LeadingAge New York

Katherine Ceroalo
Bureau of Program Counsel, Regulatory Affairs Unit
New York State Department of Health
Corning Tower
Albany, New York 12210

Via email: REGSQNA@health.ny.gov

Re: Amendments 18 NYCRR §505.14 (personal care services), and 18 NYCRR §505.28 (consumer directed personal assistance program services)

September 14, 2020

Dear Ms. Ceroalo:

I am writing on behalf of LeadingAge New York's managed long term care (MLTC) plan and provider members to raise a number of concerns and recommendations relating to the proposed amendments to the personal care services (PCS) and Consumer Directed Personal Assistance Services (CDPAS) regulations. This letter follows broader comments and recommendations on both regulatory and implementation issues that we submitted to Medicaid Director Donna Frescatore in August (attached).

We support the goal of the proposed regulations to ensure that Medicaid beneficiaries receive the appropriate PCS and CDPAS to meet their clinical needs. We also share the Department's interest in ensuring program integrity and improving efficiency. However, our members are concerned that the proposed regulations governing the independent assessment, independent medical evaluation, and clinical review processes do not include necessary safeguards to ensure the accuracy of their findings. We are also concerned that implementing these major changes in procedures for determining eligibility and level of need for PCS and CDPAS on an aggressive timeline in the midst of a pandemic, when systems and consumers are under significant strain, will exacerbate concerns related to the validity of the processes and jeopardize access to needed services. We appreciate the timeline for implementation contemplated in the State Budget, but we believe that the savings anticipated in the SFY 2020-21 Budget could be achieved through a phased implementation as discussed in our August letter. Finally, we believe the proposed regulations have inadvertently omitted certain key elements described below which should be included in future amendments.

The following is a subset of the comments and recommendations set forth in our August letter, focusing on our regulatory proposals.

Effective Date and Phased Implementation

- **Issue:** The implementation of these regulations and associated procedures entails major changes in the way that older adults and people with disabilities access community-based long-term care. It also involves changes in the processes used by mainstream managed care plans and managed long term care plans (collectively MCOs), local social services districts, providers, and

beneficiaries to coordinate assessments, enrollment, and authorizations. Launching this new process in the context of a pandemic, when face-to-face communication is generally ill-advised and when all stakeholders are operating under significant stress heightens the challenges. Communication failures, delays, technical flaws, superficial training, and/or errors in assessments may create barriers to needed care or enable ineligible individuals to access care.

- **Recommendation**: We understand that the extension of the federal health emergency and maintenance of effort requirements will require postponing the effective date of the regulations, and we support this delay. Moreover, when the regulations take effect, we recommend a phased implementation beginning with assessments of new applicants only. The savings to be achieved from these measures in the current fiscal year appear to be related to the change in the eligibility criteria for PCS and CDPAS (i.e., the ADL requirements or "minimum need requirements"). Under the statute, these enhanced eligibility criteria apply only to new enrollees. Thus, the savings associated with the independent assessment process could be achieved by launching the process at the outset for new enrollment assessments only and delaying the implementation for change in condition assessments and reassessments. This would allow existing enrollees to receive change in condition assessments through their plans and avoid delays in accessing additional services for enrollees who are being discharged from hospitals or nursing homes or experiencing a deterioration in their condition.

Accessibility and Validity of Independent Assessments, Independent Medical Evaluations, and Clinical Review Panel Recommendations (505.14(b)(1), 505.14(b)(2); 505.28(d)(1); 505.28(d)(2), 505.28(d)(4))

- **Issues:** The proposed regulations envision the assessment of the beneficiary by a nurse employed by the Independent Assessor (IA) and the referral of the beneficiary by the IA to an independent medical professional who will conduct an independent medical evaluation (IME) of the beneficiary and submit clinical findings to a physician for issuance of an order for PCS or CDPAS services. (pp. 23-26;77-81). Before a beneficiary is authorized to receive more than 12 hours daily of PCS or CDPAS, the LDSS or MCO is directed to refer the case to a Clinical Review Panel (CRP).

  Our members express significant concerns about the validity of independent assessments conducted by nurses who have little, if any, first-hand knowledge of the individual being assessed (henceforth "the beneficiary"), do not have access to their history, and are unfamiliar with their informal supports or home environment. Plans and providers note that beneficiaries often do not have accurate recall of issues or are reluctant to report to an unfamiliar person on issues addressed by assessments (e.g., flu shots, falls within 30 days, ER visits in the last 90 days, incontinence, degree of assistance needed for ADLs and IADLs, willingness and availability of informal caregivers). This lack of familiarity with the individual and his/her social and environmental context raises the possibility of either inflated assessed need that exceeds actual need *or* assessed need that understates actual need.

  These concerns are heightened by the prospect of these assessments being conducted via telephone or digital meeting platform until the pandemic is brought under control. The

regulations do not specify whether the independent assessment, IME or CRP will be conducted virtually or in-person. To the extent that pandemic safety considerations permit, we assume assessments will be conducted in the home and IMEs will generally be conducted in practitioner offices. If community spread of COVID demands continued social distancing, we assume that virtual visits will be used for assessments, IMEs and the CRP.

The shift to independent medical professionals and the addition of the clinical review panel raise the question of whether they will be as accessible as the beneficiary's personal physician. If these visits must be conducted in-person, we are concerned that they may be geographically or physically inaccessible. Will older adults and people with disabilities, who may have physical and cognitive limitations, be required to travel to unfamiliar offices for in-person evaluations? Once the beneficiary is determined eligible for PCS or CDPAS, will a trip to the office for an IME and/or a CRP be required annually, or is this one-time determination?

While virtual evaluations and CRP reviews would alleviate geographic and physical accessibility concerns (as well as COVID transmission concerns), the absence of in-person examinations heightens the risk that the evaluations and reviews will not be accurate.[1] Since the independent assessment, IME, and CRP are all conducted by professionals who are unfamiliar with the beneficiary and their medical history and social and physical environment, there is a risk that the IME and CRP may merely replicate any inaccuracies captured in the IA. Moreover, virtual visits raise their own accessibility concerns. Older adults and people with disabilities may experience difficulty managing the technology to conduct the visit. They may lack Wi-Fi or unlimited cellular data or stable internet service.

