NYLAG
New York Legal Assistance Group

March 13, 2021

New York State Department of Health
Bureau of Program Counsel, Regulatory Affairs Unit
Corning Tower, Empire State Plaza, Rm. 2438
Albany, New York 12237-0031

Attention: Katherine Ceroalo

by email to regsqna@health.ny.gov

RE: Amendment of Sec. 505.14 & 505.28 of Title XVIII to Personal Care and CDPAP regulations, published Jan. 27, 2021 (ID HLT-28-20-00019-P)

Dear Counsel:

The New York Legal Assistance Group (NYLAG) is a leading non-profit that provides free civil legal services and financial counseling, and engages in policy advocacy efforts, including health access advocacy, to help people experiencing poverty

NYLAG submits these comments on the second round of proposed regulations implementing the statutory amendment to the Social Services Law for personal care services (PCS) and consumer-directed personal assistance program services (CDPAP) enacted in the State Fiscal Year 2020-21 Enacted Budget.

Regarding the regulatory impact, we are skeptical that these new layers of assessments will result in "minimal costs" to the State and do not impose costs or burden on local government. The Department has failed to disclose or even acknowledge the increased costs in expanding Maximus' contract to perform these multiple assessments, as required by NY SAPA §202-A, subd. 3(c). For the reasons stated below, we strongly doubt that "this proposal will better facilitate access to PCS and CDPAS for people with disabilities" as claimed. NYS Register Vol XLIII, Issue 4, January 27, 2021, p. 35 (hereinafter "NYS Reg."). On the contrary, delays are likely with the added bureaucracy, violating consumer rights, and the extra scrutiny of high-need consumers to determine whether they are "safe" at home evokes the kind of assumptions that underlie the use of "safety" as a pretext to deny community services, violating the Americans with Disabilities Act.

To avoid duplication, NYLAG is attaching the comments of the NYS Bar Association Elder Law & Special Needs Section (NYSBA ELSN), and fully endorses all of these comments and incorporates them by reference. Rather than restating these comments, this letter makes some additional points. Among these is our great concern over allowing assessments to be routinely conducted by telehealth, particularly the Independent Assessment, a change that was added by the Department in this second round of regulations. The following comments are meant to apply to both the PCS and CDPAP regulations to the extent that the proposed changes are substantially the same for both.

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Topics Covered by NYSBA ELSN Comments – incorporated by reference

1. **Telehealth Should Not be Routinely Utilized for Any Assessments, Particularly the Independent Assessment by the Nurse**

We strongly believe it is premature to make telehealth a permanent mode for conducting the battery of new assessments, especially the Independent Assessment (IA) by the nurse also known as the Community Health Assessment (CHA). The proposed language states:

> 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.

505.14(b)(1). We have several concerns. The CHA tool has not been subjected to evidence-based evaluation for being conducted via telehealth. Also, "telehealth" is not defined in the proposed regulation nor elsewhere in state regulations to require synchronous audiovisual technology; this requirement appears only in the State's comments accompanying the proposed regulation. This definition must be in the regulation requiring audiovisual technology and specifically stating that a purely audio assessment by telephone is not acceptable. Additionally, while the regulation recites the federal CFCO mandate that the consumer must be provided with an opportunity for an in-person assessment and receive necessary support during the assessment (42 CFR 441.535(3), other language suggests that telehealth will be utilized by default, requiring the consumer to be very assertive about requesting an in-person assessment.

The regulation must clarify responsibility to inform the consumer of the right to request an in-person assessment and of how to do so, and specifically require that telehealth may be used only on consent. The regulation is inconsistent in terms of the consumer's right to refuse an assessment by telehealth. It states that the consumer must be assessed where they are located – be it their "home, a nursing facility, rehabilitation facility or hospital," but then says, "This provision shall not be construed to prevent or limit the use of telehealth in the assessment of an individual." 505.14(b)(2)(i)(c). This last statement both undercuts the requirement that the consumer be assessed where they are located, and the statement in 505.14(b)(1) that states the consumer must be given an opportunity for an in-person assessment.

The regulation allows use of telehealth for all three of the new assessments, but the IA by the nurse (CHA) must require an in-person assessment with the narrowest of exceptions, only if absolutely impracticable on an individual basis, such as in rural areas. The IA or CHA is the primary source of the myriad types of information used in all of the succeeding assessments and development of plan of care. Moreover, the CHA now will be done less frequently than before -- upon the initial application and then annually, with additional assessments required only if triggered by changes in medical condition or mental status. Given the reduction in the frequency of these assessments, and their critical importance, they should be conducted in person.

The Department repeatedly emphasizes that the CHA is "evidence-based," but has not demonstrated that it been reviewed for its effectiveness and accuracy when conducted by telehealth or phone. On the contrary, the NYS DOH UAS-NY CHA Reference Manual[1] shows that the assessment is designed to be done in person, with the assessor instructed to rely on observations as well as on asking questions, to keep the consumer engaged, and to rely on information from family or other third parties present or interviewed later. The Manual states the CHA "…is not a questionnaire [and]…. is not designed for the assessors to read the questions and potential responses and have the individual being assessed chose the most appropriate answer. Rather, this instrument should be used as a guide to structure a clinical and social assessment in planning for community-based care and services." CHA Manual at 3.

> Assessors will require strong speaking and listening skills to promote communication with the individual being assessed, as well as with the primary caregiver or family member if available…, [and] strong inter-personal skills to keep an individual engaged throughout the assessment process, [and] strong analytical skills to balance what is stated with **what is observed**, and what is included in a review of secondary documents."

CHA Manual at 4 (emphasis added). It is not surprising that advocates have received reports that the CHA assessments conducted by phone or telehealth during the pandemic have been less accurate in assessing need.

Another part of the CHA Reference Manual indicates that it was designed to be conducted not only in person but in the consumer's home. The Manual states:

> Whenever possible, the assessment should be performed in the person's home. Parts of the assessment can be completed in settings other than the person's home, such as a hospital, day care center, or outpatient clinic, with no loss in information quality. However, certain critical items, such as environmental factors, can best be assessed in the home.

CHA Manual p. 5. This language suggests that even though conducted in-person, an assessment conducted in the hospital has some loss in information quality compared to assessment in the home. This passage suggests it is not even contemplated that the assessment would not be conducted in person. If even an assessment conducted in the hospital suffers a loss in quality, certainly an assessment by telehealth would result in even more loss in information quality.

In its response to comments expressing concern about delays caused by the new assessments, the Department states:

> [B]ased on the Department´s experience through the COVID-19 pandemic, consumers expressed positive experiences with the ease and convenience of using

[1] NYS Dept. of Health Office of Health Insurance Programs, Division of Long Term Care, UAS-NY Community Assessment Reference Manual (Jan. 2013)["CHA Manual"].

> 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 … 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.

Reg. p. 195. While we recognize the need to utilize telehealth during the public health emergency, it is premature to make it a permanent method for home care assessment merely based on anecdotal reports of positive consumer experiences. Not all consumer experiences have been positive—or studied. The impact of using telehealth for assessments on health disparities also remains largely unknown, though preliminary research suggests inequities in accessing telemedicine across numerous demographic categories: age, race, ethnicity, preferred language, and income.[2] The prevalence of hearing impairment and consumers with limited English proficiency alone makes reliance on this technology suspect. We recognize the rapid shift to telehealth in the pandemic has led to pushes for rapid policymaking, but it is premature to entrench this modality without careful evidence-based analysis of risks, quality, accuracy, access, and availability.

Just as the Department cites reports of positive experiences with telehealth in the pandemic, advocates can also cite anecdotal reports that the CHA's conducted by telehealth and telephone have not been as thorough and accurate as ones conducted in-person. Clearly, mere anecdotal reports are not a sufficient basis for a monumental change in the mode for conducting home care assessments. The Department should defer any regulatory change allowing telehealth for these assessments until it has evidence-based research specifically determining the efficacy and validity of using telehealth to perform the IA assessments, and to verifying the actual availability of telehealth technology to consumers.

Moreover, the Department's own COVID-19 guidance provides that telehealth may not be used for the conflict-free assessment to determine eligibility for MLTC enrollment:

> … a CHA conducted by telephonic or through telehealth, but that cannot be fully completed (e.g., the functional assessment) may not be used to determine initial eligibility for members to enroll in MLTC plans… A Partially Completed CHA is a CHA which cannot be fully completed because not enough information can be obtained by using telephonic or telehealth to sign and finalize the CHA in the UAS-NY. As indicated above, a Partially Completed CHA will not be used by the Conflict Free Evaluation and Enrollment Center (CFEEC) to determine eligibility for members to enroll in MLTC plans.

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[2] Lauren A. Eberly, et al., "Patient Characteristics Associated With Telemedicine Access for Primary and Specialty Ambulatory Care During the COVID-19 Pandemic" JAMA (December 29, 2020), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2774488 .

NYS DOH, *Updated COVID-19 Guidance for the Authorization of Community Based Long- Term Services and Supports Covered by Medicaid*, dated April 8, 2021, at page 3.[3] If even with the COVID pandemic, the Department viewed an in-person assessment as indispensable for determining functional eligibility for home care services, a shift to allowing all CHA assessments by telehealth is unjustifiable.

2. The Minimum Two or Three ADL Limit Unlawfully Denies Services Based on Diagnosis, Violating Medicaid Regulations and the Community First Choice Option (CFCO) That Requires States to Provide Cueing and Supervision as well as Hands-On Assistance with both IADLs and ADLs.

We hereby incorporate by reference the attached NYSBA ELSN comments. Additionally, we make the following additional points.

A. DOH Has Authority to Interpret State Law in a Way that Does Not Discriminate Based on Diagnosis or Otherwise Violate Medicaid Law

The Department claims it is bound by the plain language of the amendments to state law prescribing the new minimum ADL requirement, and has no flexibility in implementing the law in a way that avoids discrimination based on diagnosis, or that includes consideration of IADLs as well as ADLs to determine need. On the contrary, courts have consistently deferred to reasonable interpretations of state agencies, upholding them when they are not irrational and are consistent with legislative intent. *See City of New York v. New York State Dep't of Health*, 164 Misc. 2d 247, 623 N.Y.S.2d 491 (Sup. Ct. 1995)(holding "DOH's reasonable and rationale interpretation of N.Y. Pub. Health Law § 1104(1) deserved deference" and recognizing the agency's complete autonomy under § 204 of the State Administrative Procedure Act to issue declaratory rulings based upon assumed or hypothetical facts, citing *Matter of Howard v Wyman*, 28 NY2d 434, 438 (1971)("It is well settled that the construction given statutes and regulations by the agency responsible for their administration, if not irrational or unreasonable, should be upheld")).

Moreover, courts have given special deference to administrative agencies when their interpretation is not irrational and is consistent with legislative intent. *St. Joseph's Hosp. Health Ctr. v. Dep't of Health*, 247 A.D.2d 136, 677 N.Y.S.2d 194 (App. Div. 4th Dept. 1998)(upholding DOH interpretation of statute governing reimbursement methodology as "not unreasonable or irrational"). *St. Joseph's* upheld a DOH regulation even when it arguably contravened unambiguous statutory language permitting only "intersector" reallocation, by allowing "intrasector" reallocation. The court reasoned, "The interpretation … reflected in the MOE regulations, is consistent with legislative intent and the policy underlying the concept of maintenance of effort" and was not irrational and should be upheld." 247 A.D.2nd at 149. Here, the clear legislative intent in establishing an exception to the three-ADL requirement is to ensure access for those consumers whose diagnosis gives rise to the need for supervision, prompting or cuing to perform ADLs, rather than the need for hands-on physical assistance. The Department has discretion to define this exception more broadly to carry out this evident legislative intent, and include

[3] Available at https://health.ny.gov/health_care/medicaid/covid19/docs/2020-03-18_guide_authorize_cb_lt_services.pdf.

people who need supervisory assistance because of vision impairments, traumatic brain injury (TBI), developmental disability (DD), and other cognitive, neurological or psychiatric impairments. No less than people with dementia or Alzheimer's disease, they may need supervision with two ADLs but not physical maneuvering with three ADLs, denial of eligibility. Otherwise, the statute and regulation would deny eligibility solely based on diagnosis, in violation of the Americans with Disabilities Act, the comparability requirement in the Medicaid statute and regulations as cited in the NYSBA ELSN memorandum.

Using the authority as the single state agency designated to administer Medicaid in NYS, 42 U.S.C. § 1396a(a)(5); 42 C.F.R. § 431.10, the Department should also require consideration of Instrumental ADLs (IADLs) to determine need. If an individual meets the CFCO level of care criteria, "…the State must provide …[a]ssistance with ADLs, IADLs, and health-related tasks through hands-on assistance, supervision, and/or cueing." 42 C.F.R. § 441.520(a). An individual qualifies for CFCO if, without home care services, she would require an institutional "level of care" – whether in a nursing home, psychiatric hospital, or Intermediate Care Facility for Developmental Disabilities (ICF-DD). An individual with a developmental, neurological, or psychiatric disability, TBI or other cognitive impairment, may, in the absence of PCS or CDPAP services, require an institutional level of care. In the CFCO Technical Guide, CMS clarified, "CMS reminds states that all three ways of delivering assistance with ADLs, IADLs and health related tasks must be made available. States may not limit the scope of this benefit to offer less than all three."[4] The proposed regulation would violate this requirement by denying PCS or CDPAP to a CFCO-eligible individual who needs supervision and cueing with, for example, one ADL and three IADLs.

