REVISED 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)(13), (c)(8) are added to update the scope and eligibility 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)(11) 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)(vii) and 505.14(b)(4)(viii)(c)(3)(v) are amended to clarify that a denial may be made 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 maintained in such setting.

Sections 505.14(b)(4)(viii)(c)(3)(i) and 505.28(i)(4)(ii)(a) are amended to provide that services may be reduced or discontinued in cases where voluntary informal supports 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 be effective upon 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 is amended 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 while 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 <u>for the assessment</u> 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 by 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 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 a material error of fact or observation that occurred when the assessment was performed that is not subject to the assessor's clinical judgment. An error is a material error 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 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 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 an 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 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:

* * *

(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 maintained 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 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 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 maintained 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 subdivision 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) *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.

(10) *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.

(11) *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.

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

(13) *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)] (14) *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.

[(9)] (15) 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.

[(10)] (16) *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.

[(11)] (17) *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.

[(12) *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 by 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 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 a material error of fact or observation that occurred when the assessment was performed that is not subject to the independent assessor's clinical judgment. An error is a material error 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 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 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 (l) 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 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 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:

* * *

(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 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 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 subdivisions (d) through (f), (k) and (l) 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.

REVISED 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 be effective upon publication of a Notice of Adoption in the New York State Register or as otherwise provided in such publication of a Notice of Adoption.

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REVISED 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.

REVISED 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.

REVISED 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. During the public comment period, the Department of Health (the "Department") received over 200 comments from consumers of personal care services ("PCS") or consumer directed personal assistance services ("CDPAS"); Alleghany County; the law firm of Bond, Schoeneck & King PLLC; Center for Elder Law & Justice; Center For Independence of the Disabled, New York; Chautauqua County; Coalition of New York State Public Health Plans; Downstate New York ADAPT; Jewish Association for Services for the Aged; LeadingAge New York; the Legal Aid Society; Medicaid Matters New York; New York Association on Independent Living; New York City Department of Social Services; the New York Health Plan Association; New York Legal Assistance Group; New York State Association of Health Care Providers; New York State Bar Association; New York State PACE Alliance; Ontario County; Paraprofessional Healthcare Institute, Inc.; Putnam Independent Living Services; RiverSpring Health Plans; Schuyler County; Southern Tier Independence Center, Inc.; and Tioga County.

Substantive changes have been made to the regulations in light of the comments received. Other clarifications and technical, non-substantive changes have also been made.

All comments received were reviewed and evaluated. In response to the comments:

Sections 505.14(a)(9) and 505.28(b)(1) have been revised so that the definition of "activity of daily living" refers to the tasks and activities recognized as Activities of Daily Living (ADLs) by the evidence-based validated assessment tool that must be used pursuant to statute.

Subparagraph 505.14(a)(5)(iii) was revised to clarify that supervision and cueing may not be authorized, paid for or reimbursed, except if they are provided to assist with nutritional and environmental support functions or personal care functions.

Sections 505.14(a)(7) and 505.28(b)(11) have been revised to clarify that the term "MMCO" does not include an entity approved to operate a Program of All-inclusive Care for the Elderly (PACE) plan.

Section 505.14(b)(1) and the opening paragraph of section 505.28(d) have been revised to clarify that the independent assessment, medical examination and independent review panel may utilize telehealth modalities for all or a portion of such assessments.

Sections 505.14(b)(2)(i), 505.14(b)(4) and 505.25(d)(1) have been revised to clarify that the entity designated by the Department of Health to provide independent assessment services is responsible for determining whether the individual meets minimum needs criteria; and to clarify that the independent assessment must assess the consumer where the consumer is located, provided that the consumer's home or residence is also evaluated to support the proposed plan of care or to ensure a safe discharge.

Sections 505.14(b)(2)(ii) and 505.28(d)(2) have been revised to clarify that if a practitioner signs the medical order but is not the examining medical professional, such practitioner must also be independent; and remove the requirement for a medical order to determine whether an individual can be safely cared for at home and, instead, requiring a determination as to whether the individual is medically stable.

Sections 505.14(b)(2)(iii) and 505.28(d)(3) have been revised to move provisions related to the social services district or MMCO's responsibility to coordinate with the entity or entities providing independent assessment and medical order services, and to inform those entities when a new assessment or medical order is needed and of the findings of mistakes or inaccuracies with an assessment to sections 505.14(b)(2)(iv) and 505.28(d)(4). These sections have also been revised to require the social services district and MMCO to consider consumer preferences and social and cultural consideration in combination with other factors in developing plans of care; require social services districts and MMCOs to consider the availability of informal supports and confirm the caregiver's willingness to meet the identified needs in the plan of care for which they would assist; clarify that the development of a plan of care must be done in collaboration with the consumer; clarify that an MMCO should only refer high needs cases to the independent review panel if an individual is enrolled or scheduled for enrollment in the MMCO; and clarify that, irrespective of the independent panel's recommendations, the social services district or MMCO is responsible for determining the amount and type of services available.

Sections 505.14(b)(2)(iv) and 505.28(d)(4) have been added to provide a more comprehensive process for coordinating the independent assessment, medical order and social services district or MMCO responsibilities; resolving mistakes and clinical disagreements in the assessment process; and imposing sanctions for failure to cooperate during or abuse of the resolution process.

Section 505.14(b)(2)(v) and 505.28(d)(5) have been revised to clarify that the calculation for the high needs threshold is based on the authorization of personal care services, consumer directed personal assistance, or both; require the independent review panel to produce a report providing the panel's recommendation of whether the plan of care is reasonable and appropriate to maintain the individual's health and safety in his or her home; remove the requirement for the independent review panel to make a recommendation on whether other Medicaid services may be appropriate; and clarify that the independent review panel 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. However, the panel may not recommend a specific amount or change in amount of services.

Sections 505.14(b)(3) and 505.28(g)(1) have been added to provide timeframes for the assessment and authorization of services. These sections clarify that the independent assessment and medical order processes must be completed at least annually and in sufficient time to allow social services districts and MMCOs to, as needed, comply with

all applicable federal and State time frames for notice and determination of services. Section 505.28(g)(2) has been added to mirror language under section 505.13(b)(3)(ii), which requires that all determinations by the social services district must be made with reasonable promptness, not to exceed seven business days after receipt of both the independent assessment and medical order, or the independent review panel recommendation if applicable, except as provided under the immediate need process. Section 505.28(g)(3) has been added to mirror language under section 505.13(b)(3)(iii), which provides 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) and 505.28(e)(4) have been revised to require the social services district or MMCO to consider the recommendation of the independent review panel prior to authorizing more than 12 hours of services; allow the social services district or MMCO to authorize and implement services based on a temporary plan of care, pending review of the independent review panel's recommendations; and clarify that the maximum default authorization period is 12 months from the date of the most recent independent assessment or medical order, whichever is earlier.

Section 505.14(b)(4) has also been revised to clarify that a denial of services may be made based on residence in a facility if the client is not seeking to transition into a less restrictive setting or whose health and safety cannot be maintained in a less restrictive setting, and to clarify that, for high needs cases, reauthorization of services shall not

require another panel review as long as the case remains a high needs; clarify that 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 would be required.

Sections 505.14(b)(4) and 505.28(i) have been revised to allow the social services district or MMCO to reduce or discontinue services where voluntary informal supports have become available to meet some or all the client's needs.

Sections 505.14(b)(4) and 505.28(f) have been revised to clarify the specific instances when an independent assessment and medical order are needed to reauthorize or maintain an authorization for services (i.e., upon discharge from in-patient setting, upon certain unexpected changes in condition; and upon request from the consumer); and remove the requirement for review of appropriateness and cost effectiveness of services when the change in the individual's services needs results from a change in the consumer's mental status.

Sections 505.14(b)(6) and (7) have been revised to clarify that the statement of need that an individual is required to provide to the LDSS must be from a physician with direct knowledge of the applicant's condition.

Sections 505.14(b)(8) and 505.28(m) have been added to allow the Department of Health to continue to use the current assessment process until the independent assessment and medical order services are established.

Section 505.28(h)(3) has been revised to clarify that 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 of Health.

Several proposed revisions were not incorporated because they were not consistent with the statutory authority underlying the proposed rulemaking or concerned issues outside the scope of the proposed rulemaking. Other suggestions appeared to warrant further consideration for possible inclusion of future revisions to the regulations.

Comment: Many commenters indicated that the regulations did not include precise timeframes for completion of steps between referral of an individual for an assessment and completion of community health assessment (CHA) by the independent assessor (IA), to issuance of a service authorization by Local District for Service Services (LDSS) or Medicaid Managed Care Organization (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 independent review panel (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 and has revised the regulations 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. In implementing this regulatory requirement, the Department 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 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. While doing so would add specificity, it would do so at the cost of flexibility necessary to ensure adequate independent assessments. 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: Beyond comments seeking more specificity on the timeline for completion of the process steps, 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: In response to this and other comments regarding when a new independent assessment is needed, the Department streamlined and clarified the provisions in 18 NYCRR §§ 505.14(b)(4)(xii) & (xiii), and 18 NYCRR §§ 505.28(f)(1)(ii) & (f)(2) to clarify this process. 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: Several commenters suggested that immediate needs cases be given priority in the assessment process and delivered as expeditiously as possible. These comments further advised that individuals with immediate needs should not have to go through the multi-layered assessment process, but instead should have services authorized exclusively based on the order issued by their prescribing physician, rather than by the CHA completed by the IA and the medical order completed by the IPP.

Response: The Department appreciates these comments and has made various accommodations in the regulations, such that immediate needs cases are able to receive service authorizations consistent with the timeframes that currently exist in the regulations and provisional authorizations prior to the recommendation issued by the IRP, if applicable. However, 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 has revised the regulations to ensure the needs of these consumers are addressed timely, but retained the consistency of the IA and IPP processes, which the Department believes best implements the intent of the statute.

Comment: Approximately 113 commenters generally did not support the proposed PCS and Consumer Directed Personal Assistant Program (CDPAP) changes in minimum needs criteria. Specifically, these commenters noted their opposition for the elimination of Level I functions as part of the minimum needs criteria and feel these changes will lead to increased institutionalizations and decreased quality of life for individuals who no longer qualify. Additionally, these commenters expressed that the requirement of three ADLs is excessive, and individuals will ultimately be discouraged from seeking the help they need in their everyday lives.

Response: The Department appreciates these comments from consumers 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: Building on the earlier comments, other commenters noted that, should institutionalization of individuals increase, nursing home staff are trained mainly for senior care and do not know how to care for individuals with intellectual and developmental disabilities (I/DD). Commenters asserted that care in the nursing home setting is often inadequate, which leads to decreased lifespans and increased health issues.

Response: The Department thanks commenters for raising these issues. As noted above, in drafting these regulations to implement the legislative changes from the SFY 2020-21 enacted budget, the Department has remained cognizant of these concerns raised by the commenters and worked to preserve community based care and quality of life for consumers impacted by these changes.

Comment: Approximately 125 commenters believe proposed changes will create undue burden for individuals needing PCS and CDPAS. These comments highlighted that changes will increase stress on individuals who now must go through a more cumbersome process to prove the need for care under CDPAP. Furthermore, consumers will take on the burden of educating an assessor who has no knowledge of the consumer's health care needs to date. These comments also stated that these changes are

inefficient and invasive and will force individuals to accept types of care (i.e., assisted living, social adult day programs, etc.) with which they are not comfortable.

Response: The Department does not believe that the processes contained in these regulations will 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. Further, as indicated in the response to these comments and changes to the regulation from this rulemaking, the timelines for authorization of services have not changed and still adhere to federal and State requirements. 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 has modified these regulations and 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: Approximately 12 commenters believe 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 skilled nursing facility (SNF) to cost of hiring a caretaker through CDPAP. Commenters also expressed belief that the CDPAS program 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: Approximately 11 commenters believe consumers in CDPAP are more comfortable having friends and family provide personal care than they are with someone they do not know. Commenters stated that the CDPAP allows flexibility and peace of mind to hire someone they know and trust to provide care, which then allows family members to keep their jobs outside of the home. One commenter stated that finding reliable home health aides from a LHCSA can be difficult, especially in rural areas and that the CDPAP program makes it easy to find and hire personal assistants locally.