- **Recommendations:**
  - Objective Process to Resolve Errors: In order to attempt to mitigate concerns about the accuracy of assessments and IMEs, we recommend that the regulations include an objective process managed by DOH to correct demonstrable inaccuracies. Although the proposed regulations include a provision allowing the managed care organization (MCO) or local social services district (LDSS) to bring factual inaccuracies to the attention of the IA and for the IA to correct the errors (pp. 27, 88),[2] the proposed regulations do not provide for an objective arbiter of disagreements. In addition, the proposed regulations limit this correction process to "factual" inaccuracies, implying that it is only available for issues that are clear-cut and explicit (e.g., age, gender, immunization status). However, many assessment items are more complex and nuanced. Clinical determinations, and hence eligibility, will be based on limited observations by the assessor that may be inaccurate or incomplete. Errors in the assumptions that form the basis for clinical determinations have significant implications for the individual's eligibility and potentially his/her care plan. They will also impact plan quality and risk scores. An impartial process to correct errors, if there is evidence

[1] Arguably, an in-person evaluation is less critical for the CRP because, at this point in the process, the beneficiary will have been assessed or examined by the IA, the IME, and the MCO.

[2] Page references relate to the Express Terms published at https://regs.health.ny.gov/sites/default/files/proposed-regulations/Personal%20Care%20Services%20and%20Consumer%20Directed%20Personal%20Assistance%20Program.pdf

demonstrating that the IA's or independent medical professional's findings are erroneous, would enhance the accuracy of assessments, program integrity, IA/IME accountability.

- Virtual and In-Person Visits: In order to mitigate accessibility and accuracy concerns, we recommend that the regulations be amended to encourage in-person assessments and medical evaluations to the extent feasible and safe, in light of geographic and physical accessibility and communicable disease transmission considerations. Virtual assessments and independent medical examinations should be permitted when in-person visits are infeasible or inaccessible. To the extent virtual visits are used, the process should ensure that the beneficiary has the technology and any supports needed to participate effectively in the process.

- Medical Records and Other Clinical Data: To mitigate accuracy concerns, the regulations should require the independent medical professional to review medical records or other clinical data provided by the Department, the beneficiary, or the MCO. Currently, the proposed regulations authorize, but do not require, the independent medical professional to review medical records other than the independent assessment.

- Non-Regulatory Recommendations: Our August letter proposes several additional provisions for inclusion in the contract with the IA and sub-regulatory guidance to strengthen the accessibility and accuracy of the IME and CRP. They include requiring continuity of assessors with individuals being assessed to the extent feasible; and auditing and/or quality oversight of the IA to review the validity of assessments.

Eligibility Determinations based on Minimum Need for Assistance with Activities of Daily Living (505.14(a)(3)(iv); 505.28(b))

- **Issues**
  - Failure to Identify the Party Charged with Making the Determination of Eligibility: The proposed regulations require applicants to meet minimum need requirements to qualify for PCS or CDPAS services. Minimum need is defined as:
    - for patients with a diagnosis by a physician of dementia or Alzheimer's, being assessed as needing at least supervision with more than one activity of daily living (ADL).
    - for all other patients, being assessed as needing at least limited assistance with physical maneuvering with more than two activities of daily living.

    Although the Department has stated that the IA will determine whether the beneficiary meets the minimum need requirements, the regulations do not direct the IA or any other entity or individual to make that determination. The IA is charged with assessing the "functions and tasks required by the patient, a discussion with the patient to determine perception of his/her circumstances and preferences, and an assessment of the potential contribution of informal caregivers. . . ." (pp. 20-21, p.76). The proposed regulations do not explicitly direct the IA to assess the level of assistance needed for ADLs, nor do they charge the IA with making any determination concerning minimum need requirements

The proposed regulations similarly neglect to direct the independent medical professional or the physician signing the medical order to determine the beneficiary's eligibility based on minimum need requirements. The proposed regulations require the independent medical professional to "describe the patient's medical condition and regimens, medications, and need for assistance with PCS tasks" (p. 23-26, 79-80). The independent physician signing the order must certify that the information accurately describes the patient's medical condition and regimens and must indicate whether "the patient is self-directing and can be safely cared for at home." The regulations do not speak to any determination by the independent medical professional or physician concerning minimum need for assistance with ADLs. In addition, although they do require findings concerning the patient's ability to self-direct and ability to be cared for safely at home, the regulations omit those factors from the required elements of the independent medical evaluation.

- Failure to Acknowledge PACE Eligibility Standard**:** Although the Department has recognized that PACE has its own eligibility standard (nursing home level of care) and that the minimum needs criteria do not apply to PACE, the proposed regulations do not exempt PACE applicants or enrollees from the new minimum need criteria.

- **Recommendations**:
  - The regulations should be revised to:
    - Clearly identify the party charged with determining whether a beneficiary meets the minimum need requirements (presumably the physician signing the order pursuant to the independent medical evaluation). This is a key element of the process and should be reflected in regulation, not merely in sub-regulatory guidance.
    - Align the elements of the assessment and IME with the determinations that must derived from them.
    - Recognize the federally-mandated PACE eligibility standard and clearly state that the minimum needs criteria do not apply to prospective and enrolled PACE members.

    - In addition to these regulatory recommendations, we have asked in our August letter that the Department include in contracts with the IA and in sub-regulatory guidance provisions to ensure that the IA and IME are informed of and apply the PACE eligibility standard prospective and enrolled PACE members.

Standards for Clinical Review Panel Recommendations (505.14(b); 505.28(d))

- **Issue:**
  - The proposed regulations require cases with authorized personal care services or CDPAS in excess of 12 hours daily to undergo an independent medical review by a clinical review panel (CRP) (pp.38-40, 94-97). The CRP is directed, under the regulations, to make a recommendation concerning whether the plan of care is "reasonable and appropriate to maintain the patient's health and safety in his or her own home." (p. 39, 96). Under the PCS section of the regulations, the lead physician is directed to make a recommendation in accordance with the standards set forth in subdivision (a) of 505.14, which include medical necessity, minimum

needs, and lack of alternative available and cost-effective services. The CDPAS section of the regulations directs the lead physician to "provide a recommendation on the reasonableness and appropriateness of the 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 [section 505.28], whether other Medicaid services may be appropriate, and the clinical rational [sic] for such recommendation" (p. 96).