> **RECOMMENDATION**: We propose qualifying an individual for services if they need at least one ADL, and allowing the other one or two tasks for which assistance must be needed to be either an IADL or ADL. "Extensive assistance" of an IADL should qualify, which is defined in the UAS Manual as, "Help required throughout task, but performs 50% or more of task on own." P. 27. If the individual needs help throughout the IADL, they cannot perform it without assistance.

B. Under CFCO Requirements, All Applicants for PCS or CDPAP Must be Assessed for Institutional Level of Care and, if they Qualify, Must be Provided PCS/CDPAP Services

If any CFCO-eligible person is denied PCS or CDPAP because of the new ADL criteria, the State is at risk of losing CFCO enhanced reimbursement. Therefore, any applicant who is determined not to need the new minimum ADL requirements must still be assessed to determine if they would, without home care services, need an institutional level of care -- whether in a hospital, nursing home, psychiatric hospital, or ICF-DD. The CFCO requirements require such individuals to receive "…[a]ssistance with ADLs, IADLs, and health-related tasks through hands-on assistance, supervision, and/or cueing, … and …[a]cquisition, maintenance, and enhancement of skills necessary for the individual to

[4] CMS, Community First Choice State Plan Option Technical Guide, available at https://www.medicaid.gov/sites/default/files/2019-12/cfc-technical-guide_0.pdf.

accomplish ADLs, IADLs, and health-related tasks." 42 C.F.R. § 441.520(a). This level of care assessment must specifically assess not only for nursing home level of care but for ICF-DD or psychiatric hospital level of care as well. If an individual has that level of care, but does not meet the ADL test, they must nevertheless be authorized for PCS/CDPAP through CFCO – whether accessed through the LDSS or a managed care plan.

C. To Protect Current Enrollees, The Definition of Who is "Grandfathered" under the Former Eligibility Requirements Must be Clarified and Aligned

The State Fiscal Year 2020-21 Enacted Budget adding the new minimum ADL requirements for eligibility for MLTC enrollment and PCS/CDPAP services contains three different grandfather clauses protecting current enrollees. These definitions must be aligned, using the least restrictive definition, which is for CDPAP. This alignment is necessary to minimize confusion, fully protect enrollees, and ensure that make medical services available to their enrollees to the same extent as services are made available to other Medicaid recipients in the same area who are not enrolled in their plan. 42 U.S.C. § 1396b(m)(1)(a)(i). We propose using the standard enacted in the CDPAP statute as the uniform standard, which would grandfather in anyone who initially applied for PCS, CDPAP or MLTC before Oct. 1, 2020, or such later date on which these changes become effective.

The grandfathering standard for MLTC is the most strict; an MLTC member had to be continuously enrolled in an MLTC plan since prior to Oct. 1, 2020,[5] while a person who initially applied for CDPAP before Oct. 1, 2020[6] or who was initially authorized for PCS before Oct. 1, 2020 is grandfathered.[7] This inconsistency can cause confusion and deny managed care enrollees services under the same standard that is available in FFS, violating federal law. 42 U.S.C. § 1396b(m)(1)(A)(i); 42 C.F.R. §§ 438.210(a)(2) and (a) (4)(i). For example, a new MLTC enrollee may have received PCS or CDPAP under the "immediate need" FFS program, or transitioned from a mainstream managed care plan. That individual could be denied MLTC enrollment under the new ADL requirements even though they are grandfathered in if they applied for CDPAP or were authorized for PCS before Oct. 1st. See n 5-7. If denied MLTC enrollment but grandfathered in for PCS or CDPAP, this would require cumbersome new procedures to exempt such individuals from mandatory MLTC enrollment. Similarly, for new dual eligibles transitioning to MLTC from mainstream managed care plans, new procedures would be needed for their PCS/CDPAP services to seamlessly transition to LDSS without disruption, since they would not qualify to enroll in MLTC. It would be much simpler to align the grandfathering standards for MLTC, PCS and CDPAP.

Also, individuals whose MLTC enrollment is temporarily interrupted could potentially lose their grand-fathered status and be subject to the new criteria if they have to re-enroll in an MLTC plan. For example, NYLAG commonly troubleshoots cases where errors or delays occur in the Medicaid renewal process, causing discontinuance of Medicaid, which

[5] Public Health Law §4403-f subd. 7 (b)(v)(14), added by L. 2020, Ch. 56 §18.
[6] Soc. Serv. Law §365-f, subd. 2(c)(eff. Oct. 1, 2020), as amended, L. 2020, Ch. 56 §3.
[7] Soc. Serv. Law §365-a, subd. 2(e)(v)(eff. Oct. 1, 2020), as amended, L. 2020, Ch. 56 §2-a.

in turn triggers disenrollment from the MLTC plan. The consumer must sometimes re-enrol in an MLTC plan after a gap in enrollment. Another reason for a lapse in MLTC enrollment is the new "carve-out" of Long Term Nursing Home Stay care from the MLTC benefit package. About 20,000 MLTC members have been disenrolled since August 1, 2020 because they were in a nursing home for three months. Some nursing home residents have been mistakenly disenrolled from the MLTC plan under this initiative. Others may be appropriately disenrolled, but have the right to re-enroll within six months. Whether mistakenly or appropriately disenrolled, an individual who wants to exercise their right to re-enroll in a plan to return home would not be grandfathered in because they were not "continuously enrolled" prior to Oct. 1, 2020 or later effective date. The Department should clarify that they are grandfathered in if they initially applied for or were authorized for PCS or CDPAP services prior to Oct. 1, 2020, whether through an MMCO, LDSS, or waiver.

D. The Regulation Must Clarify Which Entity Provides Adverse Notice to an Applicant who is Determined Not to Meet the New Minimum ADL Threshold – in LDSS and MMCO Denials and MLTC enrollment denial

We appreciate that the Department has clarified in the second round of rulemaking that it is the Independent Assessor's role to determine whether the threshold ADL eligibility criteria are met. This change was made by adding as a required element of the independent assessment, "…an assessment of the functions and tasks required by the individual, <u>including an assessment of whether the individual meets minimum needs requirements</u>…." Proposed 505.14(b)(2)(i)(b)(1). However, it is still not clear which entity is responsible for providing written notice to the consumer of an adverse eligibility determination, when such notice must be given, what are the consumer's appeal rights, and whether the appeal is against the LDSS, plan or Maximus. Defining these procedures is not simple, since they might be different for applications for services made to the LDSS, for requests to enroll in an MLTC plan, or for requests made by a current member to their MMC plan. The Department stated in its response to comments that policies and procedures for the MLTC and other MMCO plans would not be included in the regulations because they are subject to review and approval by CMS in the 1115 waiver. Reg. at 178. However, the regulations must delineate the procedures at least for applications to the LDSS, which would be the baseline for establishing MMCO procedures.

Where the applicant has applied to the LDSS for services, the regulation must specify which entity – Maximus or the LDSS - is responsible for providing notice of denial and at what point notice must be issued. We question whether the Department has authority under existing law to delegate the authority to Maximus to deny eligibility and issue adverse notice in fee-for-service cases, since the State, as single state agency under federal Medicaid law, has delegated this responsibility to local districts. 42 U.S.C. § 1396a(a)(5); 42 C.F.R. § 431.10; Soc. Serv. L. § 365. If Maximus and not the LDSS has the duty to provide the adverse notice, this would not only be a huge departure from decades-long procedures, but would not be permissible. Unlike the LDSS, Maximus has no responsibilities set forth in the fair hearing regulations that prescribe the content of notices, the duty to provide documents to the appellant, and many other procedures. 18 NYCRR Part 358. Yet if the determination is being made by Maximus, and it is the

LDSS that provides the adverse notice, then that raises different issues. The regulations must specify a time limit by which Maximus must convey the adverse determination to the LDSS and for the LDSS to provide the adverse notice. Procedures are needed to ensure that the applicant has the right to request a copy of the IA assessment and any other documents reviewed in making the adverse determination, and specify the duties of both Maximus and the LDSS in providing these documents upon request. The regulation should specify whether the LDSS or Maximus staff -- or both -- must appear at the fair hearing to defend the adverse determination. Since Maximus is making the adverse determination, even if notice is provided by the LDSS, the regulations must set forth duties owed by Maximus to the consumer regarding appeal rights. However, we question whether this delegation of responsibility to a private contractor for making and giving notice of an eligibility determination is permissible.

For consumers seeking to enroll in an MLTC plan, the Department's response to comments suggests that Maximus (or other contractor) will provide the notice, as it does currently under the "conflict free eligibility and enrollment" procedures. These procedures were approved by CMS under the 1115 waiver. The Department states:

> 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.

Reg. p. 203. With this clarification, it appears that as in the conflict-free assessments, Maximus will provide the notice of denial of eligibility for MLTC enrollment, and the fair hearing will be against Maximus. This will need to be approved by CMS in the 1115 waiver.

However, where a member of a mainstream Medicaid managed care plan has requested PCS or CDPAP services from the plan, and the IA, having been referred the request by the plan, has determined that the member is not eligible for PCS or CDPAP, the regulation must clearly state whether Maximus or the MMCO is responsible for providing adverse notice. This situation is different than where a consumer is seeking enrollment into an MLTC plan, because the federal managed care regulations assign responsibilities to the MMCO for denying a request for a service authorization, with specific time limits to provide adverse notice. 42 C.F.R. 438.410(c). An MMCO member has clear rights that a prospective member may not have. If the Department contemplates that Maximus and not the MMCO would provide the adverse notice, this is a departure from the federal regulation and would require CMS approval, given the strictly regulated prior authorization process set forth in Part 438 of the federal regulations for managed care plans.

If it is the MMCO that provides the adverse eligibility notice, this raises other questions: Is the member required to exhaust the plan appeal, even though the initial adverse determination was not made by the plan but by the State's independent contractor? If exhaustion is required, does the Plan have authority to consider evidence submitted with the plan appeal and reverse the Maximus eligibility determination? If not, then the plan appeal is solely a procedural hurdle with no meaningful review and would therefore not comply with the federal regulations at Part 438, which require the plan to "…take into account all comments, documents, records, and other information submitted by the

enrollee or their representative without regard to whether such information was submitted or considered in the initial adverse benefit determination." 438.406(b)(2)(iii) The regulation must also clarify the respective duties of Maximus and the MMCO with respect to providing the consumer a copy of the IA CHA assessment and any other documents considered in the initial adverse determination.

3. The Regulations Fail to Require Standards and Procedures to Ensure that the Determination Whether the Consumer may be Safely Cared for at Home Complies with the ADA and Person-Centered Service Plan requirements for CFCO and all Medicaid LTSS.

The IA, the LDSS/MMCO, and in high-needs cases – the Independent Review Panel [IRP][8] -- are asked to determine whether personal care or CDPAP services, alone or in combination with other proposed services, can reasonably maintain the individual´s health and safety in his or her own home.[9] While this is determined in all cases, the regulations create the new IRP process solely to make this determination in cases where the LDSS or MMCO determine that 12 or fewer hours/day are necessary. Because of their determined high need, every individual referred to the IRP is CFCO-eligible and is entitled to the risk analysis set forth in CFCO. Denial of PCS or CDPAP services because they would not maintain health and safety – whether for those needing more than 12 hours/day or fewer -- must be based on identifying actual risks, with their probability of occurrence, and consideration of whether reasonable modifications of policies, practices or procedures will mitigate or eliminate the risk. Since these steps in analyzing risk to health and safety are missing from the proposed regulations, they do not comply with *Olmstead* or Medicaid regulations.

Both the ADA and Medicaid regulations require that any determination of safety be based on identifying actual risks, with their probability of occurrence, and consider whether reasonable modifications of policies, practices or procedures will mitigate or eliminate the risk. Under federal Medicaid regulations, including those for CFCO, Person-Centered Service Plans ("PCSP") for long term services and supports must "[r]eflect risk factors and measures in place to minimize them, including individualized back-up plans and strategies when needed." 42 CFR § 441.301(c)(2)(vi), incorporated by cross reference in § 438.208(c)(3)(ii); § 441.540 (CFCO). This language in the Medicaid regulations is no doubt imported from the ADA regulation that similarly states, "A public entity may

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[8] The new IRP review process is described in the regulation, stating in part, "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."505.14(b)(2)(v)(f).

[9] Safety is assessed or determined in the high-needs review (505.14(b)(5)(vii), 505.28(d)(5)(vii)), and by the LDSS or plan (505.14(b)(2)(iii)(a)(1); 505.28(e)(2)). The independent nurse assessor should be trained to assess the risk factors that could affect safety, and strategies to mitigate risk.

impose legitimate safety requirements necessary for the safe operation of its services, programs, or activities. However, the public entity must ensure that its safety requirements are based on **actual risks**, **not on mere speculation, stereotypes, or generalizations** about individuals with disabilities." 28 CFR § 35.13(h).