Response: These regulations do not promote PCS over CDPAS, or vice versa.

Comment: Some commenters stated CDPAP provides financial assistance that allows families to take care of their own relatives. In addition to commenters expressing comfort with having family provide personal care, they also see it as an opportunity for family

members to earn an income, especially during a time when a lot of people have lost their jobs due to the COVID-19 pandemic.

Response: The regulations do not seek to curtail CDPAP services that are medically necessary for a consumer who meets the minimum needs criteria.

Comment: Commenters recommended that the Department adopt the definition of the "person-centered plan of care" as used in the federal Medicaid managed care regulations, which require consideration of the consumer's choice and self-determination.

Response: The current regulation requires that the social assessment include a discussion with the consumer to determine their preferences. This requirement has been maintained in the proposed regulation, though as part of the IA. While LDSSs and MMCOs are required to base the plan of care on this assessment, the Department acknowledges that the initial proposed regulation did not make clear that the LDSS and MMCO should expressly consider consumer preferences. The revised proposed regulation now specifies that the LDSS or MMCO must evaluate the consumer's preferences and their social and cultural considerations and consider these when developing the plan of care. However, the Department declines to specifically incorporate federal requirements, which apply in their own right, as such provisions are subject to amendment and incorporating them into State rules may require additional and unnecessary administrative rulemaking on the part of the Department when updates occur to the federal rules.

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 Americans with Disabilities Act of 1990 (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: Commenters recommended that the Department expand the definition of Activities of Daily Living (ADL) in the regulations, and extend PCS and CDPAS minimum needs criteria that apply the ADL definition, by expanding the "tasks of daily living" list to include Instrumental Activities of Daily Living (IADLs) and other health related tasks.

Response: Although these ADLs or tasks are not specifically enumerated in the proposed regulations, they continue to be captured by the elements in the assessment through the CHA tool and will be used to determine whether the consumer satisfies minimum needs criteria. To ensure the definition of ADL aligns with the CHA tool used by the Department, the regulatory definition of ADL has been revised to reference what is contained in the evidenced-based, validated CHA tool referenced in Section 2-a of Part MM of Chapter 56 and of the Laws of 2020.

Comment: Some comments raised concern that ADL 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.

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 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 deleted and 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 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, but has made technical clarifications to this provision. 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: One commenter requested that the regulations be clarified to affirm that MMCOs and LDSS are no longer allowed to assign hours to supervision-only levels of need (those asks that support the member performing ADLs on their own) based on the CHA. Alternatively, the commenter requested that the regulations confirm that "supervision and cueing" in this section refers to safety monitoring, which is a less intensive form of service.

Response: The Department appreciates this comment and notes that the addition of regulatory language on supervision and cueing is intended primarily to codify existing Department policies. Specifically, MMCOs and LDSS may only assign hours for supervision and cueing if that is the modality used to assist the individual with accomplishing a Level I or Level II task for which there is a demonstrated need in the CHA. LDSS and MMCOs may authorize assistance to be provided with an home care aide or personal assistant performing the task, cueing the individual to complete the task, or supervising the individual as he or she completes the task, so long as the modality is limited to the specific task and level indicated in the CHA. For example, if the CHA indicates that the individual requires assistance with bathing, the MMCO or LDSS may count hours for the aide to supervise the process of bathing. The number of hours should reflect the form of assistance indicated in the assessment (from supervision to total dependence).

Comment: One commenter asked whether the use of activities and services in 18 NYCRR § 505.28(b)(6) regarding continuous care differs from the definition of ADL in the proposed regulations.

Response: The list of activities and services in 18 NYCRR § 505.28(b)(6) is not a full representation of all ADLs, and it also includes "home health services," which is not an ADL.

Comment: One commenter recommended that the Department use "ADL" and "IADL" instead of "personal care functions" and "nutritional and environmental support functions," which would better align with national terminology, federal guidelines, and State guidance. A similar comment also requested that the Department better explain what services are included within "environment support functions." Finally, one other comment requested that the Department use "business" days, rather than "working" days.

Response: While similar, the list of personal care functions and nutritional and environmental support functions in the Department's PCS regulation, which defines the scope of services that a personal care aide may provide, is not synonymous with those activities that are considered ADLs and IADLs. For example, medication administration is considered a personal care function, and a personal care aide may provide assistance with such tasks in accordance with the regulation. However, it is not considered an ADL. For this reason, the Department has determined that no changes to the regulation are needed. The Department also notes that its initial proposed regulation replaced "working

days" with the more traditional "business days" terminology and has maintained this change in the revised proposed regulation.

Comment: Commenters requested that the regulations clarify what is meant by the term "physical maneuvering" and whether such term includes the environment, equipment, or consumer ability in determining level of assistance with ADLs.

Response: Although these ADLs or tasks are not specifically enumerated in the proposed regulations, they continue to be captured by the elements in the assessment and will be used to determine eligibility. The Department determined that changes to the regulations are not required in response to this comment.

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 eligibility standards, 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: Commenters are seeking 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: Current recipients of Level I or Level II PCS or CDPAS will not be subject to the new minimum needs criteria based on activities of daily living under Section 365-a and Section 365-f of the Social Services Law, 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 Managed Long-Term Care (MLTC) plan eligibility as established in Section 4403-f of the Public Health Law. 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 Centers for Medicare & Medicaid Services (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: Several commenters cited *Olmstead v. LC by Zimring*, 527 U.S. 581 (1999) (hereinafter, "*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 eligibility 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, and cannot be modified by the Department in regulation. The Department has determined that no changes to the regulation are needed.

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*.

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 has nonetheless made several amendments to the proposed rule 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.

Comment: One commenter expressed concern that the regulations violate federal requirements under Community First Care Option, 42 U.S.C. § 1915(k) and associated regulations, and jeopardize the enhanced Federal Medical Assistance Percentage 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 recommended to expand eligibility to people who, because of impairments other than dementia and Alzheimer's disease, such as those with traumatic brain injury, developmental or intellectual disabilities, or blindness, need supervision but not limited assistance with physical maneuvering with one ADL and an additional IADL or ADL.

Response: The Department appreciates these comments but notes that the eligibility 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 and cannot be modified by the Department in regulation. The Department also notes that several of the other conditions or diagnoses cited by these commenters are those for which other Medicaid benefits are offered and are not impacted by this rulemaking specific to PCS and CDPAS. For example, 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: 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. If the LDSS or 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 state that regulations are required to provide deference to the treating physician's assessment of need for PCS to allow for an expedited determination under 42 CFR § 438.210(d)(2)(i).

Response: The Department respectfully disagrees with the commenters that such regulations are required. State law requires that PCS and CDPAS services are assessed by an IA and that medical orders for service are provided by an independent panel of providers. Deferring to the individual's treating physician for the assessment would run contrary to both such State law requirements. To address the timeliness of assessments, even when there is a need for an expedited determination, the Department has clarified in

the regulations that the independent assessment and medical order must allow for the LDSS or MMCO to comply with applicable federal and State timeframes, such as immediate needs.

Comment: Commenters requested clarification on whether the regulations institute a process for situations where an individual refuses to utilize the assigned independent practitioner/medical professional and prefers to use their own current physician for issuing the practitioner order.

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 expressed that the proposed regulations omit treating physician documents and consumer's requested plan of care from the documents to be provided to the IRP, and that the IRP will only have access to the CHA, medical order, and plan of care.

Response: The regulations already indicate that the IRP may collect and review all information about the individual that may help in the IRP's review and recommendation process. The regulations were not intended to be all-inclusive with regard to the

information and documentation that the IRP may consider, and the IRP may certainly request and review information from the individual's treating physician. However, much of this information will be part of the record that the LDSS or MMCO provides when referring the case to the IRP, and it will not always be necessary for the IRP to proactively obtain the materials referenced by commenters. The Department has amended the proposed regulation to clarify what the LDSS or MMCO must provide to the IRP and that the list of documents in the regulation that the IRP may obtain is not all-inclusive.

Comment: Several commenters requested that the Department solicit further input from people with disabilities, consumers, and advocates to ensure that the new IA process and the IRP consider the specific needs of people with disabilities, guards against disabilities, and keeps people within the community. Variations on these comments specifically recommended forming a workgroup with consumers and advocates that may affect "safety" in the home and strategies to reduce risk.

Response: As the Department implements this IA process, it has and will continue to solicit input from all impact stakeholders, including people with disabilities. To the extent that modifications in the process will be necessary to ensure that there is no bias in the process and that the needs of people with disabilities are appropriately reflected so that they can remain safely in the community, the Department is committed to this continuous process improvement. In addition to the changes made through this rulemaking, the Department will consider this input in future revisions to the regulations.

Comment: A few commenters recommended that the regulations be amended to require the IA and IPP reviews be inclusive of a night-time needs evaluation, inclusive of sleeping accommodations for any personal assistance or home health aides. Commenters stated that this part of the assessment is critical for properly identifying what services should be authorized for an individual and for allowing individuals to safely remain in the community, as MMCOs and LDSS could inaccurately assume that an individual does not require authorization for any night-time need services if this component is not included in the completed CHA.

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 refer to the Department's previous response.

Comment: Commenters requested clarification on the IA's role in determining and documenting rationale for 24-hour personal care cases.

Response: Please refer to the Department's previous responses.

Comment: Commenters expressed concern that the regulations do not sufficiently require documentation by the MMCO or LDSS of the availability and acceptability of informal supports. 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: The Department agrees with the commenter that fully utilizing available informal supports as a reason for a discontinuance or reduction is captured already under 18 NYCRR § 515.14(b)(4)(vii)(c)(2)(i) for discontinuances or reductions based on changes in social circumstances. Accordingly, the Department is revising the regulation

to incorporate the utilization of informal supports as an example under 18 NYCRR § 515.14(b)(4)(vii)(c)(2)(i) and has clarified, in response to commentary, that such informal supports must be based on the "willingness" of the caregiver.

Comment: One commenter asked the Department to provide guidance on what it means to negotiate with an informal caregiver, as these individuals are family members who are either willing to provide care or they are not. Commenters also recommended updating language to read "willingness and availability" of informal caregiver instead of utilizing the term "motivation."

Response: While the Department appreciates these comments, it notes that the regulations have continuously required LDSS and MMCOs to consider informal supports where they are willingly provided. LDSS and MMCOs responsibility to undertake this assessment and schedule informal supports where they are available, willing and accepted, remains unchanged. That said, the Department has used this opportunity, in response to these 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.

Comment: One commenter expressed concern that coordinating informal and formal supports is difficult because informal caregivers are not required to inform the MMCO or LDSS of a change in their availability. Commenters recommended that the voluntary caregiver be required to notify the MMCO when they can no longer provide the services

Response: 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 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. These requirements have been modified by the proposed regulations and the Department does not believe that additional regulatory clarification is warranted.

Comment: The Department received many comments on the proposed process by which 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 expressed concerns about the ability of the IA to remain independent if the MMCO or LDSS is allowed to raise factual issues or other inaccuracies in the CHA to their attention, and requests removal of this process. Other commenters argued that, if this process is not removed, then requests for changes should be documented, and the consumer be informed so that they may be involved in and challenge any changes made to the independent assessment.