The standards that the CRP must apply to its recommendation are murky and potentially over-broad. It is unclear which standards from subdivision (a) or section 505.28 the lead physician must apply to this recommendation or whether all must be met. These standards include, among others: a finding that the services are "medically necessary for maintaining the patient's health and safety in his or her own home," minimum ADL needs requirements, and a finding there are not other available, appropriate, and cost-effective services to meet the beneficiary's needs. The CRP's recommendation should be a clinical one – it should not be the role of the CRP to weigh in on whether there are alternative and cost-effective substitutes for the services in the plan of care.

- **Recommendations:**
  - The proposed regulations should be revised to clarify the standard for the CRP recommendation. Rather than referencing all standards in subdivision (a) of 505.14 or in section 505.28, the CRP's recommendations should be limited to clinical considerations. It should not be charged with making recommendations based on cost-effectiveness.

Timing and Triggers of Clinical Review Panel (505.14(b); 505.28(d))

- **Issue:** The proposed regulations provide that the independent medical review by the CRP is required "*before* a social services district or MMC may authorize more than 12 hours" of services per day on average" (pp. 38, 95) (emphasis added). However, the timing and triggers of the CRP are unclear. First, it is unclear whether the CRP is initiated after selection of a plan and submission of the enrollment, or while the beneficiary is still 'shopping' for a plan. Under the current system, after the CFEEC makes a determination that the beneficiary is eligible for MLTC enrollment, the beneficiary may seek assessments from several MCOs in order to find the MCO that offers most desirable plan of care. We assume that beneficiaries will continue to shop for the best plan of care under this new system. If the CRP is triggered when a proposed plan of care is issued, but prior to enrollment, a beneficiary may present to the CRP with two or more different proposed plans of care offering different arrays of services. For example, one MCO might offer live-in services, while another MCO might offer split shift services. CRP review of multiple plans of care would be inefficient, may result in further delays, and may have unintended effects on plan of care development.

  Second, the events that trigger consideration by a CRP, under the regulations, are also unclear. The regulations do not disclose whether it is a is one-time or periodic review or whether a recommendation must be secured in response to a change in condition that requires expedited attention. It is also unclear whether the CRP is triggered when more than 12 hours of services daily

is ordered by an ALJ after a fair hearing, as opposed to when an MCO authorizes the 12-plus hours in a plan of care.

Requiring a CRP recommendation periodically will add little value and create unnecessary administrative complexity and barriers to maintaining needed services. It is unlikely that an individual receiving more than 12 hours daily of PCS or CDPAS services will experience a dramatic improvement in function. Unfortunately, conditions that require extensive personal care tend to be stable at best or worsen over time, rather than improve. Further, a requirement to obtain a CRP recommendation when a beneficiary experiences a sudden change in condition that brings their need above 12 hours could delay access to care and jeopardize the safety of the beneficiary and/or delay discharges from hospitals and nursing homes, if the CRP recommendation is not issued rapidly.

- **Recommendations:**
  - The proposed regulations should be revised to:
    - Clarify that the CRP is required only at enrollment, or upon a change in condition that requires an increase in services to more than 12 hours daily, not on a periodic basis;
    - Clarify that an enrollment CRP takes place after the plan is selected, the enrollment is submitted for processing, and a proposed care plan is issued authorizing more than 12 hours of PCS or CDPAS daily;
    - Ensure that same-day CRP recommendations are available upon a change in condition requiring 12 hours of PCS or CDPAS daily;
    - Clarify that a CRP review is not required after an ALJ orders more than 12 hours of care daily, but that it would be required upon a change in the fair hearing beneficiary's condition or subsequent reassessment of that beneficiary.

Order and Timing of Steps in the Process

- **Issues:**
  - Timeframes for Each Step: The timing of the assessment, evaluation, and clinical review and the integration of these steps into the processes for enrollment and care plan changes must be structured to support access to needed care and avoid barriers to enrollment in integrated plans. As noted above, the addition of the IME, and potentially the CRP, as steps in the enrollment process presents a risk that access to care will be delayed. Although they need not be explicitly incorporated into the regulations, the timeframes for each step must be included in the contract with the IA and in sub-regulatory guidance. We have included some recommended timeframes in our August letter.

  - Change-in-Condition Assessments: The timing of change-in-condition assessments is perhaps the most challenging aspect of the new system. It is worth noting that the elimination of semiannual reassessments and the suspension of reassessments during the pandemic may result in greater need for change-in-condition assessments, as there may be fewer opportunities to observe a gradual decline in beneficiaries' condition. While many change-in-condition assessments may be conducted on a non-urgent basis, others demand immediate attention. Under their contract with the State, MLTC plans must meet compressed time frames for expedited prior authorization and concurrent review – generally 3 business days from the request or 1 business

day from receipt of the necessary information. Our MLTC members report that they conduct same-day assessments when needed, such as prior to discharge from a hospital. It is critical that same-day assessments remain available to address unexpected needs. The time allotted for change-in-condition assessments must also take into account the need for MCOs to review and follow up on the IA's assessment, make the necessary changes in the care plan, and coordinate with the beneficiary, family members, and providers to put in place the needed services, supplies, and equipment.

- Accommodating MAP and PACE Timeframes for Enrollment and Changes in Care Plans: The timing of the steps in the enrollment process is more sensitive for MAP and PACE plans than partially-capitated plans, as they must align with the Medicare and PACE timelines. MAP plans may be forced to complete the Medicare application after the Medicaid assessment and IME are complete, thereby delaying enrollment in the Medicare plan. Likewise, the timing of periodic reassessments of MAP and PACE beneficiaries should align with federal reassessment timeframes.

