative authorization for the IA in Part MM of Chapter 56 of the Laws of 2020 was intended to cover the assessment process, but not the service authorization.

Accordingly, the Department believes that the current regulations best reflect the legislative intent for the role of the IA.

Comment: Commenters asked for clarification on the relationship between waiver services available under 1915(c) programs and person-centered service plan requirements and whether waiver services supplant personal care services.

Response: The regulations do not change the requirements around person-centered service planning and the available services that the member is accessing. This regulation also does not affect the eligibility of any 1915(c) waiver participant for any applicable waiver services.

Comment: Commenters requested that the regulations retain the ability of the individual's community physician to issue authorizing orders.

Response: As required by Section 2 of Part MM of Chapter 56 of the Laws of 2020, orders for PCS and CDPAP must be issued by an independent practitioner selected by the Department. Accordingly, the Department does not have the discretion to create an alternative process when an individual may prefer their own physician who is not independent.

Comment: Commenters questioned whether the independent assessor is actually "independent" if they are paid by the Department and thus incentivized to issue service denials.

Response: The Department respectfully disagrees with these comments for several reasons. First, the IA does not approve or authorize services and thus, does not issue service denials as indicated by this comment. Second, this construct of independence has been adopted by CMS and other federal agencies in meeting conflict-free requirements, including within New York's 1115 waiver requirements that govern MLTC benefits. Finally, the independence of the IA assessment function is now separate from the service authorization process, for the very reasons stated by the comment, such that the IA has no incentive to do anything but timely and perform assessments accurately, as their total payment does not change based on the services actually authorized.

Comment: One commenter suggested that the transition to the IA will add substantial costs to the administration of Medicaid benefits because contract costs will increase.

Response: The Department disagrees with this comment and relies on its projections that this process will streamline processes by reducing the need for multiple assessments when members seek services from MMCOs or LDSS and by separating the assessment and service authorization functions. While there may be an increase in contract costs, there will be an overall Medicaid savings based on this change in process.

Comment: One LDSS commenter wanted more regulatory clarity, without specifying the nature of such proposed clarifications, regarding the transition of assessments from the LDSS to the IA to ensure that all assessments and new applications are conducted timely.

Response: The Department appreciates this comment and agrees that a seamless transition between the role of the LDSS/MMCOs regarding assessments and the IA is essential but disagrees that the regulations require further specification regarding how the Department will manage that transition. Such specification and clarification will be managed through guidance, information, and training to LDSS and MMCOs.

Comment: One commenter requested that the IA and the CHA tool elicit information regarding the consumer's service preferences and frequency of needs in connection with completion of the CHA.

Response: The Department disagrees with the comment, in that soliciting the preference of the consumer in terms of their requested schedule for PCS or CDPAS, or other Medicaid or MMCO benefits to which they be entitled, exceeds the role of the IA and interferes with the Person-Centered Services Planning process required of MMCOs and the plan of care development process performed by LDSS. Moreover, the IA will use the current CHA tool, which has been used for years by MMCOs and LDSS and will now be used by the IA as the evidence-based validated assessment tool for determining needs for assistance with ADLs and IADLs.

Comment: One commenter sought confirmation that the assessment conducted by the IA will remain valid for 75 days, as it is today.

Response: Although not within the scope of these regulations, the Department notes that the policy that allowed CFEEC assessments to be valid for 75 days for the purpose of determining enrollment into an MLTC Plan will not apply to assessment performed by the IA. The Department currently intends for this assessment to continue to be valid for 12 months for eligibility purpose to allow the same assessment to be used as the basis for both a service authorization and plan enrollment. The Department reserves the right to reconsider this decision through the issuance of guidance, as appropriate.

Comment: Plan commenters requested clarification regarding how the IA and MMCOs would communicate regarding potential discrepancies.

Response: The regulations do not require an amendment to address this question. The Department will continue to refine the points of contact between MMCOs or LDSS and the IA to ensure a smooth and clear communication process and may issue guidance if needed.