Response: The Department agrees that there should be further clarification about the scope and procedures to resolve errors and differences in clinical judgment that may arise between the IA, on the one hand, and the LDSS or MCO, on the other. To this end, the Department has added provisions at 18 NYCRR §§ 505.14(b)(2)(v) & 505.28(d)(5) that establish a formal process for identifying and resolving mistakes and disagreements in clinical judgment and observation. Consumers will also be notified when a new assessment is ordered as a result of the LDSS's or MCO's request; the notice will include the reason for the reassessment. More specifically, this process has two components. First, the Department clarified that it is not allowing "dispute resolution," but this process allows for correction of documented factual inaccuracies if the MMCO or LDSS discovers these inaccuracies during the care planning process. This mechanism for correction is intended only for material errors, and will be limited to certain fields (e.g., demographic information, diagnosis, etc.) that may be clearly corrected with supporting

evidence and would not contradict the assessor's observation. The Department intends that MMCOs or LDSS are well-positioned to bring these inaccuracies to the attention of the IA, especially for reassessments for which the MMCO or LDSS has an ongoing care management relationship with the individual. For other aspects of the CHA that require the clinical judgment of the nurse assessor (e.g., cognition, functional needs, observed medications, observed incontinence), the remedy for a perceived inaccuracy by the LDSS or MMCO will be to request a second assessment by the IA, which would involve completion of a new CHA with the consumer's consent. Disagreements over clinical judgments must also be material. This second assessment will replace the first and must be used by the MMCO and LDSS to develop the plan of care. MMCOs and LDSS will be held accountable in making these second assessment requests in two ways: (1) the request for a second assessment will count against the timeframes the MMCO and LDSS have to develop the plan of care and make a service determination after issuance of the first CHA, such that it would not cause a delay in the ultimate service authorization to the consumer; and (2) the Department will periodically monitor changes in the CHA between the first and second assessments and may suspend an LDSS and MMCO's ability to seek these revised assessments or impose other sanctions if there appears to be abuse of this process. The Department holds a broad view of what might constitute abuse, it would not only include cases where an MMCO frequently challenges CHAs that do not yield material changes after the second assessment, but could also include attempts to challenge clinical judgments through the mistake process or to coerce individuals (who have a right to request new assessments) into unwillingly requesting a new assessment or similar actions.

Comment: Commenters recommended that the regulations clarify what is meant by "factual inaccuracies" as opposed to "differences in clinical assessments and observations." These comments noted that "factual inaccuracies" should be shared bidirectionally between the IA and the MMCO.

Response: These definitions have been clarified through changes in the regulations and the differential process between fields of the CHA tool that may be evidenced with documentation or information submitted by the MMCO or LDSS, as compared to fields in the CHA tool that require the application of clinical judgment by the nurse assessor (e.g., cognition, functional needs).

Comment: Other commenters expressed a strong desire for a more robust dispute resolution process, beyond factual issues, between the IA and the MMCO or LDSS because unresolved conflicts may impact plan of care development. Based on this belief, many of these commenters recommended an "independent process," an external review agency, so-called "independent dispute resolution entities," or the Department itself, to resolve these differences, as this independent arbiter would preserve the due process of the MMCOs or LDSS.

Response: As discussed above, the Department has amended the regulations to include a process by which to resolve clinical questions from MMCOs or LDSS by permitting a request for a second assessment. The Department declined to adopt an independent

process as duplicative of the IA's role to provide assessments. By allowing for a second assessment, it preserves the IA's role in completing the CHA, but does not leave MMCOs or LDSS without any recourse if they believe that the initial CHA was materially inaccurate and could impact development of the plan of care. Moreover, having an independent arbiter for factual inaccuracies is unnecessary because either the MMCO or LDSS can present information sufficient to correct this information in the CHA, or it cannot. The purpose of this component being limited to "factual" disputes is that there is no question regarding the accuracy or inaccuracy of the CHA, as initially completed by the IA.

Comment: Commenters sought information on how quickly disputes between the IA and the MMCO or LDSS would be resolved.

Response: The dispute resolution set forth in the revised 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: One commenter asked whether a consumer can appeal the assessment.

Response: The Department did not change the regulations as a consumer does not have the right to appeal the result of the assessment, other than determination of whether the individual meets the minimum needs criteria. For service authorizations, the appeal rights are limited to the determinations of services authorized through the plan of care.

Comment: Commenters made recommendations regarding what should be included as part of the assessment and the CHA tool. These comments emphasized that the assessment cannot focus solely on ADLs because individuals being assessed may have a variety of long-term care needs and that they should assess the frequency of an individual's needs. These comments also noted that it is critical for the independent assessment to determine the frequency of an individual's skilled needs, evaluate a consumer's ability to self-direct and, for those who cannot self-direct, identify the individual who will direct on their behalf.

Response: The Department determined the changes to the regulations were not required, as the current CHA tool, and its functional and mental health supplements, measure skilled needs and whether the individual is able to self-direct. Based on this information obtained by the IA, MMCOs and LDSS are required by the regulations to develop a plan of care that addresses the full scope of skilled and unskilled long-term care needs demonstrated by the CHA.

Comment: One commenter recommended that the regulations delineate the components of the assessment tool used by the IA and used by MMCOs and LDSS to develop a plan of care and asked whether the tool includes a mental health examination.

Response: The IA will use the CHA tool that is currently in place today, including its functional and mental health supplements. Accordingly, changes to the regulation are not required to further specify its components.

Comment: Commenters recommended that the Department, to ensure that the assessment standards incorporate the most current standards and knowledge of risk assessment and mitigation, should convene a workgroup of stakeholders to develop standards, appropriate assessment criteria, and materials for training of assessors and decisionmakers. Additionally, commenters believe that the regulations should be amended to provide that when assessors consider possible ways of mitigating risk, in every case, they must consider whether any identified risk could be mitigated with the provision of a care plan of up to 24-hour split shift care.

Response: The Department agrees that it is critically important for assessment standards to be current. To that end, the CHA tool used by assessors, and required by statute, is an independently validated assessment tool. Additionally, the CHA that the Department currently requires LDSS and MMCOs to use, and that will continue to be used to determine service needs has been independently validated by experts in the field as providing the necessary information about consumer's condition and needs to enable

professionals, such as the independent practitioner, or the LDSS's or MMCO's professional staff or contractors, to make informed decisions 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.

Comment: Several commenters raised questions about the scheduling and availability of the IA to conduct timely assessments, which could lead to delays in authorization, including whether the IA will be able to visit individuals upon their return home from a hospital stay in a timely manner and; whether there will be adequate Statewide availability, especially in rural parts of the State.

Response: The IA will be contractually required through the Department to provide Statewide assessments and to ensure timely access to assessments. The Department will monitor the performance of the IA in meeting these obligations. Moreover, 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 regulations have been amended to complete 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 be increase consumer convenience, especially in rural areas.

Comment: Commenters asked the Department to clarify that a consumer's assessment or reassessment must be conducted anywhere that the consumer resides, including the consumer's primary residence or temporary residence, such as a hospital, nursing home, or rehabilitation facility.

Response: The Department has clarified in the revised regulations that, consistent with the assessment process in place today, the Department will instruct the IA to conduct assessments wherever the consumer resides when the assessment is scheduled, which may include places outside the primary residence, such as a hospital, nursing home, or rehabilitation facility. Notwithstanding this instruction, the regulations also clarify that the IA may need to conduct at least a portion of the assessment in the primary residence to assess this physical environment on the individual's needs and complete relevant portions of the CHA tool. The ability to use telehealth, as indicated in the prior response, will further support conducting the assessment at the individual's present location and in a timely manner.

Comment: Commenters asked whether assessments would be available via telehealth or telephone, as opposed to in-home visits. Similarly, other comments asked whether MMCOs or LDSSs may conduct person-centered service planning meetings that result in development of the plan of care using telehealth modalities.

Response: As stated in a prior response, the Department will permit assessments to be conducted by the IA using synchronous, audio-visual telehealth modalities. After the

conclusion of the COVID-19 state of emergency, during which assessments are being conducted telephonically, the Department will not permit assessments to be initiated by telephone. Further, 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.

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: LDSS and MMCOs asked whether there will be any change in the LDSS's or MMCO's care planning role or the forms they utilize, including whether the LDSS will have to use a new Orientation Visit Report and Nursing Supervisory Visit Report; whether they will have the authority to authorize certified home health aide services; whether the LDSS or MMCO staff are still required to visit with the consumer to complete a plan of care; whether LDSS or MMCOs wet signatures; and whether they will make the determination for frequency of nursing supervision.

Response: The Department has not proposed any changes in the care planning requirements of LDSS or MMCO. Additionally, the processes contemplated by the regulations will not result in new forms related to authorizing these services.

Comment: Commenters asked whether the Department will create a website that makes available advance directive forms to LDSS or other parties.

Response: Such a website already exists and may be accessed at https://www.health.ny.gov/community/advance_care_planning/. In addition, NYS Office of the Attorney General has published on their website at https://ag.ny.gov/sites/default/files/advancedirectives.pdf an advance directives guide on how to make one's wishes known and honored. The Department has determined no changes to the regulation are needed.

Comment: One LDSS commenter inquired about the primary responsibility for adult protective staff, including when they must inform the New York State Office of Children and Family Services and provide training. Commenters requested clarification as to who is responsible for cross checking open adult services cases.

Response: The regulations do not change any requirements related to adult services cases. The Department has determined no changes to the regulation are needed.

Comment: Commenters asked whether the IA will now be responsible for determining eligibility for PCS and CDPAS and whether social determinants of health will be incorporated in determining eligibility.

Response: Under the regulations, the IA will determine eligibility for PCS and CDPAS under the applicable eligibility standards established by State law in Sections 2-a and 3 of Part MM of Chapter 56 of the Laws of 2020. The eligibility determination will be based on completion of the CHA tool, which considers social determinants of health. The Department is not changing the CHA tool in connection with transition to the IA process under these regulations. The Department has determined no changes to the regulation are needed.

Comment: Commenters requested clarification on whether the IA will be conducting pediatric assessments and what eligibility standards apply.

Response: The Department currently contemplates that the IA will be conducting pediatric assessments, consistent with the regulations and the eligibility requirements set forth in Sections 2-a and 3 of Part MM of Chapter 56 of the Laws of 2020. No changes to the regulations were made in response to this comment.

Comment: One commenter requested clarification on who is responsible for disenrolling individuals who require services for fewer than twelve months.

Response: The regulations do not change the responsibilities of the LDSS or MMCOs for authorizing services and supports based on the demonstrated need indicated in the CHA completed by the IA. Consistent with the current Department guidance and regulations, MMCOs are required to disenroll members for whom there are no authorized services. The Department has determined no changes to the regulation are needed.

Comment: One commenter recommended that the responsibility of determining the frequency of the nurse supervision should belong to the individual's Licensed Home Care Services Agency (LHCSA), rather than the MMCO or LDSS.

Response: The regulations, consistent with federal requirements, require MMCOs to make determinations regarding the services for which a member is authorized. MMCOs and LDSS may delegate certain functions to LHCSAs, but this rulemaking does not address this delegation or this relationship, which remains between the MMCO or LDSS and the LHCSA.

Comment: Commenters requested clarification on whether waiver services participants under Section 1915(c) waivers authorized by CMS will be subject to these regulations.

Response: The regulations govern PCS and CDPAP State plan services or services furnished as part of an MMCO benefit package. Benefits afforded to individuals under 1915(c) waivers, to the extent they are not State plan PCS or CDPAP or furnished pursuant to an MMCO benefit package, are not included within these regulations.

Comment: Commenters recommend that the paragraph renumbered as 18 NYCRR § 505.14(b)(4)(vii)(a) be deleted or amended to reflect the LDSS and MMCO responsibilities. These commenters expressed concern that MMCOs and LDSS are denying necessary services to members and indicate that they cannot remain safely in the community without proper documentation or support.

Response: The provisions at issue requires that the LDSS or MMCO deny or discontinue services that are not medically necessary. This longstanding provision is in alignment with the scope of coverage available under the State's Medicaid program, defined to include medically necessary services pursuant to Section 365-a(2) of the Social Services Law. The Department has determined no changes to the regulation are needed.

Comment: Commenter requested clarification on whether the IA will assess any individual who seeks Private Duty Nursing (PDN), Adult Day Health Care (ADHC), Certified Home Health Agency (CHHA) (skilled nursing) services and community based

long-term care (CBLTC) services or only those who are also seeking PCS and/or CDPAP.

Response: The IA will assess anyone seeking PCS or CDPAP, but also individuals who may access CBLTC services through MLTC plans. Individuals who are seeking PDN, ADHC and CHHA services will be assessed for eligibility based on the current processes that apply to authorization of these services. The LDSS or MMCO may use the CHA assessment provided by the IA in assessing individual's needs for these services. The Department determined that changes to the regulations were not necessary to address this question.