The IRP, by definition, is only reviewing care plans for individuals who require more than 12 hours/day of services, who generally cannot be safely left alone without PCS or CDPAP services. If the IRP finds the proposed plan of care appropriate to maintain health and safety, with or without modifications, it is not likely to be appealed by a consumer, unless the suggested modifications reduce services.[10] However, if the IRP finds that the proposed care plan, even with modifications, cannot maintain the individual's health and safety in the home, and recommends nursing home placement, it is this determination – and any assessments upon which it is based -- that must comply with *Olmstead*. The proposed regulation fails to require a step by step analysis identifying the actual risks to health and safety and what steps can be taken to mitigate the risks.

Responding to this criticism raised in the first round of regulations, the Department claims that because the Uniform Assessment Tool used in NYS ("UAS-NY") is reportedly an "evidence-based" independently validated tool, that fact alone means that it satisfies the requirements of *Olmstead* in any resulting determinations that health and safety cannot be maintained. We respectfully disagree that reliance on the UAS-NY is sufficient to ensure compliance with Olmstead. The IRP has access to a UAS-NY completed by the IA, but its recommendation about whether health and safety can be maintained with services is not based solely on this assessment. If it was based solely on the UAS-NY, there would be no need for this independent review panel.

The regulations must ensure that a determination that a person's health and safety cannot be maintained in the community is made only after methodically identifying the risk factors that might diminish safety for the individual – not generally -- and the measures that can be put in place to minimize them. This individualized assessment must rely on current medical or best available objective evidence to assess (1) the nature, duration and severity of the risk, (2) the probability that the potential injury will actually occur, and (3) whether reasonable modifications of policies, practices or procedures will mitigate or eliminate the risk.[11] This more nuanced process must be specified in the regulations, and will require training of the various assessors, in order to change an outdated black and white matter – the consumer is or is not safe at home.

A look at the UAS-NY does not reveal any such methodical analysis of risk and ways it can be mitigated. The "Assessment Outcomes" of the UAS-NY asks the assessor for a "yes" or "no" referral recommendation of "Community" (in consumer's own home, that of a family member or friend, or in an adult care facility) or "Not Community," meaning a

[10] The IRP is more likely to suggest modifications that involve *more* care, such as increasing the number of days/week on which services are provided, or recommending that 24-hour split shift continuous care be provided rather than 24-hour live-in, or that private duty nursing rather than personal care services is necessary to maintain health and safety. As discussed above, we oppose the last sentence of the subparagraph quoted in note 17 that could be interpreted to prohibit such recommendations by the IRP.

[11] See, e.g. letter dated May 31, 2013 from David Hickton, U.S. Attorney for W.D. PA and Thomas Perez, Ass't. Attorney General, U.S. DOJ Civil Rights Division, to Gov. Tom Corbett, Governor of Pennsylvania, available at https://www.justice.gov/sites/default/files/crt/legacy/2013/06/03/cresson_findings_5-31-13.pdf

nursing home. If the recommendation is for "Not Community," the assessor is asked to indicate YES or NO if any or all of seven listed reasons apply:

1. Adequate informal supports for assistance and/or emergency back-up are not available, and person cannot be left alone.
2. Person is medically complex, and skilled nursing services and monitoring required is not available in the home, in an adult day health-care program/assisted-living program, or on an outpatient basis.
3. Restorative therapy services are required, and the type, frequency, and duration cannot be provided in the community.
4. Person does not have an available home in the community (does not own or rent a home, is not eligible for an Adult Care Facility/Assisted Living or cannot live with family or friends).
5. Person has a home but it is not safe, adequate, or accessible to support community-based services.
6. Appropriate community-based living cannot be arranged because person's behaviors are a risk to self and others.
7. Nursing home placement has been requested by the person and confirmed

Before services are denied on any of these or other grounds finding that health and safety cannot be maintained in the community, the decisionmaker must be required to go through the risk analysis described above. The sixth reason in the UAS —that the person's behaviors are a risk to self and others and preclude community-based living -- is a clear example of the type of generalization about risk that the ADA regulations seek to address. The UAS does not ask the assessor to provide any detail about the nature, severity or frequency of the risk of harm and what mitigating steps have been or could be taken. The 1st, 2nd and 3rd reasons listed in the UAS for recommending against community care could be addressed simply by authorizing more services (for lack of informal supports) or a skilled service such as private duty nursing. The fifth reason (unsafe home conditions) should lead to increased care management or a referral to Adult Protective Services or to Open Doors). Since the UAS-NY lacks a complete ADA-compliant risk analysis, the regulations must require this elsewhere. Without such specificity, the door is open to arbitrary denials of services that violate the ADA and Medicaid requirements.

The Department's response to the recommendation that a risk analysis be specified in the regulations was that it has no discretion to change the state statute. On the contrary, the state law specifically invokes Olmstead *twice* in its requirement that all assessment standards, and specifically those for assessing whether a high-needs individual, "…who with the provision of such services is capable of safely remaining in the community [be] in accordance with the standards set forth in *Olmstead v.LC by Zimring*, 527 US 581 (1999)…." Soc. Serv. Law §365-a, subd. 2(e)(ii) and (vi) ; and §365-f, subd. 2(a). Whether by updating the UAS-NY or at another stage in the assessment process, the regulations must require the decision-maker to identify specific risk factors, evaluate the probability of their occurrence, and identify ways by which the risk can be minimized or eliminated.

Additionally, to recommend or determine if an individual is capable of safely living in the community, the IRP must be informed of both the plan's or LDSS' proposed care plan and the consumer's requested care plan. A consumer who requires suctioning of a

tracheostomy might be unsafe if the proposed care plan was only 4 hours/day of CDPAP or private duty nursing care with no informal supports, but safe with a care plan covering 24/7 needs with a combination of formal and informal care. For this reason, whoever is asked to make a recommendation or determination about safety must be provided with both (1) the proposed plan of care by the LDSS/MMCO, and (2) the consumer's proposed plan of care, including informal supports. To ask for an opinion without this information invites the assessor to speculate about safety based on assumptions that may be based on stereotypes, rather than the individual's circumstances.

We again suggest DOH compose a workgroup of stakeholders to improve the UAS-NY, the assessment forms and process to assist assessors in conducting these evaluations methodically and to eliminate individual bias, use of stereotypes and assumptions. One of the most forceful messages of *Olmstead* is to avoid stereotypes about who is "safe" only in an institution. These regulations must do a better job of ensuring that assessments meet *Olmstead* standards.

4. Concerns about the Various Assessments and Development of the Plan of Care

NYLAG supports and incorporates by reference the comments of the NYSBA ELSN, and makes the following additional points.

A. Plan of Care Must be Consistent with Consumer Preferences Concerning Alternate Services that may to Reduce PCS or CDPAP

We commend the requirement that for CDPAP the plan of care must be developed in collaboration with the consumer or their designated representative. 505.28(d)(3)(v). The same language must be included in the parallel PCS regulation, to comply with the federal person-centered-planning requirements.

We also appreciate that in this round the Department omitted the proposed requirement that that the consumer "must use" a list of alternate "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." For managed care members and all CFCO-eligible consumers, Person-Centered Service Plan (PCSP) requirements preclude requiring a consumer to accept any alternate services if they are eligible for PCS or CDPAP. While we commend the deletion of this problematic clause, there remains a mixed message. The LDSS or MMCO must determine if the "individual can be served appropriately and more cost-effectively through the provision of [alternate] services" that are determined to be available, and "…must consider the use of such services in accordance with department guidance as well as the individual´s identified preferences and social and cultural considerations … in developing the individual´s plan of care." 505.14(b)(b)(2)(iii). The alternate services include PERS, adult day care, equipment and supplies such as commodes, urinals, walkers, wheelchairs and insulin pens and voluntary care by informal caregivers. 505.14(b)(2)(iii)(a)(3); 505.28(d)(3). The language still gives MMCO's and LDSS the message that they must use such alternate services if "more cost effective," even contrary to the individual's preferences.

Preferences must be taken into account in determining whether use of commodes or other equipment, adult day care or informal caregiver support, could reduce the need for services. Now, plans often decide unilaterally that the consumer could use a bedside

commode – or incontinent pads -- at night instead of providing an aide to assist to and from the bathroom. Aside from the medical contraindication of using incontinent pads all night, or the consumer's inability to safely transfer to a commode alone, if the consumer prefers to go to the bathroom at night, thereby maintaining continence and autonomy, this preference must be considered in person-centered care planning. Similarly, it must be the consumer's choice to attend an adult day care programs, with preference elicited in person-centered care planning process. The regulations should state that voluntary assistance of informal caregivers must be acceptable to the consumer, again, honoring their preference. 505.14(b)(2)(iii)(a)(13); 505.28(d)(3).

B. New Procedure for Correction of So-called "Factual Inaccuracies" in Independent Nurse Assessment is Overly Complex, Lacks Transparency, and will Cause Excessive Delays

We are dismayed by the increasing complexity, length, and lack of transparency in the dispute resolution process, which even in the first proposed regulation was problematic. Proposed 505.14(b)(2)(iv)(d), 505.28(d)(4)(iv). Now the LDSS and MMCO will have not one but two opportunities to delay the assessment process. First, they may notify the IA of a mistake in the IA, presumably in the CHA. Later, "[a]fter reviewing the independent assessment, practitioner order and the result of any social service district or MMCO assessment or evaluation... the social services district or MMCO [may advise the IA] if it has a material disagreement regarding the outcome of the independent assessment." 505.14(b)(2)(iv)(d)(2). These opportunities for the LDSS or MMCO to dispute any finding on the IA or Independent Practitioner Panel ["IPP"] will cause enormous delays, which in the case of the managed care plan, are to *the plan's financial advantage* by delaying assessment of the consumer's request for increased services, or even an initial service plan for a new member. The sanctions for abuse of this process are simply not enough of a deterrent to prevent plans from filing unjustified disputes. It is simply not realistic or a prudent use of limited resources for the Department to divert resources from other areas of plan and LDSS oversight to monitor these disputes.

We find it particularly troubling that a time limit is proposed for the IA to "complete a new assessment within 10 days from the date it receives notice from the social services district or MMCO" of a dispute. 505.14(b)(2)(iv)(d)(3). It is striking that the Department is giving the IA 10 days to repeat an assessment, but again in this second round of regulations declined to impose time limits for plans and LDSS to make referrals for assessments, and for the IA to schedule, conduct and transmit evaluations from the new trio of assessments, We oppose having the IA complete a new CHA assessment in such circumstances, as it is burdensome for the consumer and a waste of resources. It seems that in many cases a correction or amended assessment could resolve the dispute more quickly than an entirely new assessment. However, if a new assessment is required, ten days is absolutely too much time, since an MMCO has only 14 days to decide a request for prior approval, a deadline that already is impossible to meet under the new regime. 42 CFR §438.210. In lieu of setting time limits for the main assessments, the Department merely vowed to require Maximus to complete assessments in enough time for the LDSS and MMCO to meet their federal or state deadlines. We fail to see how allowing an additional ten days for a repeat IA will achieve this goal.

Also, the regulations must require full transparency of the disputed assessments and all related communications. In the event of an appeal, the consumer must be entitled to a copy of the IA or IPP that was disputed, copies of the notification from the MMCO or LDSS to the IA that communicate its disagreement or identify an alleged mistake, with its clinical rationale and any documents, and copies of any corrected or revised assessments. Any colloquy between the LDSS/MMCO and the independent assessor about any alleged mistakes or factual inaccuracies must be memorialized and be available to the consumer, along with the original assessment and any re-do or correction.

5. Referral for High Need Review Panel is Not Authorized for CDPAP Consumers – and Other Concerns About High Need Review

The CDPAP Statute, unlike Personal Care Statute, does not authorize New High Need Review. The amended law governing PCS specifically authorizes a high need review, but no such language is included in the CDPAP statute. The amended statute defining Personal Care Services states, in part:

> "[T]he commissioner is authorized to adopt standards, pursuant to emergency regulation, for the provision [and], management and assessment of services available under this paragraph for individuals whose need for such services exceeds a specified level to be determined by the commissioner, and who with the provision of such services is capable of safely remaining in the community in accordance with the standards set forth in *Olmstead v. LC by Zimring*, 527 US 581 (1999) and consider whether an individual is capable of safely remaining in the community."
>
> Soc. L. §365-a subd.2 (e), as amended, L. 2020, Ch. 56 §2.

While DOH may require LDSS and plans to assess whether a CDPAP applicant, "…with the provision of such services is capable of safely remaining in the community in accordance with the standards set forth in Olmstead…" (§365-f, subd. 2, as amended, L. 2020, Ch. 56 §2-b), there is no authorization for DOH to require a separate high-needs review. Since the legislature specifically authorized the commissioner to adopt such standards for PCS, the lack of such legislative authorization in the CDPAP statute means that this extra level of review cannot be required for CDPAP applicants – either by local districts or plans.

6. **New Grounds for Reductions and Denial of Services**

NYLAG has joined with Cardozo Bet Tzedek Legal Services and JASA/Legal Services for Elder Justice in submitting comments on this point. Please see those comments.

We voice a particular concern about implementing the new grounds for reductions more rapidly than the other changes made in the regulations. 505.14(b)(8); 505.28(m). Since the other parts of the amendments totally revamp the procedures for reauthorizations and unexpected changes, which are often the procedural context for reductions, all of these changes should be implemented together to avoid confusion.