  In the case of PACE programs, the timing and process of changing the care plan is dictated by federal regulations and guidance. When a participant requests a change in services, the PACE Interdisciplinary Team (IDT) must notify the participant or designated representative of its decision as expeditiously as the participant's condition requires, but no later than 72 hours after the date the IDT receives the request for reassessment. If an IA is to be required for PACE program members who request a change in services, notwithstanding our recommendation below, it would have to be completed within enough time for the IDT to conduct its assessment and notify the beneficiary within 72 hours of the beneficiary's request.

- Recertification Assessments: These assessments must be conducted well in advance of the end of the month in which the recertification is due in order to provide the MCO with sufficient time to review the assessment, conduct its own assessment if needed, modify the person-centered service plan (PCSP), and issue authorizations.

- **Recommendations:**
  - Independent Assessments and IME: The proposed regulations should be amended to include provisions to:
    - Ensure timely completion of enrollment assessments, recertification assessments, and change in condition assessments, including, for expedited requests, the availability of same-day change-in-condition assessments;
    - Ensure, in response to a change in condition, the availability of same-day CRP recommendations, in response to expedited requests, if the plan authorizes more than 12 hours daily;
    - Support timely and streamlined enrollment in MAP and PACE plans.

  - PACE Programs: The proposed regulations should be amended to exempt PACE program enrollees from IA change-in-condition assessments, as PACE programs are mandated to

conduct these assessments, and assessments in response to requests for a change in services are subject to stringent timeframes under federal regulations and guidance.

- Non-Regulatory Recommendations: In addition to these recommendations, we have proposed, in our August letter, more specific timeframes and accountability controls for inclusion in the IA contract and sub-regulatory guidance.

Other

- **Assessment for Hospice:** The proposed regulations eliminate from the assessment process an evaluation of the beneficiary's appropriateness for hospice services. The Department should include in the IA contract and in sub-regulatory guidance a requirement to continue to assess beneficiaries for appropriateness for hospice and make referrals where appropriate. New York continues to experience among the lowest rates of hospice utilization nationwide. It had the third lowest percentage of Medicare beneficiaries enrolled in hospice at the time of death in 2018 among all states – only Alaska and North Dakota had lower percentages.[3] At an average of 49 Medicare hospice days per patient, New York's hospice length of stay is also among the lowest in the U.S. after Wyoming and South Dakota.[4] Given the low utilization of hospice – a service that is valued for its interdisciplinary and person-centered approach and is generally reimbursed by Medicare – the IA should continue to assess beneficiaries for the appropriateness of hospice and make referrals consistent with the beneficiary's preferences.

- **NHTD/TBI Waivers and Level 1 Personal Care:** The intent of the proposed regulations concerning assessments and authorization of services for beneficiaries seeking or receiving Level 1 Personal Care Services or personal care through NHTD/TBI waivers is unclear. This should be clarified, preferably through a revision to the proposed regulation.

Thank you for your consideration of these concerns and recommendations. We would be happy to schedule a call with you to discuss them in more detail.

Sincerely yours,

Karen Lipson

cc: Sean Doolan
Attachment

[3] NHPCO Facts and Figures, 2018 ed.
[4] Centers for Medicare and Medicaid Services, Medicare Hospice Utilization by State, Calendar Year 2018, https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareFeeforSvcPartsAB/Downloads/HOSPICE18.pdf.

ATTACHMENT

LeadingAge New York

Donna Frescatore
Deputy Commissioner and Medicaid Director
Brett R. Friedman
Director, Strategic Initiatives
Office of Health Insurance Programs
New York State Department of Health
One Commerce Plaza Albany, New York 12210

August 24, 2020

Dear Donna and Brett:

I am writing on behalf of LeadingAge New York's managed long term care (MLTC) plan and provider members to raise a number of concerns and recommendations relating to the proposed amendments to the personal care services (PCS) and Consumer Directed Personal Assistance Services (CDPAS) regulations. This letter follows a list of questions and concerns that we submitted in July. Overall, our members are concerned that this major change in the process for determining eligibility and level of need for personal care and CDPAS services is being implemented on an aggressive timeline which will likely create a risk that vulnerable older adults and people with disabilities will experience barriers to needed care. The prospect of implementing these changes in the midst of a pandemic when systems and consumers are already under significant strain is daunting. We appreciate the timeline for implementation contemplated in the State Budget, but we believe that the savings anticipated in the SFY 2020-21 Budget could be achieved through a phased implementation as discussed below.

The ambitious implementation timeline will make it difficult to address the myriad of complex questions and challenges we have identified, while ensuring access to services by eligible beneficiaries and accountability for the quality of assessments and clinical reviews. We have, nevertheless, provided a series of recommendations below related to the strengthening the validity of assessments conducted by the independent assessor (IA); the accessibility of the IA assessments, independent medical evaluations (IMEs), and clinical review panel (CRP) process; and the order and timing of steps in the process of enrollment and service authorization. Finally, we would like to raise several legal and technical concerns regarding the wording and structure of the regulations.

Phased Implementation

- **Issue:** The October 1 implementation date for this new system entails major changes in the way that older adults and people with disabilities access community-based long-term care. It also involves changes in the processes used by mainstream managed care plans and managed long term care plans (collectively MCOs), local social services districts, providers, and beneficiaries to coordinate assessments, enrollment, and authorizations. Launching this new process in the context of a pandemic, when face-to-face communication is generally ill-advised and when all stakeholders are operating under significant stress heightens the challenges. Communication failures, delays, technical flaws, superficial training, and/or errors in assessments may create barriers to needed care or enable ineligible individuals to access care.

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- **Recommendation**: According to the budget scorecard, the savings to be achieved from these measures in the current fiscal year appear to be related to the change in the eligibility criteria for PCS and CDPAS (i.e., the ADL requirements or "minimum need requirements"). Under the statute, these enhanced eligibility criteria apply only to new enrollees. Thus, the savings associated with the independent assessment process could be achieved by launching the process at the outset for new enrollment assessments only and delaying the implementation for change in condition assessments and reassessments. This would allow existing enrollees to receive change in condition assessments through their plans and avoid delays in accessing additional services for individuals who are being discharged from hospitals or nursing homes or experiencing a deterioration in their condition.