Comment: Commenters asked whether any LHCSAs engaged by the IA will be subject to the same conflict of interest rules to which the IA is subject. These comments expressed concern that this could create access problems for members in counties that already have limited numbers of LHCSAs.

Response: The Department has determined that LHCSAs will not be permitted to perform IA assessments, either as the IA or through a subcontract with the IA, due to potential conflict of interest concerns with the LHCSA being a provider of PCS. Any nurse assessors engaged by the IA will have to attest that they are not employed by a LHCSA or another agency that may provide services to individuals authorized for PCS. The Department has determined no changes to the regulation are needed.

Commenter: Commenter advised that MMCOs must be able to access IA assessment for plan development and care management activities.

Response: The regulations permit MMCOs to access the completed CHA and require the MMCO to review the CHA prior to initiation of the plan of care development process. To that end, the timelines established by the revised regulations clarify that the federal timeframes for completion of a plan of care and service authorization begin on the date that the CHA is completed by the IA, along with a signed practitioner order.

Comment: One commenter requested clarification on how the IA's role in completion of the CHA affects the Initial Adverse Determination (IAD) for MLTC plan enrollment.

Response: Consistent with the role of the IA set forth in the regulations, 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, the IA will provide notice and appear at any resulting fair hearings, if necessary. The Department has determined that no changes to the regulation are needed.

Comment: Commenters requested clarification on which entity is responsible for the social and nursing assessments under the new IA, including whether the social and nursing assessments may remain the responsibility of MMCOs.

Response: Social and nursing assessments are components of the CHA tool and will be completed by the IA under the regulations. The Department has determined that no changes to the regulation are needed.

Comment: Commenters requested clarification on what it means for MMCOs and LDSS to "directly evaluate" the individual and whether this requires a physical assessment of the individual.

Response: The Department believes that the regulations are clear with regard to the roles and responsibilities of the IA to conduct the assessment of the member, through completion of the CHA. The MMCO and LDSS remain responsible for care planning and completion of the plan of care with the member, which may involve an in-home visit, but should avoid consumer disruption.

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 recommended that the regulations be more consistent about the duties and functions of each of the entities that has a role in the assessment to avoid duplication of tasks and inconsistency and confusion across documentation, including when there is an unexpected change in social circumstances, mental status or medical condition during the authorization.

Response: The Department appreciates these comments and has reviewed the regulations regarding the roles and responsibilities of the IA, as compared to the MMCOs or LDSS. Based on its review, the Department believes the roles and responsibilities regarding the IA, which conducts the assessments and determines eligibility, is clear and distinct from the role of the LDSS and MMCOs, which continue to engage in care planning and service authorization. However, the Department has added a new provision addressing coordination between the IA and the LDSS or MMCO. Included in this provision is clarification that when a new assessment is needed, such as when an unexpected change occurs, the LDSS or MMCO is required to inform the IA in accordance with guidance or processes provided by the Department. Additionally, to the

extent that any provisions with regard to these roles and responsibilities mention the LDSS or MMCO only, they have been amended to reflect that both the MMCO and LDSS retain their care planning and service authorization responsibilities under these regulations.

Comment: One commenter asked why the Department removed the requirement for the LDSS to maintain contracts for the provision of nursing services under 18 NYCRR § 515.14(c).

Response: The references to nursing assessment within 18 NYCRR § 515.14(c) are to the same nursing assessment activities within 18 NYCRR § 515.14(b) of the current regulation. In the proposed regulations, in accordance with State statute, these activities have been incorporated into the IA process, and are no longer the responsibility of the LDSS. Accordingly, an LDSS no longer needs to maintain a contract for that purpose. However, the list of activities for which an LDSS must contract includes some nursing services, such as nursing supervision, which the LDSS (and MMCO) remain responsible for providing.

Comment: Several commenters recommended that the regulations require the IA, IPP, IRP, LDSS and MMCOs to consider ways to reduce or eliminate any risks before making a determination that the person cannot be safely cared for at home. These commenters also recommended that the regulations clarify that the mandated individualized assessment of risk be based on current medical evidence and/or the best available

objective evidence, and that assessors and decisionmakers cannot rely on stereotypes or generalized assumptions about risk.

Response: The CHA tool that the Department currently requires LDSSs and MMCOs to use, and that will continue to be used to determine service needs, 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, or the LDSS's or MMCO's professional staff or contractors, to make informed decisions 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: Commenters recommended that the regulations be amended to provide that when the IA consider possible ways of mitigating risk, in every case, the IA must consider whether any identified risk could be mitigated with the provision of a care plan of up to 24-hour split shift care.

Response: The statute and regulation require that LDSS and MMCOs determine the care needs of the individuals based on their assessed needs using an independently validated assessment tool. This can include up to 24-hour split shift care if it is determined that such services are needed to meet the consumer's needs. The Department has elected to restore portions of Section 505.14(a)(3)(iii)(b) of the current rule into the proposed regulations at 505.14(b)(2)(iii)(b) as a requirement on the care planning process. The

Department believes that an important aspect of the authorization process is for LDSS and MMCOs to consider the full needs of the individual and whether they would be otherwise eligible for PCS, up to and including 24 hour care, before considering what services and supports may be available to meet the consumer's needs.

Comment: Commenters recommended that after a consumer has made a request for services, that the LDSS or MMCO should be required to make arrangements for assessments by the IA and assist the consumer in navigating the assessment and service authorization process, including the medical order from the IPP, so that the consumer will not have to navigate this new process by themselves.

Response: The Department appreciates this comment and is working to make the consumer experience as simple and streamlined as possible. Through existing and pending policies and guidance documents from the Department, and in addition to the expanded coordination requirements in 505.14(b)(2)(iv), LDSS and MMCOs will be strongly encouraged to assist consumers with navigating the assessment process and the roles and responsibilities of the IA as compared to the MMCO or LDSS. Additionally, the Department will contractually require the IA to undertake steps to help consumers navigate the new process. The IA is also responsible for scheduling and arranging both the CHA and the subsequent medical examination from the IPP, which obviates the need for a second referral from the MMCO or LDSS and should help the consumer more easily navigate this assessment process. Based on these steps, the Department wishes to reiterate that the burden is not on the consumer to navigate the assessment process. The

LDSS or MMCO will be expected to have a three-way call with the IA and facilitate a "warm hand-off" of the consumer, at which point the IA will assist the consumer in navigating the entire assessment process.

Comment: One commenter recommended that the obligation be removed for an MMCO to refer the consumer to LDSS if they do not have Medicaid.

Response: The Department cannot make this change to the regulations. If a consumer were to contact an MMCO prior to eligibility being determined, the MMCO would need to refer them to an LDSS, which determines eligibility for Medicaid.

Comment: Commenters, including LDSS and MMCOs, requested clarification on how a referral will be made to the IA, including how notification of a complete assessment will be issued to LDSS or MMCOs, and whether an electronic portal or website will be created for submitting a referral and receiving notification of completed assessments. Additionally, these commenters requested clarification on whether there will be a minimum number of attempts required of the IA to contact the member in order to make appointments for assessments.

Response: These inquiries did not necessitate changes to the regulations, but the Department would like to clarify here that MMCOs and LDSS will refer consumers to the IA for assessment and, once completed, the LDSS or MMCOs will then be notified by the IA of a completed assessment and medical order. The IA will furnish a mechanism

for convenient notification, which the Department anticipates will be via electronic transfer of information and readily accessible by LDSS and MMCOs.

Comment: Commenters asked if the LDSS will be able to determine the means by which consumers can contact them for assistance.

Response: The regulations are not modifying how consumers interact with LDSS regarding the assessment and eligibility determinations for PCS or Medicaid eligibility, overall.

Comment: Commenter requested clarification on how the IA will conduct change in condition or return assessments in a hospital or a nursing home.

Response: As specified in the regulations, which have not been modified in this regard, these assessments will occur in the same manner as initial assessments or routine reassessments. Please see the Department's previous responses regarding where an assessment may occur, which may include a hospital, nursing home, or other location, provided that the IA does not need to observe the individual's location in connection with conducting a functional assessment.

Comment: Commenters recommended that if an MMCO refers an applicant that is not currently a member of that MMCO for an assessment, the IA must ensure that the referring plan receives the assessment completion notice without having to complete a second referral.

Response: Please see the response above regarding the mechanisms that the IA will use to notify MMCOs and LDSS of a completed assessment.

Comment: MMCO commenters have asked whether there will be a minimum number of attempts by the IA to make an appointment with an individual who has requested an assessment.

Response: Although the regulations do not require this level of specificity, the Department acknowledges that there will be a minimum number of contact attempts required by the IA pursuant to its contract with the Department. If the IA is unable to reach the individual after those minimum attempts, the IA will then be required to request outreach assistance from the MMCO or LDSS. This information will be offered by the Department in future guidance.

Comment: A commenter requested that MMCOs be provided with a reconciliation of MMCO referrals to the IA with the members who end up with the MMCO making the referral.

Response: Through implementation, the Department will instruct the IA to refer the consumer back to the MMCO that initiated the assessment; however, if the consumer is not currently a member of an MMCO, the consumer will be informed of MMCOs that are accepting enrollment, which is how the process works now with the Conflict Free

Evaluation and Enrollment Center. The Department determined that changes to the regulations were not required in response to this comment.

Comment: Commenters requested that the MMCO should not have to refer applicants to an LDSS for financial eligibility and that financial and functional eligibility should be pursued simultaneously. Further, the commenters recommended that the LDSS and MCO should assist the consumer in navigating the process as it is a burdensome and multi-layered process.

Response: The requirement that MMCOs refer individuals to the LDSS when they have not yet been determined eligible for Medicaid or CBLTC services is intended to ensure that MMCOs appropriately direct individuals to apply for the Medicaid program, so that their request can continue to be processed. The Department does not believe, however, that undergoing independent assessments and medical exams for individuals who have not yet been determined eligible for Medicaid or CBLTC services maximizes the use of limited resources, and provides an exception only when someone has submitted a complete Medicaid application and has an immediate need for PCS or CDPAS.

Comment: In connection with their support for the change in the frequency of reassessments from semi-annual to annual, several 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 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 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: These observations are correct. The IRP is issuing "recommendations," rather than authorizations and determinations. 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. Sections 505.14(b)(2)(iii)(f)(3) and 505.28(d)(3)(vi)(c) have been amended to clarify this requirement. 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: Several commenters asked whether physicians and other clinical staff on the IRP will be required to make a home visit in connection with issuing the IRP's recommendation regarding the plan of care. As part of these comments, there was a recommendation that the clinical staff on the IRP, including the lead physician, make a home visit and conduct an in-person examination.

Response: The Department disagrees that the IRP cannot make a recommendation on a plan of care without making a home visit. While a home visit may be helpful in some cases, and the lead physician has the discretion to do so under the proposed regulations if the IRP believes it is necessary for them to make a clinical judgment, the Department has determined that it is not necessary to require a home visit in all cases. Medical record review may be an accepted method of making a reasonable clinical judgment and this approach will avoid disruption and delay for the individual in having to schedule the home visit and invite one or members of the IRP's clinical team into their home when it is not necessary in all cases. The Department has determined that no changes to the regulation are needed.

Comment: Commenters stated that it is critical that the regulations ensure that the IRP for high needs cases does not improperly delay or deny care. In connection with these comments, 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 appears and receives greater than the threshold number of hours through a fair hearing. These commenters also requested that the Department provide additional clarity on the relationship between plan of care development by the MMCO or LDSS and when the IRP conducts its review through the lead physician.

Response: The Department has revised the regulations to reflect that the approval of hours through a 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: Commenters asked whether there is another review after the IRP by the MMCO or LDSS and whether the recommendation of the IRP is subject to a fair hearing,

or how the work of the IRP otherwise relates to the fair hearing process, such as inclusion in the fair hearing record. The commenter also asked what occurs should an LDSS or MMCO disagree with the recommendation of IRP.