We make the following recommendations on the amended grounds for denial. 505.14(b)(4)(viii)(c)(2); 505.28(i)(4)(ii)

A. Paragraph 505.14(b)(4)(viii)(a) should be deleted. This longstanding paragraph This paragraph confusingly discusses denial and discontinuance or reduction of services based on medical necessity together, even though a later section of the regulation was amended requiring more justification for reduction of personal care services than mere assertion of medical necessity, pursuant to the decision in *Mayer v. Wing*. See NYSBA ELSN comments which we incorporate by reference.

B. Responding to concern that **telehealth** would be used as a vague reason for denying services, the Department said that it "…has clarified that telehealth services need to be 'readily available' and 'reliably accessed' by the individual…." We note that these qualifiers that the technology be available and accessible were added to a different section of the regulation, regarding MMCO and DSS responsibilities for developing plan of care. 505.14(b)(2)(iii)(a)(10); 505.28(d)(3)(i)(g). They should be repeated in this section in the reasons for denial. However, these words are not enough. As said above, we are skeptical that **telehealth** can ever be "…demonstrated and documented to reduce the amount of [PCS or CDPAP] services that are medically necessary." 505.14(b)(4)(viii)(c)(2)(vi). Telehealth is not designed to assist with ADLs or IADLs. If somehow telehealth could assist with these activities, the notice would have to specify exactly which ADLs or IADLs telehealth reduces the need for services and at which times. To avoid being speculative, a trial use of telehealth to assist with the designated tasks should be done. As to assistive devices, services could only be denied if the consumer was totally independent with use of the assistive device.

C. This ground for denying services because **the consumer resides in a facility** was apparently removed for CDPAP, which we had requested in our previous comments, since denial on this ground violates the ADA as interpreted by *Olmstead*. However, residing in a facility remains a ground for denial of personal care services. The Department did limit denial on this ground to situations where "…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." 505.14(b)(4)(viii)(c)(2)(vi). While this qualification is an improvement, the first clause is simply unnecessary – anyone applying for PCS from a facility is seeking to transition to a less restrictive setting. This clause should be deleted as it creates a question of fact, about which errors may be made by the LDSS or MMCO, when the act of applying itself proves that transition to the community is sought. A preference to return to the community must be accommodated under person-centered care planning principles. The second clause – that health and safety cannot be maintained in a less restrictive setting – is already the first ground for denial listed in the regulation. This ground, therefore should be deleted. An MMCO may not deny services on this ground if the consumer's preference is to return to the community.

D. The first ground for denial, "that the **client's health and safety cannot be assured** with the provision of personal care services" should be amended to add "cannot be reasonably assured…." This change would codify the policy articulated in Department guidance for nearly thirty years. See, e.g. 92 ADM 49 at p. 3 (PCS "may only be authorized when the district reasonably expects that the recipient's health and safety can be maintained in the home); NYS DOH, *Guidelines for the*

Provision of Personal Care Services in Medicaid Managed Care, May 31, 2013, at p. 7 (denial appropriate if "health and safety cannot be reasonably assured"), at https://www.health.ny.gov/health_care/medicaid/redesign/docs/final_personal_care_guidelines.pdf. This change is necessary to prevent plans and LDSS from applying an excessively restrictive requirement that health and safety be guaranteed, which would violate the ADA and PCSP principles.

E. The ground for denying services by fully utilizing available informal supports should be amended to specify that the **informal care must be voluntary and acceptable to the consumer**. 505.14(b)(4)(viii)(c)(1)(ix). As discussed above, federal PCSP requirements expressly state that "natural supports" (the term used in the federal regulations) are voluntary. 42 C.F.R. § 441.301(c)(2), cross-referenced from 438.208(c)(3)(ii).

7. REAUTHORIZATIONS and UNEXPECTED CHANGES

We question the new requirement to obtain a new IA and PO "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…." 505.14(b)(4)(xi)(c)(1); 505.28(f). The regulations must incorporate requirements dictated by the Second Circuit decision in *Granato v. Bane*, 74 F.3d 406 (2d Cir. 1996) for which the Department has issued extensive guidance.[12] The Court held that where an LDSS had determined not to reinstate PCS after a hospital stay, the "LDSS was required to provide aid-continuing 'until a decision is rendered after a hearing' so long as the recipient requested a hearing 'within 10 days of the mailing of the notice of action.'" 42 C.F.R. §431.231(c)(2). The 2011 DOH guidelines for MMCO plans, see fn 13, rightly directed plans:

> For a member who is hospitalized or admitted to a facility for short-term rehabilitation and who was receiving personal care services immediately prior to entering the hospital or rehabilitation facility, the member's personal care services authorization is temporarily suspended during the hospital or rehabilitation stay, and the MCO must reinstate such services under the authorization immediately upon the member's discharge from the hospital or rehabilitation facility, unless the medical discharge plan indicates otherwise.

NYS DOH MMCO Guidelines, supra, at page 8 (fn 13). The regulation must, under the court decision and DOH guidance, require that reinstatement of services previously authorized not be delayed to do the re-assessments. Further, the regulation must require that if a determination is made to reduce or discontinue

[12] See NYS DOH, *Guidelines for the Provision of Personal Care Services in Medicaid Managed Care* (2011), Sec. I. G. v. at page 8, available at https://www.health.ny.gov/health_care/medicaid/redesign/final_personal_care_guidelines.htm; NYS DSS 99 OCC-LCM-2 (Apr. 20, 1999), available at http://www.wnylc.net/pb/docs/99OCCLCM2.pdf, reaffirming effectiveness of 96-MA-023 - New Notice, Aid-Continuing and Related Procedures Applicable to Hospitalized MA Recipients Who Received Personal Care Services Immediately Prior to Hospitalization (*Granato v. Bane*; *McCoy v. Schimke*; *Burland v. Dowling*); available at http://www.health.state.ny.us/health_care/medicaid/publications/docs/gis/96ma023.pdf

services based on health and safety or any other ground, advance notice is required and services must be reinstated as aid continuing upon a timely appeal request.

We also echo the concern raised by the NYSBA ELSN that a referral to the IRP for the high-needs review should not be required whenever the individual already was authorized for more than 12 hours and condition has not changed, whether or not the IRP had reviewed the case.. As written, the regulation would limit this waiver of the high-needs review to instances where the IRP previously reviewed the case. 505.14(b)(4)(xi)(b). The amendment we recommend would better carry out the Department's expressed intent, which is that "the IRP reviews a plan of care only when the consumer crosses the high-hours threshold." Reg. p. 216.

Regarding unexpected changes, we reiterate the concerns we raised previously and that are now raised by the NYSBA about delays in conducting the battery of new assessments. We remind the Department that federal regulations impose a particularly short deadline – only 72 hours with at most 14 more days if needed by the plan - if delay "would seriously jeopardize the enrollee's life or health or ability to attain, maintain, or regain maximum function." 42 C.F.R. 438.10(d)(2). 505.14(b)(4)(xii), 505.28(f)(2)

Also, for a change in **social circumstances**, we agree that a new IA should not be necessary, as long as the most recent one includes the necessary specific information about the availability, willingness and ability of informal caregivers, detailing exactly what tasks and at what scheduled times each informal caregiver can and will provide care that is acceptable to the consumer. As we have pointed out previously, this information is not routinely collected now on the CHA too, which merely asks "yes or no" questions as to whether family is involved. Too often, we have had clients left at risk when a caregiver daughter requires surgery or is otherwise unavailable, and the plan fails to authorize additional home care because the assessments failed to document exactly what days and times the daughter is scheduled to provide care.

8. Effective Date, Terminology, and Other Miscellaneous Recommendations

A. Effective Date – We object to the new confusing language concerning the proposed effective date of the regulations. 505.14(c)(1); 505.28(m). The Department's proposal to roll the new assessments out in stages that vary by county would have to be approved by CMS. As these assessments apply to State plan services as well as ones obtained through the 1115 waiver, this uneven implementation would violate the federal statewideness and comparability requirements. 42 U.S.C. §§ 1396a(a)(1), 1396a(a)(a)(10(b); 42 C.F.R. §§ 431.50, 440.240(a). For example, high-need consumers in some counties would be subject to the new high-need IRP review and others would not.

Most troubling is the provision describing Department guidance that may be issued delaying implementation of the new assessments in certain counties in which the new contractor, likely to be Maximus, lacks capacity to do the assessments on a timely basis. The guidance "…may require that social service districts and MMCOs first attempt assessment and authorization pursuant to the provisions of this section currently in effect." Assuming the phrase "this section currently in

effect" means the regulation as it will be amended by these proposals, this is an utterly unworkable policy for MMCOs and LDSS to follow. It requires a county DSS or MMCO operating in a particular county to first "attempt" a referral to Maximus to conduct the IA and the IPP. Then, only if there is no response within some time period that would presumably be set by the Department, the DSS or MMCO may then conduct the assessment in the old system. How long would the LDSS or MMCO need to wait before the "attempted" referral receives no response? If CMS does allow the Department to roll this new system out on a staggered basis by county, then it must designate which counties should still use the old system and which ones use the new one. It cannot be up to every LDSS and every MMCO to test the waters of the new system. In the end, it is the consumer who bears the burden of the resulting delays.

Moreover, when rolling out an entirely new complex assessment system like this, systems testing will be needed as part of a readiness review. Maximus should test out the new assessments and protocols for accepting referrals from plans and LDSS and for transmitting the results, in one or two counties, which the Department should closely monitor. Only once testing is completed showing system readiness should this be rolled out.

B. We commend the change from "Patient" to "Individual" in the second round of regulations.

C. Update Terms to IADLs and ADLs from "personal care functions" and "nutritional and environmental support functions" – The Department declined to update the regulations to utilize the terminology used in their own reference manuals, and used nationally in the field of rehabilitation assessment. The UAS Reference Manual, DOH MLTC Policy 16.07, Community First Choice Option [CFCO] law, regulations and NYS CFCO SPA, ADM, and other guidance all use these terms. Inconsistency of state regulations with all of these other sources of law and regulation leads to confusion.

D. Provision Unique to CDPAP – Physical Presence of Designated Representative Should Not Be Required at All Assessments

We continue to object to section 505.28(h)(2)(p. 129) to the extent it requires the designated representative for non-self-directing consumers be physically present for any scheduled assessment or visit by the independent assessor, examining medical professional, social services district staff or MMCO staff. Insisting on the physical presence of the designated representative is burdensome, such as if they work or have child or elder care responsibilities, and is unnecessary in light of the many other available means of communication. The designated representative for non-self-directing consumers must have the option of participating in any scheduled assessment by telephone, telehealth, or video call, instead of being physically present. Also all assessments must be scheduled in advance with accommodation of the schedule of the consumer and the designated representative. Nearly thirty years ago, the State Medicaid agency made clear that the person directing care for a non-self-directing person did not need to reside with the consumer or but need only have "substantial daily contact," which was not necessarily in person. NYS 92 ADM-49. That directive applies to personal care

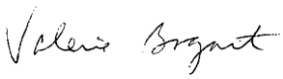
generally, not specifically CDPAP but the same principle applies. If anything, 28 years later, technology makes virtual or remote communication more feasible.

* * *

Again, we support and incorporate by reference the additional comments made by the NYSBA Elder Law and Special Needs Section.

Thank you for the opportunity to submit these comments. As always, we would welcome the opportunity to participate in a stakeholder workgroup to express consumers' concerns as policy and procedures are developed to implement these major changes.

Very truly yours,



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encl. Copy of comments by NYSBA Elder Law & Special Needs Section (filed separately by NYSBA)

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Bureau of Program Counsel, Regulatory Affairs Unit
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Albany, New York 12237-0031
Attention: Katherine Ceroalo (by email to regsqna@health.ny.gov)

From: NYS Bar Association Elder Law and Special Needs Section ("ELSN")

Date: March 12, 2021

RE: Amendment of Section 505.14 & 505.28 of Title XVIII to Personal Care and Consumer-Directed Personal Assistance regulations, published Jan. 27, 2021

Dear Counsel:

The Elder Law and Special Needs Section of the New York State Bar Association ("ELSN") submits these comments to the proposed changes to 18 NYCRR 505.14 and 505.28, which govern the Medicaid personal care services (PCS) and consumer-directed personal assistance program (CDPAP). If passed, these amendments will significantly reduce access to critical supportive services necessary to maintain community residence, forcing vulnerable elderly and disabled populations into institutional settings.

This second proposal raises many of the same the concerns that we identified in the first round of rules and, in fact, adds additional issues. Added layers of assessment and scrutiny of high utility cases, proposed under the guise of ensuring "safety" will violate the American with Disabilities Act.[1] The additional bureaucratic review will impose economic burden on local government, the extent to which remains unclear and undisclosed, as well as increased state costs with the expanded Maximus contract. As such, we remain fully skeptical that "this proposal will better facilitate access to PCS and CDPAP for people with disabilities" as claimed. NYS Register Vol XLIII, Issue 4, January 27, 2021, p. 35 (hereinafter "NYS Reg.").