Validity of Independent Assessments

- **Issue:** Our managed long term care plan (MLTC) members continue to express significant concerns about the validity of assessments conducted by nurses who have little, if any, first-hand knowledge of the individual being assessed (henceforth "the beneficiary"), do not have access to their history, and are unfamiliar with their informal supports or home environment. Plans and providers note that beneficiaries often do not have accurate recall of issues or are reluctant to report to an unfamiliar person on issues addressed by assessments (e.g., flu shots, falls within 30 days, ER visits in the last 90 days, incontinence, degree of assistance needed for ADLs and IADLs, willingness and availability of informal caregivers). This lack of familiarity with the individual and his/her social and environmental context raises the prospect of either inflated assessed need that exceeds actual need *or* assessed need that understates actual need. These concerns are heightened by the prospect of these assessments being conducted via telephone or digital meeting platform for the foreseeable future.

- **Recommendations:** In order to attempt to mitigate these concerns, we recommend the following:
  - Include provisions in the Independent Assessor (IA) contract that:
    - Require continuity of assessors with individuals being assessed to the extent feasible, require tracking of continuity, and include assessor continuity as a measure of performance under the contract.
    - Require in-person assessments to the extent that community spread of COVID permits them to be conducted safely.
    - Require IAs to consult with any medical records supplied by the beneficiary or the MCO;
    - Require independent assessors to be available to MCO care managers and vice versa when either has a question regarding an assessment item.
  - Provide through sub-regulatory guidance and/or contractual provisions:
    - A mechanism for DOH to resolve disagreements between MCOs or LDSSs and the independent assessor regarding assessment findings. The availability of an objective process for resolving disputed assessment findings would address many of the concerns related to the validity of assessments and would strengthen the accountability of the IA.
    - To accommodate dispute resolution, the current policy of locking assessments after 5 days would have to be modified to enable corrections.

- Access for nurse assessors to the beneficiary's medical history. This could be effectuated using extracts of data available to DOH (e.g., Medicaid claims, SPARCS, all-payer database, SHIN-NY).
- Provide for an auditing and/or quality oversight process to review the validity of assessments.

Accessibility, Validity, and Purpose of Independent Medical Evaluation (IME) and Orders

- **Issues:** The proposed regulations envision a referral of the beneficiary by the independent assessor to an independent medical professional (IMP) who will evaluate the beneficiary. It is unclear, based on the regulations, whether this is to be an in-person or virtual examination, whether it is in addition to the physician "note" required as part of the new financial eligibility (transfer of assets) review, and whether it is intended to inform the determination of medical necessity and minimum need. If the evaluation is intended to be in-person, we are concerned about the accessibility of the medical professionals. Will older adults and people with disabilities, who may have physical and cognitive limitations, be required to travel to unfamiliar offices for in-person evaluations? Once the beneficiary is determined eligible for PCS or CDPAS, will they be required to undergo an IME annually, or is this one-time determination?

  Inevitably, there will be a tradeoff between accessibility and accuracy. In the absence of in-person examinations, there is a heightened risk that the evaluations will not be accurate. The regulations authorize, but do not require, the independent medical professional to review medical records other than the independent assessment. Since the independent assessment is conducted by a professional who is likewise unfamiliar with the beneficiary and their medical history and social and physical environment, the IME may merely replicate any inaccuracies captured in the IA.

  Further, the IME creates an additional step that must be completed prior to enrollment in a plan which may delay enrollment and access to care if it is not completed promptly. Currently, beneficiaries may enroll in a plan prior to securing a physician order. The physician order is secured by the LHCSA for beneficiaries receiving PCS and by the plan for beneficiaries receiving CDPAS.

  The IME serves as a new hurdle for beneficiaries and potentially delays enrollment without a clear purpose set forth in the proposed regulations. Under the proposed regulations, the IMP must describe the patient's medical condition and regimens, medications, and "need for assistance with personal care services tasks." The physician signing the order must certify that the information accurately describes the patient's medical condition and regimens and indicate whether the patient is self-directing and can be safely care for at home. However, neither the IMP nor the physician signing the order is explicitly directed under the regulations to make any finding concerning the beneficiary's level of need for assistance with ADLs. In fact, although the proposed regulations define new minimum needs requirements to qualify for personal care and include a medical necessity requirement, they do not appear to identify the party responsible for making these determinations.

- **Recommendations:** In order to mitigate these concerns, we recommend:
  - Revise the regulations to clarify the function and standard for the physician order (see discussion of legal issues below).
  - Include provisions in the IA contract that:
    - Require in-person evaluations to the extent that they can be conducted safely and promptly;
    - Require in-home evaluations for home-bound individuals, to the extent that they can be conducted safely and promptly;
    - Require geographic accessibility of IMEs;
    - Require IMEs to consult with any medical records supplied by the beneficiary or the MCO.
  - Provide through sub-regulatory guidance and/or contractual provisions:
    - Access for IMEs to the beneficiary's medical history (e.g., through extracts of Medicaid claims, SPARCS, all-payer database, and/or SHIN-NY data).
    - A mechanism for DOH to resolve disagreements between MCOs or LDSSs and the independent assessor/independent medical professional regarding assessment and evaluation findings.
    - Provide for an auditing and/or quality oversight process to review the validity of evaluations and orders.
  - Consider contractual provisions requiring the completion of the IME and the IA simultaneously to minimize the burden on the beneficiary. If virtual IME visits are authorized and the IA visit is in-person, this practice would support the use of audiovisual technology, as the IA nurse could assist the beneficiary with the use of the technology platform.

Clinical Review Panel Evaluations: Accessibility, Timing, and Standard of Review

- **Issues:** The proposed regulations require an independent medical review by a clinical review panel (CRP) of cases in which an MCO's plan of care authorizes more than 12 hours of PCS or CDPAS services. Like the IA and the IME, the CRP raises accessibility concerns and the trade-off between the improved accuracy of in-person assessments versus the access barriers they present. Arguably, an in-person evaluation is less critical at this point in the process because the beneficiary will have been assessed or examined by the IA, the IME, and the MCO.