Response: After the IRP recommendation, the LDSS and MCO reviews the recommendation and makes its own determination as to whether to amend the prepared plan of care. The IRP itself does not authorize or determine the consumer's plan of care, such that the recommendation itself is not subject to fair hearing. However, the recommendation is relevant clinical documentation that may be used by the consumer, or by the LDSS or MCO, in considering the plan of care as part of the fair hearing record. The Department has determined that no changes to the regulation are needed.

Comment: Several commenters 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.

Response: An IRP does not occur under these circumstances. However, based on these comments, the Department revised the regulations to clarify that the IRP reviews a plan of care only when the consumer crosses the high-hours threshold. 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: Commenter asked how the referral is made between the LDSS or MMCO and the IRP and how long the IRP will have to make a recommendation.

Response: The Department expects referrals will be made by the MMCO or LDSS to the IA once a plan of care has been proposed that exceeds the high needs hours threshold, which will arrange for the IRP to occur. The Department has amended the regulation to indicate that a provisional or temporary plan of care with a service authorization will be permitted by MMCOs and LDSS prior to the IRP review, to ensure adherence to federal authorization timeframes or State regulations.

Comment: One commenter asked what should happen if the IRP determines that the individual cannot be maintained safely in the community with the proposed plan of care and is unable to recommend services that the IRP believes, in its clinical judgment, would be able to maintain the individual in the community. Specifically, the commenter asked whether the MMCO would be required to disenroll the member.

Response: The IRP must rely on its clinical judgment in evaluating whether the plan of care is able to safely maintain the consumer in the community, or if there are alternative CBLTC services that would assist the individual to remain safely in the community, if

authorized pursuant to the plan of care. If the IRP comes to the clinical determination that additional or alternative services would not assist the individual to remain safely in the community, then the IRP must not recommend such services. Decisions and reasons for disenrollment are not addressed by these regulations, but the Department notes that the IRP's recommendation must be reviewed and considered by the MMCO. The recommendation may be accepted, accepted in part, or rejected by the MMCO, such that the MMCO will never be required to disenroll based on the findings of the IRP.

Comment: One commenter suggested that the IRP should not be able to recommend alternative services to be considered as part of the plan of care because the IRP is not sufficiently qualified to make such a clinical judgment, and that the review should be limited to whether the plan of care can maintain the consumer's health and safety in the community.

Response: The Department disagrees that, based on the composition of this panel, the IRP will lack the clinical experience or information to make clinical judgments as to what additional or alternative services would assist in maintaining the consumer safely in the community, or whether services recommended in the plan of care may be more than what is required. The IRP will be overseen by a physician licensed under Article 131 of the Education Law and will include other professionals who may have different clinical backgrounds and expertise. Collectively, this panel will review information that is similar to the information that LDSS and MMCOs use to develop the plan of care and authorization. The IRP will be sufficiently qualified then to make recommendations about

whether, in their clinical judgment, additional or alternative services are needed to maintain the consumer's health and safety in the community, but will not be recommending specific increases in care hours, consistent with the previous draft of the regulations. The Department has determined no changes to the regulation are needed.

Comment: Some commenters argued that individuals should not be required to complete the IRP in order to change their authorization if the services would have been authorized based on the initial assessment but were not utilized.

Response: The Department agrees with this comment. The IRP review is triggered by the authorization of services, rather than whether services were ultimately utilized by the member, but the Department does not believe that additional clarification is necessary in this regard.

Comment: Commenters asked that the proposed regulation indicate how the IRP process should be handled when a consumer has not yet selected an MMCO and is still seeking enrollment.

Response: The Department appreciates this comment, as 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 has 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 recommended that the IRP review cases where the consumer has requested more than 12 hours, even when the plan of care authorizes fewer than 12 hours.

Response: The Department appreciates this recommendation and directs these commenters to the response above, which indicates that these consumers will be able to avail themselves of any internal appeals and then the fair hearing process, consistent with current practice. Based on amendments to the regulations, any findings by the Hearing Officer that the consumer needs greater than 12 hours of PCS or CDPAS will not be subject to review of the IRP. The purpose of the IRP, as reflected in the statute, is not designed to serve as a dispute resolution body or a pre-appeal mechanism to the MMCO's internal appeal process or fair hearings. Further, giving the IRP this role would contravene federal regulations or existing processes that already offer an avenue for consumers to resolve disputes in the amount, duration or scope of services with their MMCO or the LDSS.

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: The Department 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 has 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.

Comment: One commenter suggested that the IRP must contact and consider the records and opinions of the treating physician, and of the consumers subject to review, in order to comply with federal regulatory requirements in 42 C.F.R. §§ 438.208 and 210.

Response: The Department agrees that the IRP has the ability to contact the treating physician and consider the opinions of the consumer in its process of making a recommendation, but disagrees that federal rules require that the IRP do so in any instance. The MMCO is the subject of these federal requirements regarding care planning and service authorization, and is bound to comply in addition to considering the recommendation of the IRP. Notwithstanding the lack of federal rule applicability, the Department has provided that the IRP may obtain this information from the treating physician and the consumer at the professional discretion of the lead physician on the

IRP, but the recommendation of the IRP should not be delayed if the lead physician believes a recommendation can be made without such review.

Comment: Commenters recommended that the IRP be able to recommend specific changes in approved personal care or CDPAS care hours.

Response: The Department appreciates this recommendation and, while the IRP can recommend specific CBLTC services that may help the consumer remain in the community or suggest where fewer services may be warranted, the Department believes that enabling the IRP to recommend a specific care hours both usurps the care planning and authorization function that is the responsibility of the LDSS or MMCO under federal and State rules and may inappropriately function as a dispute resolution function, as indicated above, which contravenes the intended purpose of the IRP from the legislative authorization. The Department has determined that no changes to the regulation are needed.

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: Commenter recommended rearranging the location of the IRP requirement so that it better aligns with the timing of when the LDSS and MMCO must perform care planning activities, as the IRP must be conducted after the plan of care is completed.

Response: The Department agrees with commenter's suggestion and has made various changes to the order of provisions in the regulation to align better with the timing of how and when LDSS or MMCO responsibilities should be performed in relation to the IRP.

Comment: Several commenters expressed confusion as to the purpose of the IRP process if it is not allowed to recommend specific hours of care or a specific plan of care.

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 is confirming their own clinical assessment, or identifying high needs cases that the LDSS or MMCO may need to review more carefully. The Department has determined that no changes to the regulation are needed in response to this comment.

Comment: Commenters requested that the Department confirm that the IRP is able to review the plan of care proposed by the MMCO or LDSS in making a recommendation of whether the individual can remain safely within the community, as sometimes the only impediment to being served in the community is an insufficient plan of care.

Response: This comment speaks to the value of the IRP, as currently structured. The IRP must have the plan of care developed by the MMCO or LDSS in determining whether the individual can remain safely in the home with the CBLTC services to be authorized in the plan of care. If the IRP determines the plan of care inadequate to keep the individual in the community, the IRP may recommend changes to the plan of care (not inclusive of specific increases in PCS or CDPAS care hours) that would keep that individual in the community, if possible.

Comment: Commenters requested a revised Person-Centered Plan of Care template and recommended that regulations require that the assessment identify the consumer's skilled needs, including timing and frequency of such need. These commenters also recommended that the regulations should require MMCOs to assess whether a member's

needs are able to be addressed by other services in the plan benefit package, not limited to PCS and CDPAS.

Response: The proposed regulations do not change the content requirements of the plan of care nor the care planning process in which MMCOs and LDSS must engage under federal and State rules, as applicable. The Department has determined that no changes to the regulation are needed.

Comment: Commenters requested clarification as to what the proposed regulations intended when they required the plan of care to "reflect" the assessment.

Response: The Department believes that the terminology is clear, as the proposed regulations require the plan of care to be based on and derived from the assessment and medical order as the primary source of information on which the plan of care is based, rather than any assessments and observations by the MMCO or LDSS. Specifically, this language was intended to ensure that the plan of care addresses the consumer's needs, circumstances and preferences, as identified in the assessment and medical order. The Department has determined that no changes to the regulation are needed.

Comment: Commenters recommended that the proposed regulations should define "medical necessity" because community supports are not subject to clinical criteria. Further, these commenters requested that the regulations indicate if the reasons for denial,

reduction, or discontinuation of services in the rule are sufficient or if an MMCO or LDSS must provide additional rationale or justification behind a determination.

Response: Please see response above regarding the definition of medical necessity. Additionally, the proposed regulations provide reasons for the denial, reduction or discontinuation of PCS or CDPAS, but does not limit an MMCO or LDSS to these reasons; however, consistent with State and federal law and regulations, LDSS and MMCOs are required to provide the full clinical rationale to support any adverse determinations based on medical necessity, which may be subject to internal appeal and fair hearing.

Comment: Commenters recommended that the plan of care development be moved from the description of the assessment process section within the regulations. The regulations should separate independent assessor and LDSS and MMCO responsibilities.

Response: The Department disagrees and believes that regulations appropriately delineate the separation of the IA role from the MMCO and LDSS in evaluating the needs of the consumer and the level of service to be provided to that consumer. The Department has determined no changes to the regulation are needed.

Comment: Commenters expressed concern that Social Day Care services do not offer the same type of assistance with personal care needs, such as bathing and therefore, and

should not be treated by MMCOs and LDSS as a substitute for personal care services or CDPAP.

Response: The Department disagrees that social day care (SDC) should not be considered as part of the care planning process when appropriate to meet the needs of the individual, and notes that PCS may not be provided at the same time as SDC for doing so would constitute a duplication of services. When evaluating appropriateness of services and alternative the MMCO or LDSS must consider the nature of both the service/alternative and the needs of the individual. If an alternative service or support would meet the individual's needs, then it would be appropriate to authorize such services in place of PCS.

Comment: Commenters requested clarification on whether the MMCO's or LDSS's plan of care development considers only the medical order or if it can consider medical reports from other sources, including the individual's own physician.

Response: The regulations require the plan of care to consider the independent assessment and the medical order from the IPP; however, the regulations do not prohibit the MMCO or LDSS from considering or consulting other reported information about the consumer's condition in development of the plan of care. The Department encourages MMCOs and LDSS to consider such information, when appropriate. The Department has determined that no changes to the regulation are needed.

Comment: Commenters recommended that the regulations replace the “clinical rationale” requirement with a reasonable supporting statement for the reduction in services.

Response: The requirement to provide a clinical rationale is within the context of actions to deny, reduce or discontinue services based on medical necessity. As such the Department believes that it is appropriate that the MMCO or LDSS have a clinical rationale to support its determination, and that this is provided in the notice. The Department has determined that no changes to the regulation are needed.

Comment: Commenters requested that the Department clarify that the requirement for service authorizations, including "the individual supervising the services," will apply only to LDSS, but not to MMCOs.

Response: The need to provide nursing supervision of PCS applies to both LDSS and MMCOs. Accordingly, the requirement to provide the agency or individual performing such supervisory role with a copy of the plan of care applies to both LDSS and MMCOs as well. The Department acknowledges, however, that this role may be performed “in house” by some MMCOs, and in such cases the individual in question may not be part of a separate agency or entity. The Department has determined no changes to the regulation are needed.

Comment: Commenters requested clarification on reauthorizations of Level II PCS permitted without a medical order and how it is determined that the consumer has no change in mental status.

Response: The Department has clarified that service may be reauthorized without a medical order; provided however, that such an order is obtained at least annually for the continued authorization of services. A PO may also be required upon the occurrence of certain events, including an unexpected change in mental status. Whether such a change has occurred is a clinical determination that may be relayed to the LDSS or MMCO by practitioners; however, the Department does not define in this regulation for the medical profession precisely what does or does not constitute such a change. The Department has determined no changes to the regulation are needed.

Comment: One commenter noted that Section 505.28(b)(14) seems similar to Level I services under PCS and asked if Level I is available to CDPAP consumers.

Response: The scope of PCS available through CDPAP includes the same scope of services as available pursuant to 18 NYCRR § 505.14. The Department declined to further revise the regulations based on this comment, as CDPAP has never used service levels the same way as the PCS program.