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[1] "… In establishing any standards for the provision, management or assessment of personal care services the state shall meet the standards set forth in *Olmstead v. LC by Zimring*, 527 US 581 (1999) and consider whether an individual is capable of safely remaining in the community…." Soc. Serv. Law §365-a, subd. 2(e)(personal care) and §365-f, subd. 2 (CDPAP). Both the ADA and Medicaid regulations require that any determination of safety be based on identifying actual risks, with their probability of occurrence, and consider whether reasonable modifications of policies, practices or procedures will mitigate or eliminate the risk.

The following comments apply to both the PCS and CDPAP programs.

I. The New Minimum ADL Eligibility Thresholds Must be Amended to Comply with Medicaid Law and Regulations

A. The Definition of Activities of Daily Living Must Be Specific

> *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.

18 NYCRR 505.14(a)(9) & 18 NYCRR 505.28(b)(1)

In this second round of rulemaking, instead of listing the ADLs that apply toward the minimum threshold, the revised proposed regulation simply cross-references the Community Health Assessment (CHA or UAS-NY). This change responded to comments criticizing the omission of key ADLs like transfer for purposes other than toileting, medication administration, and assistance with elimination that is not use of the toilet (incontinence or catheter care). We sought clarification through an expansion of the list of qualifying ADLs. Instead, the pendulum swung in the opposite direction. The failure to identify any ADLs in the new proposed regulations gives an enormous amount of discretion to each Independent Assessor to determine which ADLs are to be counted toward the minimum needs requirement for eligibility. The lack of a clear definition will lead to arbitrary and inconsistent decision-making, including wrongful denials due to ADL undercounting.

While reference to the CHA list of ADLs has one improvement over the previous proposed version, the CHA omits other key ADLs that must be counted toward the new minimum ADL threshold. The CHA defines the ADL of "Toilet Use" as, "How uses the toilet room (or commode, bedpan, urinal), cleanses self after toilet use or incontinent episode(s), changes pad, manages ostomy or catheter, adjusts clothes." This definition of toileting is more comprehensive than the one proposed in the first round of rulemaking.

However, like the first round of regulations, the UAS limits the ADL of transfer to "how moves on and off toilet or commode," and does not include the ADL of transfer apart from toileting. Assistance with "transfer" should include assistance with any transfers to and from a standing, seated, or lying position. Also, a transfer is a distinct ADL from ambulation: an individual may be able to walk independently to her kitchen using a walker but not be able to stand up (transfer) even if the walker is right in front of her, without assistance. Responding to the earlier comments, the Department attempts to justify the omission of "transfer" apart from transfer for toilet use by stating that an "individual also likely needs assistance transferring from a bed to a chair" if they need assistance toileting. However, this is not true for some persons who are totally incontinent and rely on incontinent pads or a catheter, and do not use a toilet or commode at all. Listing "transfer" as a separate ADL would ensure these individuals are not wrongly denied services because they lack three ADLs.

In addition, if medication administration is not considered an ADL, then it is an IADL, which must be considered if an individual does not meet the ADL threshold but cannot perform this or other essential IADLs without assistance. As long as an applicant needs assistance with one ADL, IADLs should count to meet the minimum threshold if needed to maintain health and safety in the home. Some individuals need cueing and supervision to

take medication from a pre-poured medication box, or assistance opening the container. Others need an aide to bring them the pre-poured medication –and a glass of water for them to self-administer. These needs should be included within the definition of ADLs that qualify an individual to receive services.

In summary, a list of ADLs should be included in the regulations to ensure consistency, prevent arbitrary denials, and ensure reviewability of this new threshold determination. This list should include bathing, personal hygiene, dressing, walking, locomotion, transferring, bed mobility, eating, toileting (defined as in the CHA, set forth above), and medication administration. Before eligibility is denied based on not meeting the threshold, as long as one ADL need is present, an IADL need should qualify to meet the minimum threshold.

B. The Regulation Must Make Individuals with Diagnoses other than Dementia who need Supervisory Assistance with More than One ADL Eligible -- to Avoid Violating Medicaid Law and Jeopardizing CFCO Funding

18 NYCRR 505.14(a)(3); 505.28(b)(13)

The minimum needs requirement in the newly enacted State law violates federal Medicaid law and regulations requiring "comparability"[2] and banning discrimination based on diagnosis and requirements of the Community First Choice Option (CFCO). "The Medicaid agency may not arbitrarily deny or reduce the amount, duration, or scope of a required service under §§ 440.210 and 440.220 to an otherwise eligible beneficiary solely because of the diagnosis, type of illness, or condition." 42 C.F.R. §440.230(c). Earlier, we proposed that the State had discretion to interpret the law through regulations in a way that at least partly saved the law from being applied illegally. The exception to the 3-ADL requirement, that qualifies those with a diagnosis of Alzheimer's or dementia for services if they need *supervision* with two ADLS, can be expanded by regulation to those with a host of other medical conditions that give rise to the need for supervision, prompting or cuing to perform ADLs. Denying services to people with vision impairments, traumatic brain injury (TBI), developmental disability (DD), and other cognitive, neurological or psychiatric impairments even though they, just like people with dementia or Alzheimer's disease, need supervision with two ADLs but not physical maneuvering with three ADLs, denies eligibility solely based on diagnosis in violation of federal law.

Additionally, New York's enhanced federal match for Community First Choice Option (CFCO) services -- over $287 million in FY 2016 alone[3] -- is jeopardized because the CFCO regulations also prohibit discrimination based on diagnosis. "States must provide Community First Choice to individuals …[i]n a manner that provides such services and

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[2] See, e.g. *Oster v. Lightbourne*, 2012 WL 691833 (N.D. Cal. Mar. 2, 2012) (finding likely violation where use of functional ranks to determine eligibility for in-home services particularly disadvantaged people with cognitive disorders), earlier injunction sub nom. V.L. v. Wagner, 669 F. Supp. 2d 1106 (N.D. Cal. 2009) (cuts to in home support services likely violate comparability requirement); *Parry v. Crawford*, 990 F. Supp. 1250 (D. Nev. 1998) (holding that comparability requirement prohibits the state from conditioning service on a particular diagnosis, if individuals have the same functional need).

[3] See Report of U.S. HHS Office of the Inspector General, Feb. 6, 2020, available at https://oig.hhs.gov/oas/reports/region2/21701015.asp

supports … *without regard to the individual's age, type or nature of disability*, severity of disability, or the form of home and community-based attendant services and supports that the individual requires to lead an independent life." 42 C.F.R. § 441.515 (emph. added).

Responding to earlier comments urging the Department to exercise its authority as the Agency delegated to implement the law to interpret it in a way that avoids illegality, the Department claims it is bound by the plain language of the state statute and has no flexibility in implementing the law. Yet in these same revised proposed regulations, the Department has diverged from the plain language of the state law to permit nurse practitioners and physician assistants to conduct the new independent practitioner exam and sign the resulting orders. The statute specifically requires personal care services to be prescribed by a physician, with the recent 2020 amendment specifying that the physician be a "qualified independent" one selected by the Department:

> …determined to meet the recipient's needs for assistance when cost effective and appropriate, and when prescribed by a qualified independent physician selected or approved by the department of health, in accordance with the recipient's plan of treatment…. ;

N.Y. Soc. Serv. Law 365-a(e)(i)(underlined language was added in L. 2020, Ch. 56 Part MM). In its commentary published with the second round of regulations, the Department claims to have flexibility to diverge from the very plain language of the state law because swapping in an NP or PA for a physician 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.[4]

Reg at 237.[5] Significantly, here the Department invokes its authority as the agency charged with implementing the law to interpret the word "physician" in the statute to include NPs and PAs, a clear departure from the plain statutory language. Yet, DOH claims it lacks any such flexibility to interpret the statutory language establishing the ADL threshold. The Department should use the same authority used to expansively define "physician" to include NPs and PA's to interpret the statutory ADL threshold to include diagnoses other than dementia or Alzheimer's disease. Failure to do so will violate the comparability mandate and jeopardize New York's CFCO funding. Without this

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[4] State law still requires nurse practitioners to work in collaboration with "…physicians qualified to collaborate in the specialty involved, provided such services are performed in accordance with a written practice agreement and written practice protocols." NY Ed. Law § 6902, subd. 3(a)(i). This will continue to be true when amendments take effect July 1, 2021. Moreover, the cited option afforded under federal Medicaid regulations must be made by state law and approved by CMS in an amendment to the State plan. See 45 C.F.R. § 205.5.

[5] References to "Reg at p. xx" are to the *Summary of Express Terms for Proposed Amended Regulations regarding Personal Care Services and Consumer Directed Personal Assistance Program Services* (CDPAS) (18 NYCRR 505.14 & 505.28) (06.30.20) - Updated 01.11.21, available at https://www.health.ny.gov/health_care/medicaid/redesign/mrt2/docs/express_terms_summary.pdf

expansion the law on its face discriminates based on diagnosis and will deny services to thousands of consumers living with disabilities.

Finally, the Department wrongly claims participants in the TBI or OPWDD waiver are not hurt by the new minimum thresholds because they may access services through the TBI or OPWDD waivers, for which eligibility criteria have not changed. Reg at p. 181. On the contrary, TBI and OPWDD waiver participants rely on "State Plan" services such as personal care and CDPAP for their core daily needs, which they access either through mainstream MMCO plans, if they enroll at their option, or through their LDSS. Either way, the discriminatory minimum ADL criteria would be applied to deny them PCS or CDPAP services. Under federal law, State Plan services must be available to every Medicaid recipient, including those who are in a waiver. The waivers supplement those State plan services with waiver services like Respite, Residential Habilitation, Day Habilitation, and Community Habilitation. However, these waiver services do not substitute for the essential daily care needs met by PCS or CDPAP. Also, there is reportedly no consumer-directed option for some waiver services, such as Home and Community Support Services (HCSS) available under the NHTD waiver. The following example illustrates the reliance on CDPAP for an OPWDD waiver participant.

> **EXAMPLE**: Sam, age 22, is autistic and has an intellectual disability. He lives with his parents and a sibling who also has a developmental disability. Sam is enrolled in the OPWDD waiver through which he receives some supplemental waiver services. However, his main daily care is provided through 84 hours/week of CDPAP services. Since most of the assistance with ADLs he needs is "supervisory," he could be denied CDPAP services altogether under the new restrictions. He could be forced into an institution without these services.

Even though Sam in this example is "grandfathered in" as a current recipient, there is a new "Sam" who applies for these vital services every day, whether because of a developmental disability, a vision impairment, or many other diagnoses. They are all at risk of being denied care under the new ADL threshold and being forced into institutions, which will no doubt invite litigation and jeopardize CFCO funding.

Moreover, under CFCO regulations, "…the State must provide …[a]ssistance with ADLs, IADLs, and health-related tasks through hands-on assistance, supervision, and/or cueing." 42 C.F.R. § 441.520(a).[6] A PCS or CDPAP applicant is eligible for CFCO if, without home care services, they would require an institutional "level of care" – whether in a nursing home, psychiatric hospital, or Intermediate Care Facility for Developmental Disabilities (ICF-DD). Many OPWDD participants like Sam in the above example would require institutionalization without PCS and CDPAP services. Since they meet the level of care CFCO criteria, they must be given supervision and cueing assistance with ADLs and IADLs. By not counting the need for supervision and cueing with ADLs toward the minimum ADL threshold, the state would unlawfully deny CFCO-eligible individuals services, violating CFCO requirements and jeopardizing that funding.

[6] Also see CMS, Community First Choice State Plan Option Technical Guide, available at https://www.medicaid.gov/sites/default/files/2019-12/cfc-technical-guide_0.pdf.

The regulation must qualify for personal care and CDPAP individuals who, because of dementia, Alzheimer's disease or any another diagnosed impairment, requires supervisory assistance with more than one ADL, or one ADL with an IADL.

C. The Requirement that Supervision or Cueing Assistance be Authorized for Safe Performance of ADLs or IADLs Must Conform to Longstanding Guidance and CFCO Requirements

The introduction to the proposed regulation states that the proposed new paragraph 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." State Reg. at p. 34. However, as drafted, the proposed regulation is less comprehensive than DOH MLTC Policy 16.07, which in turn clarified longtime NYS DOH GIS 03 MA/003[7] for MLTC, just as 2011 guidance clarified related policies for mainstream plans.[8] See also 19 OHIP/ADM-01, *Community First Choice Option* at p. 4. By omitting some key concepts, the definition will be wrongly used to deny services. The proposed new paragraph, which was not revised in the second round of regulations, states,

> … 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 separately from or in addition to the performance of nutritional and environmental support functions or personal care functions.

505.14(a)(5)(iii).

We appreciate that the Department is making an effort to incorporate clear federal policy and regulation that defines personal care services to include cueing and supervisory assistance with both ADLs and IADLs.[9] The CFCO regulations, discussed above with

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[7] NYS DOH GIS 03 MA/003 was issued in 2003 to clarify the meaning of a 1999 federal court decision, which held that the NY Medicaid program was not required to provide stand-alone safety monitoring as a service separate from personal care services. *Rodriguez vs. City of New York*, 197 F.3d 611 (2d Cir. 1999). When that decision was improperly misinterpreted to ban personal care aides from assisting a consumer to safely perform ADLs, the State issued GIS 03 MA/003 e to clarify that personal care does include "…the appropriate monitoring of the patient while [a personal care aide is] providing assistance with the performance of a Level II personal care services task, such as transferring, toileting, or walking, to assure the task is being safely completed."