Comment: Plan commenters sought confirmation that there were no changes that would limit their ability to capture "prospect data" prior to the IA.

Response: The Department has not imposed any new requirements or restrictions on capturing prospect data, as compared to the current rules and limitations.

Comment: Health plan commenters sought additional detail about the data feeds from the IA regarding the completion of the assessment process, including whether information other than the UAS-NY output will be received.

Response: The Department appreciates the desire of health plans and LDSS to understand more about the specific data feeds and information, but these questions and discussions are, by definition, not addressed in the regulations and are more appropriate for guidance outside of the rulemaking process.

Comment: Commenters expressed a need to have the regulations be more specific on the timeframes and content of the notices that the IA will issue when an individual is deemed not to have met the minimum needs criteria for PCS or CDPAS, including the party responsible for providing the written notices, information on consumer appeal rights, and whether the appeal is against the LDSS or the IA. Commenters also asked for clarification on whether an individual would have to exhaust the MMCO internal appeal process if the IA assessment results in the individual not meeting the criteria for MLTC enrollment.

Response: As indicated in the prior Assessment of Public Comment in response to similar concerns expressed by commenters, the IA will advise those assessed of their options and assist them in enrolling in an MMCO, including an MLTC, or refer them to the LDSS for services and supports under fee-for-service. In cases where the individual is not eligible for MMCO enrollment or for PCS or CDPAS on initial request, the IA will generally provide notice and appear at any resulting fair hearings, if necessary. For IA and PO results that could lead to a disenrollment or a termination of services, the IA will provide appropriate oral and written communication, with notice and appeal or fair hearing rights coming from either the MMCO, LDSS, or Enrollment Broker as appropriate based on the particular action(s).

Even when the due process notice is not provided directly by the IA, the Department will work with Office of Temporary and Disability Assistance (OTDA) and stakeholders to ensure that the IA is made aware of any fair hearings, and makes itself available as appropriate to ensure the timely completion of such process.

To ensure that each entity understands its roles in every context, the Department will issue guidance on its website prior to the implementation of the IA and new ADL criteria, as it has committed to do for other components of the regulations, to ensure that all stakeholders understand their expected roles and responsibilities, have enough time to develop notices for these purposes, and that these regulations comply with applicable MOE requirements. Additionally, the Department is setting the effective date of these

regulations to begin on the 60th day following publication of the Notice of Adoption in the New York State Register and will issue guidance in accordance with 505.14(b)(8) and 505.28(m) to pend implementation of the IA or minimum needs criteria if needed to provide time to ensure stakeholders have been apprised of their roles in this process. However, no new rules are needed for implementation.

The Department also appreciates the commenters pointing out that determinations on MLTC enrollment, either denials or disenrollment, are not benefit determinations and are not normally subject to internal appeal exhaustion requirements. Given the potential for misalignment in the appeals process, the Department is considering whether the exhaustion of the internal appeals process should be required to ensure effective judicial administration of actions that may affect both benefits and enrollment. The Department is also reviewing whether amendments to other provisions of regulation such as 18 NYCRR 360-10.8 would be needed to align these processes.

Comment: One commenter requested that the Department permit the IA to contract with LHCSAs for nurse assessors.

Response: The rule does not require nor preclude the IA from contracting with LHCSAs or CHHAs to assist in the performance of IA functions, although such entities are precluded from being selected by the Department as the IA under state law. The Department also has conflict of interest concerns with allowing the IA to contract with LHCSAs or CHHAs that would perform assessments on behalf of the IA, as they may

also have relationships with LDSSs and MMCOs in the individual's service area, or be serving the individual directly, both of which would call into question the provider's independence. While conflict of interest controls could mitigate this, the Department does not see such a policy, which may impose burdensome and complex reporting requirements, as necessary unless dictated by a lack of availability of assessors. The Department has determined that no changes to the regulation are needed at this time.

Comment: One commenter requested clarification on the need of MMCOs to conduct nursing supervision visits, as the commenter did not believe the obligation applies to MMCOs previously.