  In addition, the timing, triggers, and standard of review of the CRP are unclear. First, it is unclear whether the CRP is initiated after selection of a plan and submission of the enrollment, or while the beneficiary is still 'shopping' for a plan. Under the current system, after the CFEEC makes a determination that the beneficiary is eligible for MLTC enrollment, the beneficiary may seek assessments from several MCOs in order to find the MCO offers most desirable plan of care. We assume that beneficiaries will continue to shop for the best plan of care under this new system. If the CRP is triggered when a proposed plan of care is issued, but prior to enrollment, a beneficiary may present to the CRP with two or more different proposed plans of care offering different arrays of services. For example, one MCO might offer a combination of personal care and adult day health care with live-in services, while another MCO might offer split shift

services. CRP review of multiple plans of care would be inefficient, may result in further delays, and may have unintended effects on plan of care development.

The events that trigger a CRP are also unclear. The regulations do not disclose whether it is a is one-time or periodic review or whether a recommendation must be secured in response to a change in condition that requires expedited attention. It is also unclear whether the CRP is triggered when more than 12 hours of services daily is ordered by an ALJ after a fair hearing, as opposed to when an MCO authorizes the 12-plus hours in a plan of care.

Requiring a CRP recommendation periodically will add little value and create unnecessary administrative complexity and barriers to maintaining needed services. It is unlikely that an individual receiving more than 12 hours daily of PCS or CDPAS services will experience a dramatic improvement in function. Unfortunately, conditions that require extensive personal care tend to be stable at best or worsen over time, rather than improve. Further, a requirement to obtain a CRP recommendation when a beneficiary experiences a sudden change in condition that brings their need above 12 hours may delay access to care and jeopardize the safety of the beneficiary and/or delay discharges from hospitals and nursing homes.

In addition to the ambiguity of the timing of the CRP review, the standard(s) that the CRP must apply to its recommendation is murky. The proposed regulations require the lead physician to make a recommendation on the "reasonableness and appropriateness of the plan of care to maintain the patient's health and safety in his or her own home, in accordance with the standards and scope of services in subdivision (a)." It is unclear which standards from subdivision (a) the lead physician must apply to this recommendation or whether all must be met. These standards include: a finding that the services are "medically necessary for maintaining the patient's health and safety in his or her own home," minimum ADL needs requirements, and a finding there are not other "available, appropriate, and cost-effective services" to meet the beneficiary's needs. The CRP's recommendation is a clinical one – it should not be the role of the CRP to weigh in on whether there are alternative and cost-effective substitutes for the services in the plan of care.

- **Recommendations:**
  - Revise the regulations to:
    - Clarify the standard for the CRP recommendation and ensure that the standard is clinical (see discussion of legal issues below);
    - Clarify that the CRP takes place after the plan is selected and enrollment is submitted for processing;
    - Clarify that the CRP is required only at enrollment, not on a periodic basis;
    - Clarify that a CRP review is not required after an ALJ orders more than 12 hours of care daily, but that it would be required upon a change in the fair hearing beneficiary's condition or subsequent reassessment of that beneficiary.
  - Include provisions in the CRP contract that:
    - Authorize evaluations via audiovisual platforms or telephones, unless the CRP or beneficiary determines that an in-person evaluation is necessary;

        - Require geographic accessibility of CRPs and home visits to the extent that in-person evaluations are necessary;
        - Require CRPs to consult any medical records supplied by the beneficiary or the MCO or considered by the IA or IME;
        - Require reviews of authorizations in response to a sudden change in condition requiring more than 12 hours of care daily within timeframes that support compliance with MLTC contract terms governing prior authorization and concurrent review and permit the prompt initiation of needed services (see below).
    - Provide through sub-regulatory guidance and/or contractual provisions:
        - Access for CRPs to the beneficiary's medical history.
        - An auditing and/or quality oversight process to review the validity of evaluations and recommendations.

Order and Timing of Steps in the Process

- **Issues:** The timing of the assessment, evaluation, and clinical review and the integration of these steps into the processes for enrollment and care plan changes must be structured to support access to needed care and avoid barriers to enrollment in integrated plans.
    - Relationship to Existing Timeframes for Enrollment: As noted above, the addition of the IME and potentially the CRP as steps in the enrollment process presents a risk that access to care will be delayed. Under the current system, the MCO's initial assessment must be conducted within 30 days of first contact by an individual requesting enrollment or of receiving a referral from the enrollment broker or other source. It is unclear whether this requirement will be maintained under the new regulations. Our member MCOs intend to continue conducting their own assessments in order to develop appropriate care plans. However, the insertion of the IME into the eligibility process will likely make it difficult for MCOs to complete an assessment after the eligibility determination, but within 30 days of first contact. Moreover, if a beneficiary is referred in mid-month, it will be challenging for all three steps -- the IA, IME, and plan assessment -- to be conducted by the 20th day of the month in order to avoid a five-week delay in enrollment.

      The CRP is triggered after the MCO issues a care plan, which may occur up to 30 days after initial referral, under the current contract. Further, under the current system, the beneficiary has 75 days to select a plan and enroll before the CFEEC assessment expires. It is unclear, as noted above, whether the CRP occurs before or after the beneficiary selects a plan. If the beneficiary's selection is delayed, the CRP may be forced to rely on an expired assessment. On the other hand, if the CRP must be completed prior to plan selection, the CRP process could delay the enrollment beyond the 75-day expiration of the assessment.

    - Change-in-Condition Assessments: The timing of change-in-condition assessments is perhaps the most challenging aspect of the new system. It is worth noting that the elimination of semiannual reassessments and the suspension of reassessments during the pandemic may result in greater need for change-in-condition assessments, as there may be fewer opportunities to observe the gradual decline in beneficiaries' condition. While many change-in-condition assessments may be conducted on a non-urgent basis, others demand

immediate attention. Under their contract with the State, MLTC plans must meet compressed time frames for expedited prior authorization and concurrent review – generally 3 business days from the request or 1business day from receipt of the necessary information. Our MLTC members report that they conduct same-day assessments when needed, such as prior to discharge from a hospital. It is critical that same-day assessments remain available to address unexpected needs. The time allotted for change-in-condition assessments must also take into account the need for MCOs to review and follow up on the IA's assessment, make the necessary changes in the care plan, and coordinate with the beneficiary, family members, and providers to put in place the needed services, supplies, and equipment.