[8] NYS DOH, Guidelines for the Provision of Personal Care Services in Medicaid Managed Care (2011), posted at https://www.health.ny.gov/health_care/medicaid/redesign/final_personal_care_guidelines.htm.

[9] A cognitively impaired individual "…may be physically capable of performing ADLs and IADLs but may have limitations in performing these activities because of a cognitive impairment. Personal care services may be required because a cognitive impairment prevents an individual from knowing when or how to carry out the task. For example, an individual may no longer be able to dress without someone to cue him or her on how to do so. In such cases, personal assistance may include cuing along with supervision to ensure that the individual performs the task properly." CMS State Medicaid Manual §4480, available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021927.

respect to the minimum needs threshold, also require that cueing and supervisory assistance as well as physical assistance be provided with ADLs and IADLS or CFCO-eligible individuals. See Section I.B, supra. However, we are concerned that the proposed language spends more time explaining what cannot be covered rather than clarifying what can and must be covered. The language should explain that cueing and supervisory assistance are bona fide forms of assistance that must be authorized, and that the frequency and times of day in which such assistance is needed must be considered.

A glaring omission from the new proposed paragraph is clarification that the need for supervisory and cueing assistance with personal care functions (ADLs) and nutritional and environmental support functions (IADLs), may "be unscheduled or may occur at unpredictable times during the day or night." MLTC Policy 16.07. The regulation does not make clear what the Department has previously stated, that the plan or LDSS must:

> …evaluate and document when and to what extent the enrollee requires assistance with IADLs and ADLs and whether needed assistance can be scheduled or may occur at unpredictable times during the day or night. All plans must assure that the plan of care that is developed can meet any unscheduled or recurring daytime or nighttime needs that the enrollee may have for assistance.

DOH MLTC Policy 16.07. Policy 1607 also clarifies that assessments "…must reflect sufficient time for such safety monitoring, supervision or cognitive prompting for the performance of those particular IADLs or ADLs."

The requirement that services must be authorized over a span of time in which the need for assistance is frequent or recurring, as described in Policy 16.07, is simply absent from the proposed regulation. As written, a plan or LDSS could read the regulation as permitting it to authorize hours or even minutes of care only while a consumer is actually ambulating or using the toilet. This would violate longstanding guidance and CFCO requirements. Clarifying language is needed to require assistance to be provided if needs are unscheduled or recurring during the day or night. Without such language, the second sentence of this section stating that supervision and cueing may not be "paid for or reimbursed separately from or in addition to" ADLs and IADLs could be applied to improperly deny authorization of personal care or CDPAP services to provide supervision or cueing assistance for safe performance of ADLs or IADLs that are unscheduled or recurring over a span of time. We recommend eliminating that sentence and using the clearer language from the longstanding guidance cited above.

Since the Department placed the new paragraph in the "definitions" section of the regulation in section 505.14(a), this provides an opportunity to amend the definition to clarify that every reference to "need" for assistance with an ADL or IADL (personal care or environmental and nutritional support functions) throughout the regulation 505.14 is defined to include a need for supervisory or cueing assistance and/or for physical assistance, and require that any determination of "need" take into account whether the needs are unscheduled or frequent and at what times of day and night they arise.

Alternately, or in addition, language must be added in each separate part of the regulation that discusses the "need" for assistance with ADLs or IADLS to specifically include the need for supervisory and cueing assistance, not just for physical assistance. Some sections of the regulation that need this clarification include the definitions of 24-hour live-in and

"continuous" split-shift care in 505.14(a), and the "Mayer 3" regulation that prohibits use of task-based assessment for individuals "…determined by the social services district or the State to be in need of 24-hour personal care . . .or the equivalent provided by formal services or informal caregivers." 505.14(b)(4)(viii)(d).[10] Similarly, it must be made clear that the new criteria for the LDSS or MMCO to assess the "need" for 24-hour care must consider the need for supervision and cueing assistance as well as for physical assistance. These criteria include –

> (1) whether the physician order indicated a medical condition that causes the individual to need frequent assistance during a calendar day with toileting, walking, transferring, turning and positioning, or feeding;
>
> (2) the specific personal care functions with which the individual needs frequent assistance during a calendar day;
>
> (3) the frequency at which the individual needs assistance with these personal care functions during a calendar day;
>
> (4) whether the individual needs similar assistance with these personal care functions during the individual´s waking and sleeping hours and, if not, why not….

505.14(b)(2)(iii)(d); 505.28(d)(3)(iv)**(**proposed language). If the new "definition" language requested above is not amended to make clear that the needs for assistance with personal care functions referenced throughout the regulation includes the need for supervision and cueing, not only physical assistance, and that the span of time during which the need arises must be considered, then this section of the regulation must separately be amended to clarify that the "assistance" referenced in this section includes the need for cueing and supervision.

As a side note, the fact that 505.14(b)(2)(iii)(d) does require consideration of whether needs are frequent and the same during waking and sleeping hours does not satisfy the need to state these concepts clearly in the "definitions" section. Section 505.14(b)(2)(iii)(d) only pertains to 24-hour care. The same factors of frequency of need and time of day in which needs arise must be considered for all individuals including those who do not need 24-hour care.

In summary, the proposed regulation is not as clear as either the 2003 GIS, the 2011 managed care guidelines **(**see fn 9), MLTC Policy 16.07, or the 2019 CFCO ADM. The regulation must be strengthened to clarify that all "need" for assistance referenced throughout 505.14 includes supervision and cueing as well as physical assistance, and that the frequency and recurring nature of these needs and the times of day when they arise must be considered. The last sentence of proposed 505.14(a)(5)(iii) should be stricken as confusing and misleading.

[10] This "Mayer 3" regulation should be added to the CDPAP regulation. It was added to the personal care regulation as a result of the *Mayer* litigation, which addressed personal care. CDPAP was a newly enacted program at the time with no regulations. NY SSL § 365-f, added L.1995, c. 81, § 77. The regulations should be aligned to ensure that consumers in both programs have the same protections.

II. The Definition of Medical Necessity is Unduly Restrictive and Must be Expanded to Comply with State Law and Federal Medicaid Regulations

The NYSBA ELSN appreciates the Department's deletion of language proposed in the first round of rulemaking that would have permitted plans or MMCO's to authorize "…only the hours or frequency of services that the patient actually requires to maintain his or her health and safety in the home." Proposed 505.14(b)(4)(iv), 505.28(e)(2). We and others commented that this language wrongly limited services to only those necessary to maintain health and safety in the home, a more limiting standard than that in state Medicaid law and federal regulations. In the second round, the same subparagraph is (noting changes from existing regulation):

> The social services district [~~shall~~] or MMCO may authorize only the hours or frequency of services actually required by the individual.

Id. While deletion of the overly limiting language is commendable, the new language limiting plans and LDSS to authorizing only services "actually required" cultivates a breeding ground for inconsistent, arbitrary determinations, with each local district and plan free to apply its own subjective definition of the hours and frequency of services that is "required.[11]" The Department need not reinvent the wheel on defining "medical necessity." Both State Medicaid law and federal Medicaid regulations have clear definitions that should be incorporated in the regulation.

Under the New York Medicaid statute, Medicaid covers services that are "necessary to prevent, diagnose, correct or cure conditions in the person that cause acute suffering, endanger life, result in illness or infirmity, interfere with such person's capacity for normal activity, or threaten some significant handicap. Soc. Serv. L. § 365-2, subd. 2. Personal care services must be authorized as necessary to prevent a medical impairment from interfering with the person's capacity for normal activity. Thus the aide must be authorized to assist the consumer in participating in desired outside activities, or in engaging in daily activities in the way that the consumer prefers (helping the consumer shop rather than shopping for the consumer).

Under the federal managed care regulations as amended in 2016 require the MCO contract define "medical necessity" in a manner that addresses the extent to which the MCO is responsible for covering services that address, in part:

> … (C) The ability for an enrollee to attain, maintain, or regain functional capacity [and] (D) The opportunity for an enrollee receiving long-term services and supports to have access to the benefits of community living, to achieve person-centered goals, and live and work in the setting of their choice."

42 C.F.R. § 438.10(a)(5)(C)-(D). The New York MLTC Model contract fails to address the plan's responsibility to enable members to achieve these goals. The State should take the opportunity in amending these longstanding regulations – and the model contract -- to bring the definition up to date with the 2016 federal requirements.

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[11] Nearly 25 years ago, a federal court reviewed the same New York Medicaid regulations regarding personal care, stating, "Due process demands that decisions regarding entitlements to government benefits be made according to 'ascertainable standards' that are applied in a rational and consistent manner. . . Part of the problem stems from the absence of standards in the regulations governing the reauthorization of personal care services…." *Mayer v. Wing*, 922 F. Supp. 902, 911 (S.D.N.Y. 1996)(citations omitted).

In its response to comments in the second round of rulemaking, the Department dismisses the specific definitions of medical necessity in state law and federal regulations set forth above as mere "generic definitions of 'medical necessity.'" Reg at p. 171. "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." Id. On the contrary, it is the Department's duty to synthesize the definitions of medical necessity that appear in both federal and state law and regulations, so that plans, reviewers including Administrative Law Judges and external appeal reviewers, as well as consumers, all have one consistent definition. Instead, the Department abdicates this role by leaving the regulation silent.

RECOMMENDED EDIT: The social services district or MMCO ~~may~~ must authorize ~~only~~ the hours or frequency of services that the consumer actually requires to maintain his or her health and safety in the home, that are necessary to prevent the consumer's medical impairments from interfering with their capacity for normal activity, and that are necessary to enable the consumer to access the benefits of community living, to achieve person-centered goals, and live and work in the setting of their choice.

III. The Treating Physician Must Have the Opportunity to Request Services and Provide Information in Support of the Consumer's Request

We appreciate that the Independent Practitioner Panel (IPP) and Independent Review Panel ("IRP") *may* consult with the Consumer's treating physician. 18 NYCRR 505.14(b)(2)(ii)(e), (b)(2)(v)(d); 505.28(d)(2)(v), (d)(5)(v). However, simply permitting, and not requiring them to do so violates federal law and strips the consumer of any meaningful opportunity to produce relevant information from his/her treating practitioner. The regulations fail to provide any procedure by which the consumer can introduce such evidence during either the initial independent assessment, to the IRP, or to the LDSS or MMCO. This second round of rulemaking now requires the MMCO or LDSS to transmit to the IRP "…clinical records … used to develop the plan of care, such as records from treating providers…." Revised 505.14(b)(2)(iii)(f)(1); 505.28(d)(3)(vi)(a). However, there is no procedure for the MMCO or LDSS to obtain treating provider records, and no requirement that they consider them if received. Further, the rules do not require that the LDSS or MMCO transmit records that were *not* used to develop the plan of care to the IRP. This scheme vests in all of these state appointed officials the sole and overly broad discretion to determine when, how and whether the treating physician will be consulted.

To reiterate our prior comments, the regulations must provide an opportunity for the consumer's treating physician to submit information regarding the consumer's medical diagnoses, functional impairments, and service needs. Not only is this required by federal regulations for managed care plans, but it is necessary for the IA to obtain information about the medical condition to supplement information from the consumer, who may not always be an accurate or knowledgeable reporter of their medical history and status.

In response to our prior comments, DOH states that it does not agree that federal law requires the IRP to consider information/documentation from a treating physician. Reg. p. 221; see also pp. 183, 227. The failure of the proposed regulations to provide any process for the consumer to present his/her treating physician's opinion to the ultimate arbiter of the care plan (whether that be the MCO or LDSS) runs afoul of the mandates of patient

centered care, and for managed care plans, violates 42 C.F.R 438.208 and 210. A plan must ensure that a plan appeal "take[s] into account all comments, documents, records, and other information submitted by the enrollee or their representative without regard to whether such information was submitted or considered in the initial adverse benefit determination." 42 CFR 438.406(b)(2)(iii). In short, the absence of any compulsory requirement that the creators of the care plan consider the treating physician's opinion and prior medical records deprives the consumer of any meaningful opportunity to present highly relevant documentation of their medical needs.

Finally, the proposed regulation still fails to require plans to defer to the treating provider's judgment that emergency circumstances warrant an expedited determination, contrary to the federal regulation, which provides:

> For cases in which **a provider indicates**… that following the standard timeframe could seriously jeopardize the enrollee's life or health or ability to attain, maintain, or regain maximum function, the MCO …must make an expedited authorization decision and provide notice as expeditiously as the enrollee's health condition requires and no later than 72 hours after receipt of the request for service."

42 C.F.R. § 438.210(d)(2)(i)(emphasis added). To ensure compliance with the federal mandate the consumer's treating physician should be given an opportunity to provide a statement for review in all of these assessments, including the high-need independent review panel.