Comment: Commenters requested confirmation that the Nurse Supervisory Reports apply only to LDSS and not MMCOs.

Response: Both LDSSs and MMCO must provide nursing supervision, and documentation of nursing supervisory visits must occur regardless of whether the service is provided or arranged by an LDSS or MMCO. However, the Department has removed substantive amendments to subdivision 505.14(f), and will consider providing additional guidance regarding nursing supervision. Provided however that until additional guidance is provided, previous guidance will still remain applicable.

Comment: Commenters recommended that the regulations should require the member or consumer to identify a back-up caregiver in the event that their primary caregiver is unavailable.

Response: The Department appreciates this recommendation and agrees with the importance of having a back-up caregiver identified through the care planning process, but does not believe it requires an update to the regulations at this time. Rather, the Department will issue further guidance on this topic to guide LDSS and MMCOs in care planning.

Comment: Comments cited 42 C.F.R. Part 438 and the federal care planning requirements that require "a discussion with the patient to determine perception of his/her circumstances and preferences." Based on this requirement, commenters recommended that the regulations should be amended to require the LDSS and MMCO to consider the consumers preferences of her circumstances.

Response: The Department did not specifically incorporate or duplicate the federal care planning requirements, which are applicable, as appropriate, and are subject to change. However, the Department did clarify the role that consumer preference should have in the evaluation for services and the development of the plan of care.

Comment: Commenters indicated that the regulations require a consumer to use "formal services" outside of Medicaid, but the regulations then do not define the services to which this term refers. To that end, the commenters requested that the term be defined to avoid this item being used as an inappropriate rationale for the reduction of care.

Response: This term is in the current the regulation and includes programs provided outside the Medicaid program, such as Medicare and the Office for the Aging programs. It is well understood that Medicaid is the payor of last resort, and a definition is not required to reinforce that in these regulations.

Comment: Commenters requested clarification on whether a client needs to meet their spenddown requirements before services are authorized, including for budgeting that includes pooled trusts and other methods to meet a spenddown. Additionally, these comments asked if the LDSS remains responsible for entering prior authorizations.

Response: Consistent with current policy, which remains unchanged by these regulations, an individual who is eligible with a spenddown may have services authorized and use those services to meet a spenddown. The Department has determined that no changes to the regulation are needed.

Comment: Commenters asked for the Department to clarify whether an LDSS will determine the aggregate costs for services.

Response: There is no change to the policy or process on the determination of aggregate costs and who is responsible for that determination. The Department has determined that no changes to the regulation are needed.

Comment: One commenter asked whether immediate needs applicants will be required to attest to 30-months for the asset transfer look-back period and, if the attestation is incorrect, if the LDSS will be allowed to close the case and services.

Response: The commenter is referring to the new look-back period for assets transfer involving non-institutionalized, or community based, individuals, which was authorized pursuant to Section 13 of Part MM of Chapter 56 of the Laws of 2020. This rulemaking addresses the transition to the IA process, and associated eligibility changes for PCS and CDPAS; implementation of the look-back period referred to by the commenter will be addressed through separate processes and we refer the commenter to that guidance, when issued.

Comment: Commenters asked if annual medical orders, obtained through the IPP process, will satisfy the requirement for a physician's statement of need that is needed for the transfer of assets evaluation.

Response: The physician's statement of the need for CBLTC services in relation to the 30-month look-back requirement for a Medicaid application requesting coverage of CBTLC services will be on a form developed by the Department, which will be distinct from the medical order completed by the IPP. Because the IA and IPP process are not initiated until after someone is determined CBLTC services eligible, the order from the IPP cannot be used to serve as the physician's statement of need.

Comment: Commenters asked for clarification regarding whether individuals currently receiving only Level I PCS will be assessed by the IA and be assessed for eligibility using the new minimum needs criteria, as they may not satisfy them.

Response: 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 eligibility standards set forth in 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 recommended that the Department adopt the definition of the person-centered plan of care as used in the federal Medicaid managed care regulations, which require consideration of the consumer's preference in development of the plan of care.

Response: Although the Department declined to specifically incorporate or duplicate the federal waiver and CFCO care planning requirements, which are applicable in their own right as appropriate and are subject to change, the Department agreed with commenters and clarified in the regulations the role that consumer preference should have in the evaluation for services and the development of the plan of care. Specifically, the regulations now require the individual's "preferences and social and cultural considerations" to be part of the care planning process.

Comment: Commenters expressed concern that the regulations mandate that consumers use equipment and supplies, such as commodes, when the use of such equipment has always considered the consumer's preference regarding use of a toilet. Similar comments also raised concerns about the regulations requiring the use of informal supports, adult day health or social adult day care, and formal services outside of Medicaid, even if contrary to consumer preference.

Response: The Department 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. Consistent with the earlier comment, 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: One commenter noted that CDPAS are optional under Section 365-f of the Social Services Law and consumers cannot be required to accept such services, even if cost-effective. Based on this reading of the law, the commenter recommended deletion of regulatory language.

Response: The Department agrees with this comment and has deleted language from the regulation that could be read as requiring a consumer accept CDPAP.

Comment: Commenters stated that because of the new minimum need criteria, service recipients will no longer receive PCS or CDPAS solely for monitoring their medical condition and well-being, and requested the care planning considerations to be amended to ensure that Personal Emergency Response Services (PERS) is authorized to supplement PCS and CDPAS at those times that the consumer needs monitoring but is not treated as a substitute for assistance with ADLs.

Response: There has been no change to the considerations of when PERS may be authorized, which is not affected by the implementation of the new minimum needs criteria. Previous Department guidance on the use of PERS—including GIS 04 MA/029, which provides that PERS may not be authorized as a substitute for, or in lieu of, assistance with recognized PCS tasks, such as transferring, toileting or walking—remains relevant and should continue to be followed. Current regulatory language specifies that PERS should be considered as a substitute for individuals receiving PCS "solely for

monitoring the patient's medical condition and well-being." Although commenters are correct that the implementation of the minimum needs criteria may decrease the number of such individuals over time, it will not eliminate the relevance of this provision. While PERS may not be an appropriate substitute for assistance with personal care tasks, there are other alternatives that can do so, such as adaptive or specialized medical equipment. Because the provisions in the regulation will maintain their relevance after adoption, the Department has decided that an amendment to these provisions is not needed at this time.

Comment: Commenters have requested that the Department retain the current process for obtaining medical orders from community physicians, rather than through an independent provider panel (IPP).

Response: Part MM of Chapter 56 of the Laws of 2020 instructed the Department to utilize an independent panel, rather than community based physicians, to issue medical orders in connection with the authorization for personal care services. Accordingly, the Department does not have discretion to not impose this requirement as part of the regulations.

Comment: Commenters have indicated that the regulations are not consistent with State and federal law in requiring the physician to sign the order when a nurse practitioner (NP) or physician assistant (PA) conducts the examination. Commenters have also requested that an individual's representative should be able to attend the clinical examination. Finally, commenters raised questions about the scope of the order,

including whether the order should include a determination of an individual being self-directing and being able to remain safely in the community.

Response: Section 505.14(b)(3) of the regulations have been amended to clarify that a physician signature on the order form is no longer required when an NP or PA conducts the clinical examination. Based on these 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. Additionally, 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 medical examination. The order will help determine whether the individual can remain safely in the community and is capable of self-directing; however, this component of the review will follow the completion of the community health assessment, such that the examining practitioner will have the benefit of the CHA to inform the order and these determinations.

Comment: Commenters requested that the practitioners who conduct the medical examination in connection with the medical order have relevant clinical experience in geriatrics, rehabilitation medicine, or related fields.

Response: The Department agrees with this comment and will work with the IA to retain examining providers and physicians with relevant clinical experience in the areas cited by the commenters.

Comment: Commenters made suggestions about how the physician should certify to the accuracy of the medical order form if the physician is not also the examining provider, including that the physician indicate his or her name, affiliation, and licensure number.

Response: This comment is obviated by no longer requiring a physician to certify the order when the underlying examination was performed by an NP or PA.

Comment: Commenters expressed support for the change in the medical order process because it will diminish the need of an individual's primary care physician to recommend services based on the relationship, rather than need. Commenters also asked how the Department will ensure that there are adequate practitioners on the IPP to preserve access in rural areas and how medical orders will be scheduled, especially during the COVID-19 pandemic.

Response: The Department acknowledges and appreciates these comments. In addition to having the IA retain a sufficient number of examining practitioners to meet projected

demand of assessments, the regulations promote the use of telehealth-based medical examinations through technology facilitated by the IA. The use of facilitated telehealth encounters by the IA to obtain the required orders will help preserve access across the State to these medical examinations. Further, no longer requiring a physician signature on every order will allow the use of NPs and PAs to conduct these examinations independently. In terms of scheduling, the IA will work to schedule these examinations as part of the assessment scheduling process. If an in-person examination is requested, the IA will find a conveniently located practitioner, but individuals will be encouraged to use telehealth services as these encounters promote efficiency, improve access, and limit in-person interactions during the COVID-19 public health emergency.

Comment: Several commenters expressed confusion as to the relationship or differences between the independent medical examination and the assessments completed by the IA. Specifically, commenters asked for clarity regarding whether the IPP or the IA makes the determination of eligibility based on the ADL requirements and whether the member is self-directing in order to receive CDPAS.

Response: The regulations have been amended to clarify that the IA makes the determination of PCS and CDPAP eligibility based on the needs of the consumers and the standards set forth in this rulemaking; however, consistent with federal requirements and historical regulations, the medical examiner evaluates the individual's clinical status, including whether the individual is self-directing and medically stable.

Comment: Commenters asked for clarification whether LHCSAs will need to obtain an order for personal care services beyond the medical order resulting from the independent medical examination.

Response: The Department believes that the regulations are sufficiently clear and that the LHCSA does not need to obtain a second order under State law or regulations for PCS beyond the medical order required by these regulations.

Comment: Commenters asked for further clarification on what it means for an examining practitioner to be deemed "independent," such that the practitioner can issue an order in connection with the authorization of PCS, including whether the independence is imputed to the entire group practice or when the practitioners can regain his or her independence after a certain period of time.

Response: To clarify, independence is not imputed at the group practice level, but at the individual provider-patient relationship, which aligns with the intent behind this legislative change. Moreover, there is no time period that a provider regains independence, but that the individual must be no longer be considered a patient of that practitioner, which could occur by virtue of a letter being sent by the provider to the individual to inform the individual that they are no longer a patient.

Comment: Commenters sought clarification regarding who may sign the medical order.

Response: Based on revisions made to this regulation, the order may be signed by the examining provider, who may be a physician, NP or PA. A physician does not need to sign the order if that physician is not the provider who conducted the medical examination.

Comment: One commenter has asked about how the new IPP process will impact program integrity efforts by the Department, Office of the Medicaid Inspector General (OMIG), and MMCOs.

Response: The Department does not believe that the change in the medical order and IPP process will change the Department's, OMIG's or MMCO's program integrity obligations. To the extent that medical orders will be obtained from the IPP, rather than by LDSS, MCOs, or individuals seeking care, it will potentially reduce the circumstances where services are authorized, but the medical order cannot be located.

Comment: Commenters asked technical questions about the form that the IPP will use to determine the medical necessity of PCS/CDPAS and whether the consumer is self-directing pursuant to CDPAS requirements. Included in these comments is whether LDSS, especially those in New York City, will be able to continue using their current form.

Response: In connection with implementation of this process, the Department intends to issue a new practitioner order (PO) form to reflect the regulatory requirements. The IPP

will use this PO form and it will reflect the determination regarding whether a person is self-directing and needs PCS or CDPAS.

Comment: Commenter opposes the additional processes, including the IPP and IRP, contained in proposed regulations beyond the initial and annual assessment for CDPAP and the ability of the consumer to fulfill these responsibilities.

Response: The Department appreciates these comments, but these regulations are enacting processes set forth in State legislation and does not have discretion not to implement them.

Comment: One commenter calls for 150% of minimum wage and benefits for CDPAP workers and modifying Medicaid rate to fiscal intermediaries (FIs). Another commenter opposed reimbursement reductions to CDPAP. Finally, a related comment opposed the proposed regulations as they relate to live-in aides or assistants because of concerns with State wage and hour laws.