- Accommodating MAP and PACE Timeframes: The timing of the steps in the enrollment process is even more sensitive for MAP and PACE plans, as they must align with the Medicare and PACE timelines. MAP plans may be forced to complete the Medicare application after the Medicaid assessment and IME are complete, thereby delaying enrollment in the Medicare plan. Likewise, the timing of periodic reassessments of MAP and PACE beneficiaries should align with federal reassessment timeframes.

  In the case of PACE programs, the timing and process of changing the care plan is dictated by federal regulations and guidance. When a participant requests a change in services, the PACE IDT must notify the participant or designated representative of its decision as expeditiously as the participant's condition requires, but no later than 72 hours after the date the IDT receives the request for reassessment. If an IA is to be required for PACE program members who request a change in services, notwithstanding our recommendation below, it would have to be completed within enough time for the IDT to conduct its assessment and notify the beneficiary within 72 hours.

- Recertification Assessments: These assessments must be conducted well in advance of the end of the month in which the recertification is due in order to provide the MCO with sufficient time to review the assessment, conduct its own assessment if needed, modify the person-centered service plan (PCSP), and issue authorizations.

- **Recommendations:**
  - Independent Assessments and IME at Enrollment:
    - Include provisions in the IA contract that:
      - Set forth timeframes for performing the independent assessment and the IME to support completion of the enrollment documentation by the 20th of the month if the referral is made prior to the 10th of the month. These timeframes should include sufficient time for the MCO's assessment and completion of the care plan prior to the enrollment deadline of the 20th of the month.
      - Support streamlined enrollment processes for MAP and PACE, consistent with Medicare and PACE enrollment processes.
  - Clinical Review Panel:

        - Clarify in sub-regulatory guidance that a CRP is required only after plan selection and submission of the enrollment or upon a change in condition that requires an increase in services to more than 12 hours daily, not periodically.
        - Include provisions in the IA/CRP contract that require CRP recommendations pertaining to new enrollees to be completed within 3 business days of enrollment submission. The timing of the recommendation must allow the MCO sufficient time to finalize the care plan with the beneficiary and family members and issue authorizations for services before the initiation of the enrollment and start of care.
        - Include provisions in the IA/CRP contract requiring, for expedited service requests in response to a change in condition, same-day CRP recommendations if the plan authorizes more than 12 hours daily.
    - Change-in-Condition Assessments:
        - Include provisions in the IA/CRP contract requiring, for expedited requests, same-day change-in-condition assessments.
        - Standard change-in-condition assessments should be completed by the IA within 3 business days**.**
        - Provide an exemption, in regulations or sub-regulatory guidance, of PACE program enrollees from IA change-in-condition assessments, as PACE programs are mandated to conduct these assessments, and assessments in response to requests for a change in services are subject to stringent timeframes under federal regulations and guidance.
- Recertification Assessments: Ensure through IA contractual provisions and/or sub-regulatory guidance that recertification reassessments are conducted early enough in the month to permit MCOs to validate the IA reassessment, modify the PCSP and issue authorizations.

Standards for Authorizing Services and Legal Considerations

- **Issues:**
    - Eligibility and Authorization Standards**:** Because the proposed regulations build on existing regulations that appear to have incorporated several layers of revisions and standards and requirements, the clinical and legal standards for eligibility and authorization of services are varied and inconsistent, and the parties that are charged with applying these standards are unclear. This may cause confusion and lack of predictability for consumers, MCOs, the IA, medical professionals issuing orders, ALJs, and the courts. For example, the proposed regulations include the following eligibility standards and do not specify the party responsible for making the minimum ADL needs determination:
        - Personal care services are defined in the proposed regulations as being "medically necessary for maintaining the patient's health and safety in his or her own home, as determined by the social services district or [MCO]." (505.14(a)(1)).
        - Personal care services can be provided only if the patient meets applicable minimum needs requirements . . . and the social services district or [MCO] reasonably expects that the patient's health and safety in the home can be maintained by the provision of such services . . .." (505.14(a)(3)).

      The proposed regulations include the following standards for authorizing services:

- Personal care services may be authorized by the LDSS or MC only to the extent that the patient "actually requires" the hours or frequency of services to maintain his or her health and safety in the home.
- Personal care services shall not be authorized to the extent that the [LDSS] or [MCO] determines that any of the [specified] services or supports . . . are available and appropriate to meet the patient's needs and are cost-effective if provided instead of personal care.
- The CRP must make a recommendation concerning whether the plan of care is "reasonable and appropriate to maintain the patient's health and safety in his or her own home." (p. 39). The lead physician is directed to make a recommendation in accordance with the standards set forth in subdivision (a) of 505.14, which include medical necessity, minimum needs, and lack of alternative available and cost-effective services.

- Failure to Acknowledge PACE Eligibility Standard**:** Although the Department has recognized that PACE has its own eligibility standard (nursing home level of care) and that the minimum needs criteria do not apply to PACE, the proposed regulations do not exempt PACE applicants or enrollees from the new minimum needs criteria.

- Misalignment of Independent Assessment Elements and Eligibility Standards: The independent assessment includes an assessment of the "functions and tasks required by the patient, a discussion with the patient to determine perception of his/her circumstances and preferences, and an assessment of the potential contribution of informal caregivers. . ." (505.14(b)(2)(i), pp. 20-21). Although the Department has stated that the IA determines whether the beneficiary meets the minimum needs requirements, the regulations do not explicitly require the IA to assess the beneficiary's ability to perform activities of daily living or the level of assistance needed, or make any findings concerning minimum needs requirements.