IV. The Three Amended Grounds For Reduction of Home Care Services Either Violate Due Process or Need Further Protections

We strongly oppose the proposed new ground for reducing personal care or CDPAP services, which allows arbitrary reductions after a mandatory "continuity of care" period. We also request modification of some of the other amended grounds for reduction – concerning changes in availability of informal caregivers and telehealth.[12]

A. The New Ground that Allows Plans to Reduce Hours after a "Continuity of Care" Period Violates Due Process

The new ground for reductions essentially nullifies the due process protections required by *Mayer v. Wing*,[13] codified in the longstanding "Mayer regulation" requiring that any reduction be justified by a medical improvement, change in circumstances, or a mistake in the previous authorization. 505.14(b)(4)(viii)(c)(3)(i); 505.28(i)(4)(ii)(a)(using proposed renumbering). The Mayer regulation was promulgated as part of a settlement in *Mayer v. Wing*, in which the federal court held that reductions in personal care services were arbitrary and violated due process where there was no change in the consumer's

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[12] The regulation would permit a reduction if telehealth or assistive devices render "certain services unnecessary or less time-consuming," and "it can be demonstrated and documented to reduce the amount of services that are medically necessary." 505.14(b)(4)(iv)(c)(2)(iv), 505.28(h)(4)(ii)(d) (pp. 45, 112). Notice must be required specifically identifying how these technologies reduce the need for personal care or CDPAP services. We recommend that the regulation require the notice to identify the specific ADLs or IADLs for which telehealth services or specifically identified assistive devices reduce the amount of services that are medically necessary and how and when they reduce the need for assistance.

[13] *Mayer v. Wing*, 922 F. Supp. 902 (S.D.N.Y. 1996), modified in part, unpublished Orders (May 20 and 21, 1996); Stipulation & Order of Discontinuance (Nov. 1, 1997).

circumstances or other enumerated reasons. In 2011 and again in 2016, DOH reaffirmed that the Mayer regulation is binding on mainstream managed care and MLTC plans.[14] While the proposed regulation nominally leaves intact the five grounds for reductions stated in the Mayer regulation and Policy 16.06, it adds a sixth ground for reductions that essentially nullifies the others, opening the door for the same arbitrary reductions that the *Mayer* court found violated due process. 505.14(b)(4)(vii)(c)(2)(i)-(ii); 505.28(h)(4)(ii)(h)-(i). The proposed change would newly allow an MMCO to reduce services after the *continuity of care* or "transition" period ends that followed the consumer's mandatory enrollment in the plan if:

> viii) 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.

505.14(b)(4)(viii)(c)(3)(vii); 505.28(i)(4)(iii)(h). This provision would violate Mayer by allowing the plan to reduce home care without identifying and proving any specific change in the consumer's condition or circumstances. The proposed new requirements for plan notices of reduction do not remedy these defects.

In publishing the second set of proposed regulations, the Department weakly attempts to justify its proposed circumvention of the *Mayer* holding, allowing plans to reduce home care services after the "continuity period" without specifying any change in circumstances or mistake in the prior authorization:

> …[T]he rationales furnished by MMCOs and LDSS for … 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 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.

Reg. at 244. This analysis is simply wrong under *Mayer v. Wing*. It is true that the federal district court rejected the *Mayer* plaintiffs' requested relief as "too broad" that would have limited reductions solely to a change in medical condition or other circumstances. 922 F. Supp. at 912. The Court acknowledged the defendant's argument that allowing reductions only for a change in the consumer's circumstances "…would prevent the City Defendant from rectifying any mistakes it makes in the initial authorization process." Id. The Court stated,

> …Still, some restriction must be placed on the City Defendant's arbitrary issuance of notices of reduction. Accordingly, I find that prior to issuing any such notice, the City Defendant **must first identify some development that justifies altering a recipient's level of services**. Specifically, Defendants are enjoined from reducing a recipient's home care services unless they state in the notice that a reduction is justified because of: (1) a change in the recipient's medical, mental, economic or social circumstances; (2) a mistake that occurred in the previous authorization of services; (3) a recipient's refusal to co-operate with the required reassessment; (4) a technological development rendering

[14] See fn 9 and DOH MLTC Policy 16.06.

> certain services unnecessary or less time consuming, or (5) a finding that the recipient can be more appropriately and cost effectively served through other Medicaid programs.

922 F. Supp. at 912 (emphasis added). The list of five permitted justifications for reductions delineated in *Mayer* does not say that the five reasons are mere examples of permitted reasons. The court's holding *does not* say reductions are permitted for reasons "including but not limited to" the five stated reasons. Rather, the list is exclusive, requiring the LDSS or plan to "first identify some development that justifies altering" the current care plan. Id. If anything, the *Mayer* list of justifications for reducing services is quite expansive, providing the plan or LDSS with the flexibility needed to address mistakes in the previous authorization, or to utilize technological developments or other Medicaid programs if appropriate and cost-effective. 922 F. Supp. at 910, 912. But there is no reading of *Mayer* that supports the Department's characterization that a plan has more latitude to reduce services that a different plan or DSS had authorized, after a mandatory continuity of care period, than is allowed if a plan were reducing services it had authorized earlier.

Under the terms of the 1115 waiver that governs the MLTC program, the MLTC/MCO must continue the previously authorized plan of care for a "continuity of care" or "transition" period following a consumer's mandatory enrollment in that plan.[15] The CMS Special Terms & Conditions ["ST&C"] of the 1115 waiver authorizing mandatory enrollment in MLTC expressly provides:

> *MMMC or MLTC Enrollment and Transition of Care Period.* For initial transitions into MLTC or MMMC from fee-for-service, each enrollee receiving community-based LTSS must continue to receive services under the enrollee's preexisting service plan for at least 90 days after enrollment or until a care assessment has been completed. Any reduction, suspension, denial or termination of previously authorized services shall trigger the required notice under 42 CFR § 438.404 and applicable appeal rights.[16]

The *Mayer* holding requires that any reduction of personal care services be based on one of the five grounds enumerated in the decision and incorporated in the Mayer regulation, set forth above. The plan or DSS must allege and meet its burden of proof that one of these grounds exists. 18 NYCRR. 358-5.9(a)("… the social services agency must establish that its actions were correct…"). The proposed standard -- allowing Plan B to

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[15] The continuity of care period may be 90 days or 120 days depending on the circumstances. A 90-day transition period follows mandatory enrollment into an MLTC plan after a consumer received PCS or CDPAP services through the LDSS, such as through the "immediate need" procedure. A 90-day period also is required after a consumer transitioned from a mainstream Medicaid MCO to an MLTC plan upon enrolling in Medicare. DOH MLTC Policy 15.02 - *Transition of Medicaid Managed Care to MLTC*. A 120-day continuity of care period applies when a consumer's MLTC plan closed; after the consumer enrolls in a new MLTC plan, the new plan must continue the closing plan's plan of care for 120 days. DOH MLTC Policy 17.02.

[16] CMS Special Terms & Conditions ("ST&C"), NYS Medicaid Redesign Team Section 1115(a) Medicaid Demonstration, CMS Approved: December 7, 2016 through March 31, 2021, Last Amended on December 19, 2019 § V. 4.g. p. 31, available at https://www.health.ny.gov/health_care/managed_care/appextension/docs/2020-04-16_ny_stc.pdf.

reduce services simply by claiming that the previous plan or LDSS "authorized more services than are medically necessary," with each plan using its own proprietary and likely unwritten standard of "medical necessity," is essentially the same standard that the *Mayer* court rejected outright as inadequate to justify reducing services, as a matter of due process. Reviewing the former version of 505.14(b), the Court stated, "For example, services may be reduced or discontinued because a reassessment indicates that personal care services are inappropriate or that the personal care services hours authorized must be reduced or discontinued." §504.14(b)(3)(iv)(f)(2). The Court found this version of the regulation gave excessive discretion to the LDSS. "The absence of standards governing the withdrawal or modification of services permits arbitrary decisionmaking." 922 F. Supp. at 927-28.

The *Mayer* Court further stated:

> At a minimum, due process requires that government officials refrain from acting in an irrational, arbitrary or capricious manner. *[cite omitted]*. This is precisely the manner in which the City Defendant appears to have acted. The testimony of the named Plaintiffs … indicates that the City Defendant has, without any adequate justification, repeatedly determined to reduce services initially authorized to home care recipients. The capricious nature of these decisions is evidenced by the fact that Plaintiffs received notices of reduction while in the same or worse physical condition they were in when home care was initially authorized, and were given no explanation for why they were assessed differently the second time around.

922 F. Supp. at 911. The same result is likely to happen under the proposed regulation; with no burden on the plan to identify and establish a change in the consumer's condition or circumstances since the earlier authorization, or a mistake made in the earlier authorization, consumers will likely be "in the same or worse physical condition they were in when home care was initially authorized" by the previous plan or LDSS, yet be subject to threatened reduction of services. Id., 922 F. Supp. at 911.

The Department points to the proposed new notice language for reductions, stating in its response to comments that the plan "…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." Reg. at 247. The added notice requirements, however, do not remedy the due process violation created by allowing plans to reduce services without alleging and proving a change in medical condition or circumstances. The proposed revised notice language is as follows:

> Social services districts and MMCOs that deny, reduce or discontinue services based on medical necessity 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.

505.14(b)(4)(viii)(c)(1), 505.28(i)(4)(i). The requirement that the plan indicate a "clinical rationale that shows review of the client's specific clinical data and medical condition" is

not a reviewable standard for appeal. It is not the same as requiring the plan to specify a *change* in the consumer's condition or circumstances from when the services were previously authorized. It requires no meaningful standard to justify reducing services other than the plan's own unilaterally defined "benefit coverage criteria" for "medically necessity." The proposed notice requirements dilute the requirements for *reduction* notices to the same minimal criteria used for notices by which a plan denies a request for an increase. Such denials – unlike reductions – may be based on the plan's finding that the requested increase is not medically necessary. Reductions, in contrast, require the plan to allege and meet a burden of proof. The proposed regulation essentially absolves the plan of meeting any burden of proof for reducing services. This will allow plans to engage in the same arbitrary decision making that the *Mayer* Court found violated due process.

The Department also points to Public Health Law section 4403-f (11)(b)[17] that requires MLTC plans that received members from an MLTC plan that closed, pursuant to a merger or acquisition agreement, to report to DOH within 12 months after the transition information about the enrollees´ service authorization both before and after the transfer and continuity period. According to the Department:

> ...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.

The department points to the statutory requirement that it "…shall make a summary of the report available to the public" as "…an additional layer of transparency for the public to ensure that plans are authorizing services in accordance with appropriate medical necessity criteria." The required reporting and its alleged availability to the public might be more reassuring if the Department pointed to any reports made pursuant to this statute, and how such reports have been used to hold plans accountable. A review of state webpages concerning MLTC reports reveals nothing publicly posted.[18]

Moreover, even if this statutory reporting requirement was an effective deterrent to arbitrary plan behavior, the provision applies only in some of the many circumstances in which plans are subject to a mandatory "continuity of care" period. This Public Health Law provision does not apply to transitions to MLTC from local districts, which includes those who were authorized for Immediate Need personal care or CDPAP services. Nor does it apply to transitions to MLTC from mainstream managed care plans for those who newly enroll for Medicare.

Even among situations where MLTC Policy 17.02 applies because an MLTC plan closed or reduced its service area, PHL § 4403-f (11)(b) applies only where the "receiving MLTC plan" is a party to an approved merger or acquisition of an MLTC. Reporting should have been done, for example, when VNS Choice received members of the closing ICS MLTC

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[17] added L. 2018 Ch. 57 Sec. 6 (S. 7507-C)

[18] See, e.g. https://www.health.ny.gov/health_care/managed_care/mltc/reports.htm and https://www.health.ny.gov/health_care/medicaid/redesign/mrt90/. A Freedom of Information request has been filed requesting any such reports.

plan, and when Fidelis received members of the closing Wellcare plan. When Guildnet closed in 2018 and United Health Care reduced its service area in Feb. 2019, on the other hand, their members were randomly assigned by NY Medicaid Choice to other MLTC plans if they did not select a plan on their own. Those receiving plans do not appear to be required to file reports under PHL § 4403-f (11)(b).

B. Reductions Based on Informal Caregiver Availability Need Added Protections

We commend the Department for withdrawing the proposal to add a new ground for reductions because needs can be met "by fully utilizing any available informal supports…that are documented in the plan of care." Instead, the Department amended the existing ground for reducing service, adding the availability of voluntary informal supports as an example of a change in social circumstances. We recommend one change in this amendment to ensure the plan has confirmed that the newly available informal supports are acceptable to the consumer:

> (i) the client's medical or mental condition or economic or social circumstances have changed and the district determines that the personal care services provided under the last authorization … are no longer appropriate or can be provided in fewer hours. … [T]his includes but is not limited to cases in which: … voluntary informal supports **that are acceptable to the client** have become available to meet some or all of the client´s needs….

18 NYCRR 505.14(b)(4)(viii)(c)(3)(i); 505.28(i)(4)(iii)(a)**(**ELSN's proposed revision in second round in **bold**). While we believe that this amendment is not necessary because the regulation already allowed for reductions based on a change in social circumstances, we appreciate that the proposed amendment specifies that the informal supports must be voluntary and that they "have become available," which implies that the plan must allege and prove that this new availability is a change. These qualifiers must remain in the final regulation.

Federal person-centered service planning requirements permit use of informal supports only if acceptable to the consumer. 42 CFR § 441.301(c)(1) and (2), incorporated by cross reference from 438.208(c)(3)(ii). An elderly woman, for example, must have the right to decline assistance by her grown son with incontinence care, however willing the son may be to provide this care. The Independent Assessment appropriately includes assessment of consumer "preferences" and acceptability of informal supports to the consumer. 505.14(b)(2)(i)(b)(3); 505.28(d)(1)(ii)(c). The regulation must also make clear that the LDSS or MMCO's reliance on informal supports in a plan of care, or reduction of services based on informal supports, must specify that the caregivers' involvement is acceptable to the consumer.