Response: These topics are not addressed by the current rulemaking, but the Department will consider these comments in future rulemakings. The Department has determined that no changes to the regulation are needed.

Comment: Commenters expressed concern that the process of enrolling in a plan or securing PCS and CDPAS will become more bureaucratic and challenging to navigate.

Response: The Department appreciates these comments, but these regulations are enacting processes set forth in State legislation and does not have discretion not to implement them. The Department has determined that no changes to the regulation are needed.

Comment: One commenter questioned the savings to the State from these changes and requested the Department's expected increase in contract costs from the IA engagement.

Response: The SFY 2020-21 enacted budget contemplated the increased contract costs associated with implementation of this proposal when authorizing this initiative. The Department does not provide contract cost information in response to regulatory comments.

Comment: Commenters suggested the Department consult consumers and advocates on the Uniform Tasking Tool and question whether the CHA needs to be amended to account for supervision and cueing.

Response: The Department appreciates these comments, but consideration and implementation of a Uniform Tasking Tool is not relevant to the scope of the proposed regulations. The Department has determined that no changes to the regulation are needed.

Comment: Commenters 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 MLTC coverage of these services. The commenters raised concerns regarding the reasons for which MCOs 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.

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 rationales, provided that notice is appropriately provided. 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.

Comment: Similar comments 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 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 appreciates these comments, but strongly disagrees 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 rational 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 the Section 4403-f(11-b) of the Public Health Law 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 indicated that the stipulation of settlement with the plaintiffs in *Caballero v. Senior Whole Health* prevents the Department from implementing changes in the listed rationale for denials, reductions and discontinuance until the stipulation of settlement expires because the Department is obligation to "maintain" the requirements of 18 N.Y.C.R.R. §§ 505.14(b)(5)(v)(c)(2)(i) through (vi), for PCS, and 18 N.Y.C.R.R. §§ 505.28(h)(5)(ii)(a) through (f) for CDPAS. Accordingly, to the extent that the Department adds any additional circumstances whereby an MMCO may reduce services, the Department is failing to "maintain" the regulatory requirements and violating the stipulation of settlement.

Response: The Department disagrees with the commenter's reading of the stipulation of settlement from the *Caballero* case. Nevertheless, the Department notes that in any final adopted rule it may establish appropriate effective dates to ensure alignment with any applicable legal obligations.

Comment: Commenters expressed concern that technological developments and telehealth will be given as a vague reason for a denial without providing any specificity as to how a consumer's needs can be met through this modality. Commenters suggested that this added language on telehealth should either be removed or clarified to only permit the substitution of "telehealth services that are readily available and that the applicant can successfully and reliably access . . . " in 18 N.Y.C.R.R. §§ 505.14(b)(5)(v)(c)(1)(ix), 505.14(b)(5)(v)(c)(2)(iv), 505.28 (h)(4)(i)(e), and 505.28(h)(4)(ii)(d).

Response: The Department appreciates this comment and has clarified that telehealth services need to be "readily available" and "reliably accessed" by the individual as part of an MMCO's or LDSS's consideration of these technological development when making a determination on service needs.

Comment: Commenters requested that the Department expand the regulations to require LDSS MMCOs to confirm the availability of these alternative services and precisely identify how these technologies reduce the need for PCS and CDPAS, and expressed concern that without these additional requirements the proposed regulations will invite arbitrary decision making that leaves consumers in unsafe conditions at home. See proposed 18 N.Y.C.R.R. §§ 505.14(b)(5)(v)(c)(1)(vi) (pp. 44-45), 505.14(b)(5)(v)(c)(2)(iv) (p. 46), 505.28 (h)(4)(i)(e)(p. 110), and 505.28 (h)(4)(ii)(d)(p. 112).

Response: The Department acknowledges the concerns expressed by the commenters, but adding this specificity to the regulations is not necessary because the underlying obligations of the MMCO and LDSS will not change, which is to take actions that are appropriately supported by the assessment of the individual and their clinical needs, and to provide required notice that describes this rationale, as required by *Mayer v. Wing* and related case law. The purpose of the rationale list is to guide LDSS and MMCOs towards rationales that can be supported, but not describe exactly how to support them as applied to specific facts. That said, the Department will consider issuing guidance with specific examples, as technologies develop to help guide MMCOs and LDSS to use this newly listed rationale.

Comment: Several commenters requested clarification related to the Immediate Needs process and whether the IA will be involved, and whether they will be able to complete their portions of the review in sufficient time to allow the LDSS or MMCO to comply with statutory timeframes.

Response: The Department has clarified in the regulations that the IA must complete the IA and medical order processes in sufficient time to allow for the LDSS or MMCO to meet federal and State required timeframes, including those related to Immediate Needs. In cases where the IRP review is required but has not been completed in sufficient time to allow the LDSS or MMCO to review the IRP's recommendation before State or federal timeframes expire, the LDSS or MMCO may issue a temporary authorization pending

completion of the IRP process. Taken together, these changes and procedures will enable LDSS and MMCOs to remain in compliance with the Immediate Needs timeframes and other State and federal requirements.

Comment: Commenter suggested, in the case of Mainstream Medicaid Managed Care (MMMC) to MLTC transition, modifying 18 NYCRR §§ 505.14(b)(1) and 505.28(d) to read ". . . and, if needed, the MMCO shall refer the applicant to the social services district and the social services district shall begin to determine the applicant's financial eligibility for medical assistance services, including community based long term care services."

Response: The Department amended the provisions which required that MMCOs refer individuals to their LDSS for eligibility determination and specified that this includes when someone requires a determination of eligibility for CBLTCS. This would include instances where an enrollee reaches out to their Mainstream plan to discuss possible enrollment in an MLTC plan.

Comment: One commenter suggested that an MMCO should never have to forward consumers to the LDSS to determine eligibility because consumers cannot enroll in the MMCO plan until they have had that determination of eligibility made.

Response: The Department is unclear as to the basis for the commenters' assertion. The Department is aware that individuals regularly, if not frequently, reach out to individual MMCOs, sometimes before they have been determined Medicaid eligible, to discuss

enrollment. Where the MMCO is aware that the individual's Medicaid eligibility status would not allow for receipt of services, they must refer the individual to the LDSS to apply for appropriate eligibility.

Comment: Related to physician's statement of need for PCS on a form required by the Department of Health to initiate an Immediate Needs review, commenters request clarification on who determines immediate need cases—whether it is the IA, or the individual's primary care physician, or either.

Response: 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. However, for purposes of administrative efficiency and in order to discourage those with real immediate needs from waiting for the independent medical order process to occur, as well as because the IPP does not require the order to be issued by a physician, the IPP order will not be sufficient to meet the statement of need requirements necessary to initiate the immediate needs process.

Comment: Commenters question whether Level I services will still be available under the new eligibility rules pursuant to the amended regulation.

Response: The Department has not changed the scope of PCS, including the provision of Level I services. Anyone who meets minimum needs criteria will be able to access

Level I services to meet IADL needs. Anyone who has been assessed and authorized for services prior to the effective date of these regulations will be entitled to be determined eligible for such services without consideration of whether they satisfy the new medical necessity thresholds, and may continue to access Level I services as well. The Department has determined that no changes to the regulation are needed.

Comment: Commenters expressed concern that the use of more than two ADLs to determine eligibility in MLTC will limit the availability of CDPAS and PCS.

Response: The regulations do not address changes to MLTC eligibility. The determinations for MLTC enrollment eligibility and PCS and CDPAP service eligibility are separate determinations, although based on the same ADL criteria. The Department has determined that no changes to the regulation are needed.

Comment: One commenter suggests that the Department should replicate the definition of Level I PCS in both 18 NYCRR Part 505.14 and 505.28.

Response: The definition of PCS in 18 NYCRR Part 505.28 refers to PCS, as defined in 505.14. This definition includes both Level I and Level II PCS, which available under CPDAP. Accordingly, no changes to the regulation are required.

Comment: Commenters request the Department include clear guidance on the process for determining minimum need as defined in the regulations, including which entity makes the determination, and whether the entity will be responding to fair hearing requests.

Response: The Department agrees that more specificity in the regulation is needed to clarify who is responsible for determining whether someone meets minimum needs criteria. As set forth in the revised regulations, the Department expects this determination will be made by the IA. The IA will support any determinations at fair hearings.

Comment: Once commenter questioned whether encouraging MMCOs to first seek alternative services prior to authorizing PCS could impact an individual's eligibility for PCS and CDPAS.

Response: LDSS and MMCOs must perform the authorization determination for PCS within the required timeframes, as provided for in State and federal requirements. Consideration of other available services and supports that may meet the consumer's needs does not by itself permit a delay in these timeframes and associated authorizations, but is a component part of that process. Additionally, as discussed in response to other comments, the Department has clarified that the LDSS or MMCO must first determine the full scope of need for PCS or CDPAS and then work to identify possible alternatives that would also meet the individual's needs in developing the plan of care.

Comment: Commenters asked whether the qualifying diagnosis of dementia and Alzheimer's can be made by the individual's primary care physician and what recourse these individuals will have if they are assessed to not meet new minimum necessary ADL requirements for PCS.

Response: A diagnosis of Alzheimer's or dementia may be determined and documented by any qualified clinician, including the individual's existing primary care physician, and the Department would expect that condition to be documented in the individual's medical record that is available for consultation by the IA or the IPP during the assessment process, consistent with earlier responses to comments in that regard. Additionally, if the IA nurse assessor, as part of the cognitive assessment in the CHA, believes that the individual has a qualifying diagnosis of Alzheimer's or dementia, the nurse assessor may advise the individual to receive a medical examination at their primary care provider or another community physician to validate the diagnosis.

Comment: Commenters expressed a legal concern that the application of the IA to Program of All-Inclusive Care for the Elderly (PACE) Organizations may conflict with CMS's interdisciplinary care team, in-person assessment, and care planning requirements. Based on concerns regarding federal preemption of the IA process and requirements, these commenters advised that PACE is exempt from the new IA process as this process is inconsistent with the fundamental PACE program design as set forth in federal statute, regulations and policy.

Response: The Department agrees that federal regulations preempt many of these regulatory requirements, as applied to PACE Organizations and has amended the regulations to exclude PACE from the IA, medical order, and IRP processes, which conflict with the PACE assessment processes governed under federal regulations at 42 C.F.R. Part 460.

Comment: For similar reasons, one commenter advised the Department that eligibility for PACE should be dictated by eligibility rules established by federal regulations, under 42 C.F.R. Part 460, which require a nursing home-level of care, rather than the minimum needs criteria set forth in the regulation for PCS and CDPAP.

Response: 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.

Comment: Several commenters representing MMCOs queried whether and how the Department planned to conduct quality assurance and performance improvement of the IA with regard to the accuracy of assessments and completion of the CHA. Specific queries including the use of software analyzers that determine internal consistency of the CHA or errors made by nurse assessors. Additionally, these commenters asked whether the Department would utilize dedicated assessors for specific MMCOs or LDSS to promote familiarity between assessors and members of specific MMCOs.

Response: Pursuant to contractual requirements and Department oversight, the IA will use industry standard quality assurance tools to ensure that internal inconsistencies are corrected before the assessment can be signed and finalized. The Department also expects to implement other quality assurance practices, in consultation with MMCOs and LDSS, to preserve the integrity and accuracy of the completed CHA; however, the use of dedicated assessors to specific plan membership may be viewed as compromising the independence of that nurse assessor and will not likely be one method used by the Department to achieve accuracy in CHA completion. The Department has determined no changes to the regulation are needed.

Comment: One commenter asked what will happen if the IA is unable to complete a reassessment or obtain signed medical orders; and whether an MMCO would have an audit risk if services continue to be authorized and capitation collected for that member.