- Misalignment of Independent Medical Professional Evaluation with Physician Order and Eligibility and Authorization Standards: Under the proposed regulations, the independent medical professional "describes the patient's medical condition and regimens, medications, and need for assistance with PCS tasks." The physician signing the order must certify that the information accurately describes the patient's medical condition and regimens and must indicate whether "the patient is self-directing and can be safely cared for at home." In addition, for cases involving continuous or live-in services, the MCO or LDSS must look to the physician order for a medical condition that causes the patient to need frequent assistance with toileting, walking, transferring, turning and positioning, or feeding.

  However, as noted above, although the Department envisions the IA (presumably through the IME) determining whether the beneficiary meets minimum ADL need requirements, the proposed regulations do not appear to include any requirement that the IA or the independent medical professional make that determination. Not only do the regulations omit any finding by the IME or the physician signing the order concerning the minimum need requirements, they also omit from the IME any evaluation of the patient's ability to self-direct and be cared for at home. Nor do the proposed regulations governing the IME and the physician order require any

evaluation for the presence of a medical condition that requires frequent assistance with toileting, walking, transferring, turning and positioning, or feeding.

Recommendations:

- The regulations should be revised to:
  - Clearly identify the party charged with determining whether a beneficiary meets the minimum needs requirements (presumably the physician signing the order pursuant to the IME). This is a key element of the process and should be reflected in regulation, not merely in subregulatory guidance.
  - Recognize the federally-mandated PACE eligibility standard and clearly state that the minimum needs criteria do not apply to prospective and enrolled PACE members.
  - Clarify the standards that the CRP must apply rather than referencing all standards in subdivision (a) of 505.14. Specifically, the CRP's recommendations should be limited to clinical considerations, and it should not be charged with making recommendations based on cost-effectiveness.
- The Department should include in contracts with the IA/CRP and in sub-regulatory guidance provisions that:
  - Require the IA and the IME to assess and evaluate the beneficiary for level of assistance needed with ADLs and the presences of cognitive deficits, Alzheimer's, and/or other dementias. In addition, require the assessment to include the identification of any medical conditions that cause the patient to need frequent assistance with toileting, walking, transferring, turning and positioning, or feeding.
  - Require the physician(s) conducting the IME and signing the order to make a determination concerning the beneficiary's eligibility based on minimum needs requirements.
  - Specify the standards to be applied by each of the parties participating in reviews and evaluations, including limiting the CRP to clinical standards.
  - Ensure that the IA and IME are informed of and apply the PACE eligibility standard to prospective and enrolled PACE members.

Quality Measurement and Risk Score Concerns

- **Issues:** Currently, an MLTC plan's performance on quality measures rests largely on the UAS assessment. Mainstream plans, by contrast, are evaluated based on a variety of measures derived from several sources. MLTC performance is determined, for purposes of the Department's public-facing MLTC annual quality report and distributions from the MLTC quality pool, by the most recent UAS-NY CHA assessments for the enrollees in each plan during a specified period. Similarly, MLTC risk scores are developed based on an enrollment snapshot and associated UAS-NY CHAs within an assessment window. The most current UAS-NY CHAs used to determine both quality performance and risk scores are typically conducted by the MLTC plans, rather than the CFEEC.

  Both quality ratings and risk scores have significant financial implications for MLTC plans. Quality ratings also impact enrollment growth, and this impact will only increase with the implementation of the enrollment cap and the role of quality in determining the allowed growth in plan-specific enrollment. As a result, MLTC plans are understandably concerned that the IA

assessments conducted by individuals who are unfamiliar with the beneficiaries and lack knowledge of their medical histories and cognitive deficits will result in less accurate quality measures and risk scores. Moreover, if there are errors (e.g., the beneficiary is recorded as not having received a flu shot, when in fact he/she was immunized), the assessment is locked after only 5 days and cannot be corrected.

- **Recommendations:**
  - As recommended above, promote accuracy of assessments through contract provisions and sub-regulatory guidance, audits and oversight.
  - Consider alternative sources for quality measures, such as claims or encounter data.
  - Provide a mechanism for DOH to resolve disagreements between MCOs or LDSSs and the independent assessor/independent medical professional regarding assessment findings.
  - Modify the policy of locking assessments after 5 days to allow for corrections.

Other

- **Assessment for Hospice:** The proposed regulations eliminate from the assessment process an evaluation of the beneficiary's appropriateness for hospice services. The Department should include in the IA contract and in sub-regulatory guidance a requirement to continue to assess beneficiaries for appropriateness for hospice and make referrals where appropriate. New York continues to experience among the lowest rates of hospice utilization nationwide. It had the third lowest percentage of Medicare beneficiaries enrolled in hospice at the time of death in 2018 among all states – only Alaska and North Dakota had lower percentages.[1]At an average number of Medicare hospice days per patient of 49, New York's hospice length of stay is also among the lowest in the U.S. after Wyoming and South Dakota.[2] Given the low utilization of hospice – a service that is generally reimbursed by Medicare – it would make sense to continue to assess beneficiaries for the appropriateness of hospice and make referrals consistent with the beneficiary's preferences.

- **NHTD/TBI Waivers and Level 1 Personal Care:** The intent of the proposed regulations concerning assessments and authorization of services for beneficiaries seeking or receiving Level 1 Personal Care Services or personal care through NHTD/TBI waivers is unclear. This should be clarified, preferably through a revision to the proposed regulation.

Fair Hearings

The 2019-20 budget included a provision to reform the fair hearing process. LeadingAge New York, together with other plan associations, conducted a survey of MLTC plans on their experience with the fair hearing process and outcomes that were inequitable or not supported by program standards. Those survey results and examples of troubling decisions were shared with the Department. However, reforms to the process were not implemented. The fair hearing process should be reviewed in conjunction with

[1] NHPCO Facts and Figures, 2018 ed.

[2] Centers for Medicare and Medicaid Services, Medicare Hospice Utilization by State, Calendar Year 2018, https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareFeeforSvcPartsAB/Downloads/HOSPICE18.pdf.

these regulatory changes to ensure that regulatory standards and requirements are fairly and properly applied.

Thank you for your consideration of these concerns and recommendations. We would be happy to schedule a call with you to discuss them in more detail.

Sincerely yours,

Karen Lipson