Response: Under the proposed rules, the need to ensure appropriate nursing supervision applies to both LDSSs and MMCOs. This requirement is not new for MMCOs which have been required to provide Medicaid services in accordance with all applicable requirements. See NYS DOH, *Guidelines for the Provision of Personal Care Services in Medicaid Managed Care*, May 31, 2013, at pp. 8-9, available at https://www.health.ny.gov/health_care/medicaid/redesign/docs/final_personal_care_guidelines.pdf.

Comment: Commenters raised concerns with the method by which the UAS-NY CHA tool assesses need for PCS and CDPAS given the new minimum needs requirements and MLTC enrollment eligibility criteria that will be based on the output from the CHA.

Commenters felt that the CHA tool may not be adequate for these purposes and proposed a new workgroup to improve the UAS-NY and CHA tool.

Response: The Department reiterates its response from the prior Assessment of Public Comments in that the new proposed regulatory requirements work in concert with the current CHA tool, which has been used for years by MMCOs and LDSS, and will now be used by the IA as the evidence-based validated assessment tool for determining needs for assistance with ADLs and IADLs. The Department has maintained the responsibility to assess frequency of needs with the MMCOs and LDSS because the current CHA tool does not ask these questions, and the Department does not have another evidence-based validated assessment tool that can be used for this purpose, as is required under Section 365-a(2)(e)(v) of the Social Services Law. To the extent that changes to the CHA tool itself are proposed, the Department has taken them under advisement but has determined that such changes are not immediately needed to implement the IA.

Comment: In connection with the encouragement to use telehealth modalities where appropriate, commenters indicated that the regulations should make clearer that telehealth assessments may occur only with the express consent of the individual.

Response: The Department appreciates these comments but does not believe that changes to the regulations are warranted as the content requirements for telehealth services are already set forth in other provisions in New York laws with which the IA will comply. In accordance with past Medicaid Updates, including the May 2020

Comprehensive Guidance Regarding Use of Telehealth Including Telephone Services

During the COVID-19 State of Emergency, practitioners are required to "confirm the member's identity and provide the member with basic information about the services that he/she will be receiving via telehealth/telephone." Similar consent practices will be followed by the IA in connection with guidance and instructions issued by the Department.

Comment: Several commenters felt that telehealth assessments would not yield assessments that are as accurate as in-person, face-to-face assessments and should not be permitted as an option for assessments after the end of the Federal public health emergency.

Response: The Department appreciates this perspective on the concern regarding the quality of telehealth assessments as compared to traditional, in-person assessments. It does not believe any changes to the regulations are necessary, but clarifies in this comment that as part of the initiation of telehealth assessments it plans to work with interRAI, the developer of the CHA tool, to study the accuracy and quality of remote assessments. The ability to continue performing telehealth assessments will be subject to review and input of interRAI for the reasons stated in the comment, but the regulations must provide the authorization should telehealth assessments remain a possibility into the future, especially given the convenience and efficiency of this assessment modality.

Comment: Plan commenters sought expanded use of telehealth for their own care planning processes.

Response: These regulations do not address changes to the care planning process outside of the federal public health emergency. As stated in the prior Assessment of Public Comment, the regulations do not restrict LDSS or MMCOs from conducting person-centered service planning meetings, or other enrollment or related tasks, via telehealth modalities, absent other restrictions that may exist on this care planning or enrollment processes via other sources of authority or best practices. The Department also notes a prior recommendation from the Medicaid Redesign Team II that permits MMCOs to request additional flexibilities in the care management process, consistent with flexibilities in the CMS-approved model contracts. The Department continues to work with plans on these care management flexibilities, which are not related to the current regulatory development process associated with these reforms.

Comment: Plan comments sought permanent telephonic assessments. Other commenters sought to restrict use of telephonic assessments after the federal public health emergency.

Response: The Department will permit assessments to be conducted by the IA using synchronous, audio-visual telehealth modalities. After the rescission of guidance authorizing remote assessments in July 2021, the Department will not permit assessments to be initiated by telephone. The Department does not believe the regulations have to be further modified to make this position clearer.