Response: If the IA is unable to complete a reassessment, the IA would contact the MMCO or LDSS to discuss the reasons for the inability to do so. Depending on the reasons underlying the inability to complete the reassessment, the MMCO or LDSS may be asked to assist the IA in conducting outreach to the member to complete the reassessment, but the MMCO or LDSS may need to adjustment the plan of care or even disenroll the member based on the circumstances. Continued receipt of capitation following when an MMCO is required to disenroll a member would be grounds for an audit recovery or other program integrity activity.

Comment: Two commenters expressed concerns on proposed changes to the MMCO internal appeals and fair hearing process that were not proposed during this rulemaking.

Response: These comments relate to a separate rulemaking regarding Medicaid Managed Care State fair hearings and External Appeals Processes and Standards, published on the State Register on July 8, 2020, rather than this rulemaking, published on July 15, 2020. The Department will respond to these comments in its Assessment of Public Comment for the applicable rulemaking.

Comment: Commenters asked about when MMCOs or LDSS should notify an individual in writing when it is only "considering" a change of authorization or when that change has occurred. Based on this query, commenters requested that the Department remove language form the regulation that indicates that LDSS and MMCOs should notify consumers in writing when a change in the amount of services is being considered.

Response: The Department has removed this requirement from the regulations. MMCOs and LDSS, or contracted agencies, should maintain contact through the care planning process. The Department will consider guidance as to the types of communications and notices that may be appropriate during such process.

Comment: Commenters requested clarification on how the IA assessment process will relate to the fair hearing process under State and federal regulations and the interactions between the IA and IRP, on the one hand, and the fair hearing process, on the other.

Response: The Department clarifies that neither IA nor the IRP is responsible for developing the plan of care or for authorizing services, such that the ultimate decision to provide services remains with the LDSS or MMCO. Any rights to due process related to the ultimate authorization of services are with respect to the decision made by the LDSS or MMCO, not by the IA or IRP. As it relates to a determination of whether an individual satisfies the minimum needs criteria for PCS or CDPAS, the IA is responsible for that determination, which has been clarified with additional language in the regulation. In most cases, these findings by the IA will result in an action being taken, such as a denial or service or plan enrollment, which will generate appropriate notice with fair hearing rights. As clarified in our earlier responses and is reflected in the regulations, the IRP does not take action or make determinations with regard to service authorizations nor the minimum needs criteria, such that the role of the IRP does not create any separate and distinct fair hearing rights.

Comment: Commenters requested that the Department clarify in the regulations that the decisions of the clinical review panel are, in fact, "recommendations" that are not appealable by the individual.

Response: These observations are correct. The IRP recommendation is not an action or determination that is designed to inform the plan of care established by the LDSS or MMCO, but does not itself deny, discontinue, or reduce services. Accordingly, the recommendation itself is not appealable by the member, but may inform and be used as

evidence in the course of an appeal following a service authorization or determination by a MMCO or LDSS. The Department has determined that no changes to the regulation are needed.

Comment: Commenters asked whether MMCOs were required to retain IAs, medical orders, and IRP reviews for their required retention period under the State Model Contract.

Response: MMCOs should consult the terms of the State Model Contract or other applicable federal and State legal requirements to determine the appropriate retention period for these records.

Comment: Commenters requested the Department should require the physical 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 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 representation 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: Many commenters either objected 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. In connection with these comments, LDSS and MMCO commenters asked the Department to identify a tool or further guidance on how to determine cost effectiveness among CBLTC services that could be authorized (e.g., PCS

vs. ALP or an enriched housing program). Other 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.

Response: At the outset, the Department 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 in apparent attempt to comply with caselaw. To that end, the Department 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 specify a process for balancing these interests or provide a specific definition of "cost effectiveness," as this consideration process will 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 adoptive 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: In relation to LDSS and MCOs evaluating cost effectiveness of providing PCS, commenters asked how this would impact consumer choice.

Response: See response above. The Department 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-effectiveness with available alternatives, social and cultural consideration, and consumer preferences.

Comment: One commenter claimed that the required review for appropriateness and cost effectiveness of services after a consumer experiences a change in their mental condition constituted impermissible discrimination based on diagnosis.

Response: The Department has clarified the language used to describes LDSS and MMCOs responsibilities when a consumer experiences a change in their mental status was not clear. The expectation of LDSS and MMCOs when a consumer experiences either an unexpected change in mental status or physical/medical condition is that the

LDSS or MMCO will refer the individual to obtain a new IA and medical order, redetermine the authorization, and amend the plan of care as appropriate in accordance with 18 NYCRR § 505.14(b)(2)(iii). Accordingly, revisions have been made to 18 NYCRR §§ 505.14 (b)(4)(xii)(b) and (c) to align and clarify these provisions.

Comment: Commenters asked whether members can 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: The changes to the regulation, as described in a response to the above comment, 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: Some commenters asked whether the new CDPAP program provision requiring members to have no more than one FI applies to new members only or current members as well.

Response: The requirement to access CDPAS through a single FI will apply to all consumers in the CDPAP, regardless of when services were first authorized; however, consistent with MLTC Policy 20.01, which may be further amended in connection with issuance of these regulations, consumers will have up to 90 days to transition to a single FI.

Comment: Commenters raised concerns and opposed removal of a provision within the proposed regulations that LDSS must have agreements and refer members to hospice when the LDSS determines it would appropriate for hospice services.

Response: This requirement imposed on LDSS was originally included as part of a legislative enactment set forth in Chapter 165 of the Laws of 1991 and Chapter 41 of the Laws of 1992; however, the statutory authorization expired in 1999 and has not been reenacted. Accordingly, the Department has removed this requirement because the underlying statutory authorization has expired. Removal of this provision does not preclude LDSS from referral of individuals to hospice, but that the process set forth in these regulations is no longer statutorily prescribed.

Comment: In light of the deletion of hospice referral requirements, one commenter asked whether a hospice would be providing PCS concurrently with an MMCO's or LDSS's authorization of PCS.

Response: This comment is not related to issuance of this rulemaking. MMCOs and LDSS should continue to coordinate benefits for members consistent with their current obligations.

Comment: A commenter questioned whether the bolded bracket in the statement below was a typo or meant to be there: ". . . The medical professional must examine the individual and accurately [describing] . . . home health aide services and skilled nursing tasks**[;** and provide only such other information as the medical's order form requires . . . ."

Response: The Department confirmed the presence of an appropriate closing bracket.

Comment: One commenter suggested that the usage of "patient" should be updated to "consumer" and "personal care functions" as "Activities of Daily Living" throughout the regulations to update the use of medicalized terms.

Response: The regulation has been amended to reflect the use of new terminology in relation to persons seeking or receiving services. However, instead of "consumer" or "patient" the Department has decided to adopt the term "individual" in 18 NYCRR § 505.14 to prevent confusion with the defined term "consumer" in 18 NYCRR § 505.28, which is someone who has been determined eligible for CDPAP.

Comment: Commenter queried whether there were unintended errors in 18 NYCRR §§ 505.14(b)(4)(xi)(c) and 505.28(f)(1)(ii) regarding numeration and when medical orders would be required.

Response: The Department made these technical corrections to the regulation.

Comment: Commenters question which entity—the IA, MMCO or LDSS—will be responsible for sending notices to individuals to inform them of their upcoming routine reassessment.

Response: The IA will send notices to assessed individuals making them aware of their upcoming routine, annual reassessments based on the date of their last assessment. It is imperative that the MMCO and LDSS ensure that information in certain designated electronic databases is kept current and accurate to ensure that the IA has sufficient information to provide notices and coordinate the scheduling of assessments. In light of this the Department has amended the regulations to include additional requirements for cooperation between the MMCO or LDSS and the IA. MMCOs and LDSS will work with the IA to schedule non-routine reassessments upon a significant change in condition, a return to service, a discharge from inpatient care, and other applicable circumstances.

Comment: Commenters asked when will existing recipients of PCS/CDPAP services transition to be assessed by the IA.

Response: Existing recipients will transition to the IA upon their next reassessment, whether routine or due to another reason, such as a significant change in condition.

Comment: Commenters supported not requiring an IRP if both IA and medical order indicates no change in PCS authorization and recommend removing the third factor that "the authorization is unchanged" because IA does not authorize services.

Response: Changes to the IRP process address this change. Specifically, the Department has clarified the regulations, such that the IRP does not review cases that already exceed the 12-hour threshold for IRP review. Accordingly, even if the authorization changes, but the PCS or CDPAS hours have already exceeded this threshold and the IRP conducted its review, then no further IRP review is required.

Comment: Commenters asked whether a 12-month authorization includes continuous care.

Response: The Department clarifies here that the 12-month authorization includes continuous care, but has determined no changes to the regulation are needed.

Comment: Commenters asked whether a hospital stay is considered a change that must be sent to the IA.

Response: The IA will conduct a return to service or discharge assessment after a hospital stay to ensure that needed changes in services and supports are identified. The Department has determined no changes to the regulation are needed.

Comment: One commenter asked whether there will be a mechanism in place to evaluate a consumer in some fashion every six months, now that the reassessment process is now annual.

Response: Routine reassessments will now occur annually, but this change does not preclude consumers from being reassessed upon a significant change in 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. Nursing supervision of services must also occur at least every six months, or more frequently as needed. The Department has determined no changes to the regulation are needed.

Comment: Given the extension of the routine reassessment assessment to annual, commenters asked what happens if an ADL impairment is expected to last less than the recertification period.

Response: Changes in ADL impairments could form the basis of a significant change in condition assessment that could result in a new plan of care and service authorization.

Comment: A commenter suggested implementation of the new PCS and CDPAP regulations be postponed entirely until after the COVID-19 pandemic is over, citing concerns of potentially exposing vulnerable population to the virus by requiring them to travel outside of their home for medical exam that is not medical necessary and that the Maintenance of Effort (MOE) rules prevent such actions from taking effect without jeopardizing enhance federal medical assistance percentage under the Families First Coronavirus Response Act (FFCRA).

Response: The Department has provided guidance on the waiving of certain requirements regarding the authorization process for PCS and CDPAP services in light of the COVID-19 pandemic emergency. The Department will issue further guidance to clarify how current or future waivers may apply to the new regulations if they the waivers are still in effect when the rule is adopted. Additionally, the Department is aware of its obligations under Section 6008(b)(3) of the FFCRA. In accordance with the Fourth COVID-19 Interim Final Rule (IFC-4), issued by CMS on October 28, 2020 (after comments were collected from this rulemaking) and codified as 42 C.F.R. § 433.400, the Department is able to implement the IA assessment process, the minimum needs criteria, and other changes proposed by this rulemaking without implicating the Maintenance of Effort requirements under this provision of FFCRA. *See* 85 Fed. Reg. 71161 (Nov. 6. 2020). Notwithstanding this flexibility, the Department amended the regulations to provide flexibility regarding implementing of components of the IA process in case circumstances, such as the COVID-19 public health emergency and required federal approvals, necessitate a phased implementation.

Comment: Commenters suggest CDPAP regulations should indicate how many days/hours an aide can work, and the number of back-up aides required.

Response: Given the nature of CDPAP as a self-directed program, the Department declines to specify in these regulations how a consumer may choose to staff their care.

Comment: Commenters asked who will be responsible for monitoring personal assistants, approving consumer choice of a designated representative and FI, given that the FIs are now contracting with the State.

Response: These comments are outside the scope of this rulemaking. However, the Department notes that the CDPAP regulations (18 NYCRR Part 515.28) continue to require the consumer to hire, manage, train and fire their own personal assistants. The LDSS or MMCO will remain responsible for developing the consumer's plan of care. This care planning process includes the consumer choice of Fiscal Intermediary, as well as, the need or choice for a designated representative.

Comment: Commenters requested that the Medicaid premiums of MLTC plans that retain their nurse assessors be subject to a special adjustment to ensure adequate reimbursement of this function into the future.

Response: 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. Accordingly, it would not be appropriate given this statutory direction to afford MMCOs with a special adjustment should MMCOs decide to retain their own nurse assessor function.

Comment: One commenter asserts that plans are likely to continue to conduct assessments, thus premium rates should not be reduced.

Response: See comment above. MMCOs are no longer required to conduct assessments, which will be reviewed by the Department and its actuaries under actuarial soundness principles, consistent with federal regulations.