C. Reductions based on Telehealth Need Further Protections

We appreciate that the Department has added that a reduction of services may be based on use of telehealth services or assistive devices only if such services are "readily available" and "accessible" to the individual. However, we remain unconvinced that telehealth can reduce a consumer's need for assistance with ADLs and IADLs in their plan of care, and we oppose reductions on this ground. Any allegation that telehealth would "reduce the amount of services that are medically necessary," as the proposed regulation allows, would be speculative. Proposed §§ 505.14(b)(4)(viii)(c)(2)(vi), 505.28(i)(i)(4)(ii)(e). A reduction should only be permitted after a trial period in which the technology

was demonstrated to reduce the need. If such reductions are permitted, plan notices must *identify the specific AD*Ls and IADLs for which telehealth services or assistive devices are available, and specify how these technologies or devices reduce the need for assistance.[19] Also, the regulation must require the notice to specify when and how the consumer *agreed* to use this technology, consistent with Person-Centered Service Planning requirements that require taking into account consumer preferences. The notice should also specify that the technology or devices are available and accessible to the consumer, including that they are cognitively and physically able to use the technology.

V. Concerns about "Undue Delay" that Violate Federal and State deadlines for Managed Care Plans, Those in "Immediate Need," and other Consumers

Two changes made in the second round of rulemaking are inadequate to address concerns about delays caused by the new layers of assessments, which will cause plans to violate federal and state deadlines for authorizing services, and will cause undue delays by local districts. The State may not set up a system that, by its design, prevents local districts and MCO's from meeting federal and state time limits for authorizing services, including specific time limits for managed care members. The Medicaid Act requires the provision of medical assistance "with reasonable promptness to all eligible individuals." 42 U.S.C. § 1396a(a)(8), 42 C.F.R. § 435.930, § 435.911(e)."[20] Members of managed care plans have additional rights to plan service determinations within the strict timeframes in federal Medicaid regulations[21] and state Insurance Law.[22] "Each State must ensure that all services covered under the State plan are available and accessible to enrollees of MCOs …in a timely manner." 42 C.F.R. §438.206(a).

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[19] Proposed 505.14(b)(4) (viii)(c)(2)(vi); 505.28(i)(4)(i)

[20] If there was any doubt that this provision requires prompt provision of services as well as prompt eligibility determinations, the Patient Protection and Affordable Care Act ["ACA"] clarified that medical assistance is defined as payment for "care and services, the care and services themselves, or both." 42 U.S.C. § 1396d(a), added by ACA § 2304. "As one court has already noted, it appears that Congress intended to squarely address the circuit split and 'to clarify that where the Medicaid Act refers to the provision of services, a participating State is required to provide (or ensure the provision of) services, not merely to pay for them[.]" *Leonard v. Mackereth*, No. CIV.A. 11-7418, 2014 WL 512456 (E.D. Pa. Feb. 10, 2014), citing *John B. v. Emkes*, 852 F.Supp.2d 944, 951 (M.D.Tenn.2012); see also *Disability Rights N.J., Inc. v. Velez*, Civ. No. 05-4723, 2010 WL 5055820 (D.N.J. Dec. 2, 2010) (reconsidering earlier decision that medical assistance is only payment and reinstating plaintiffs' claim challenging delays in accessing waiver services).

[21] 42 CFR 438.210(d) (requiring standard authorizations in 14 calendar days and expedited authorizations in 72 hours absent a proper 14-day extension).

[22] New York Insurance Law requires utilization review determinations in writing within three business days of receipt of the necessary information, and within one business day for home health care services following an inpatient hospital admission. NY Insurance Law §4903(b)(1), 4903(c)(1); proposed 505.14(b)(3)(ii) and 505.28(e)(i)(8) pp. 40, 102.

A. Setting Time Limits in the Department's Contract with the Third Party Independent Assessor is Not an Adequate Substitute for Setting Time Limits to Refer, Schedule, Conduct, and Transmit Recommendations on the Assessments

The Department stated in the second round of rulemaking that "…it has declined to impose more specific timeframes in the regulation…" that consumer advocates requested for scheduling, conducting and filing reports of the myriad new assessments. Reg. at 164. Instead, the Department "…will impose and contractually enforce timeframes on the independent assessor (IA) in connection with these processes…." Id. To that end, only a vague requirement was inserted in the revised regulation:

> (i) The independent assessment and practitioner order processes shall be completed … 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….

505.14(b)(3)(i); 505.28(g)(1**).** The Department rationalizes its refusal to establish clear deadlines as intended to preserve "… the same flexibility that already exists in the processes for MMCOs and LDSS…." Yet current regulations allow little flexibility; local districts must determine both Medicaid and personal care or CDPAP eligibility within 12 days of an application in "immediate need" cases, and otherwise must conduct the nurse's assessment within five days, 505.14(b)(3)(iii)(b), 505.14(b)(7)(iv) and plans are under strict time limits. See n 22-23. Unfortunately, delays in processing requests for new or increased services are common now, and will only grow in the new system.[23] At a minimum, the regulations must set a time limit for the LDSS or MMCO to refer a request for services to the IA to conduct the IA and IPP, to refer a case to the IRP if the consumer is determined to need more than 12 hours/ of services, and to deny or authorize services. Likewise, a time limit must be set for the IA to conduct its assessments. These deadlines must be stated in the regulations, since the consumer has no recourse against the third party contractor for its failure to meet deadlines solely set forth in its contract.

The Department says it will "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." We object to characterizing the "needs" of MMCO's and LDSS as something to be balanced against the "needs" of consumers. Consumers' rights to timely processing of their requests for services under federal and state Medicaid law and regulations and state Insurance law cannot be relegated to state contracts with third party assessors. The failure to set clear deadlines for each step of this complex new process will lead to delays that will violate these clear consumer rights. We suspect the Department has not set deadlines because it is simply impossible for each of these assessments to be scheduled, conducted, and their reports transmitted in time for plans or local DSS to make final determinations in the required time limits.

The sole time limit in the proposed regulation requires that local districts "…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

[23] See, e.g. *Bucceri et al. v. Healthfirst and Zucker,* 16 CIV 08274 (EDNY)

the independent review panel recommendation if applicable…" 505.14(b)(3)(ii); 505.28(g)(2). The 7-business day limit, even if it was feasible, will not allow sufficient time for the MMCO to refer the case to the IRP because more than 12 hours are needed and still issue a standard authorization in the required 14 calendar days (**see n. 22**), It is simply not feasible for that referral to be made, and the IRP scheduled and a report issued in time for the MMCO to meet the 14-day time limit. Where an expedited authorization is warranted, the 72-hour limit is impossible to meet.

B. LDSS and MMCO's must be required, not permitted, to Authorize and Implement a "Temporary Plan of Care" Pending the High-Need Independent Medical Review

We recommend two small revisions in the new provision allowing local districts and MMCO's to authorize and implement a "temporary plan of care" in cases referred for the high need review based on a determined need for more than 12 hours/day, "[p]ending review of the independent review panel´s recommendation and if necessary to comply with federal or state timeliness requirements, including immediate needs cases." We appreciate this addition, showing the Department's recognition that the new Independent Medical Review of high-need cases will inevitably cause delays in authorizations and prevent MMCO's and local districts from meeting federal and state time limits.

The first recommended change is that the regulation should state that the social services district or MMCO ***must,*** not **"*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….if necessary to comply with federal or state timeliness requirements." 505.14(b)(4)(vi), 505.28(e)(4)(emphasis added). If a temporary plan of care is merely allowed, not required, the consumer has no right to obtain this relief from the district or plan.

Second, the timing of the temporary authorization should be earlier than indicated in the proposed language. The proposed language states, "Pending review of the independent review panel´s recommendation…." the LDSS or MMCO may authorize and implement services based on a temporary plan of care. Id. This language suggests that the LDSS or MMCO may only authorize a temporary plan of care *after* they have made the referral for the IRP, having determined that the service plan requires more than 12 hours of services per day on average, and *after* the IRP has transmitted its recommendation to the LDSS or MMCO. Only after all of these steps would the proposed new language apply. The temporary authorization should be issued and implemented earlier, at the point that the LDSS or MMCO first determines that the service plan requires more than 12 hours of services per day on average and makes the referral to the IRP for review. At that point, the LDSS or MMCO has already determined that a service plan of more than 12 hours is medically necessary, and the LDSS or MMCO would already know at that point if the applicable federal or state timeliness requirements are not likely to be met with referral for the high needs review. Possible suggested language is indicated in **bold**:

> Pending **referral to ~~review of~~** the independent review panel **for its ~~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.

C. Telehealth Should Not be Relied On as a Means for Expediting the New Assessment Regimen

We have concerns about making telehealth visits a permanent mode for conducting the battery of new assessments, especially the initial nurse Independent Assessment using the CHA tool, as now proposed. Please see Section VI.A. below for these concerns.

D. Additional Recommendation for Meeting State time Limits for Authorizing Immediate Need

Applicants for services based on Immediate Need are entitled to a determination of both Medicaid eligibility and an authorization for services within 12 days. Soc. Serv. L. § 366-a(12). Even now, many LDSS's do not meet the short 12-day deadline, despite efforts by HRA and other districts. The proposed regulation says that LDSS must make a determination and provide notice "with reasonable promptness," and within 7 business days after receipt of the independent assessment, physician order, and clinic review panel recommendation if applicable. 505.14(b)(3)(ii), 505.28(g)(2). However, this timeline is unrealistic and the entire process will more likely run for months, leaving consumers without critical care.

We appreciate the new provision for LDSS to authorize a "temporary plan of care" for those determined to need more than 12 hours/day of services. Please see our recommendations above (Sec. V.B.) to make such temporary authorizations mandatory, especially in Immediate Need cases.

Additionally, we recommend that in lieu of the IPP review in these applications, that the determination be made based on the new required "physician statement of need" on a new state form. Otherwise, no local district could comply with the statutory deadline of 12 days to authorize Medicaid and services.

VI. Concerns about the Various Assessments in the New System

A. The Use of Telehealth for Conducting Assessments is Overly Broad and Must be on Consent

ELSN is concerned about giving discretion to the IA, plans and LDSS to use telehealth for all assessments**.** 18 NYCRR 505.14(b)(1); 505.28(d). Telehealth should not be used at all in the independent nurse assessment, and should be permitted only on a limited basis for the other assessments. A nurse assessor completing the CHA must be able to observe a consumer perform his/her ADLS and observe the home environment to determine need for services. Relying only on the representations of the Consumer and/or their representative on a smartphone or other device is not conducive to the probing dialogue that is contemplated over the 3-4 hours the CHA commonly takes to complete, especially given the lack of English proficiency of many consumers and their families. The assessor is trained to elicit and observe clinical subtleties surrounding performance of ADLs that the consumer and their family member might not be aware of or be able to communicate. This is mostly an older population that may not be comfortable with using or able to use audiovisual technology, even if available, further inhibiting disclosure of functional

limitations and other crucial information. Especially considering the lack of required input from the Consumer's treating physician, telehealth does not provide the independent assessor with adequate opportunity to examine and understand the nature of the Consumer's functional limitations.

This lack of accurate information puts both the consumer and the State at risk. The Consumer may not provide all the relevant information and details resulting in incomplete under documentation of the actual needs. On the other hand, a consumer or representative may overstate needs to the ultimate detriment of the State.

Additionally, it must be made clear that telehealth may be used only on consent, with the consumer having the right to request an in-person assessment. The Department's commentary says the IA will only be "encouraged" to offer telehealth to "willing consumers," which can increase "convenience, especially in rural areas." Reg. at pp. 195, 239. However, the regulation just says telehealth "may" be used for the IA and the IPP, leaving the IA's discretion unlimited with no standards for justifying its use, such as documenting that the consumer lives in a rural area or otherwise why in-home assessment is not possible. Also, after stating that the IA assessment must be done where the consumer is located, whether home, hospital or nursing home, the proposed regulation states, "This provision shall not be construed to prevent or limit the use of telehealth in the assessment of an individual." 505.14(b)(2)(i)(c). This language can be read to override the requirement elsewhere "that the individual is given an opportunity for an in-person assessment." 505.14(b)(1). The consumer should not have the burden to request an in-person assessment; rather, in person assessment should be the default, with telehealth offered only as an alternative.

While we recognize the need to utilize telehealth during the pandemic, even the DOH guidance has not allowed the CHA to be conducted by telehealth for the functional part of the eligibility assessment. See NYS DOH, COVID-19 Guidance for the Authorization of Community Based Long-Term Services and Supports Covered by Medicaid – UPDATED 4.8.20, available at https://health.ny.gov/health_care/medicaid/covid19/docs/2020-03-18_guide_authorize_cb_lt_services.pdf. We do not believe that the anecdotal reports of positive consumer experiences with telehealth are sufficient to make telehealth the primary means for conducting these assessments. Reg p. 195. On the contrary, advocates have heard reports that the assessments conducted by telehealth and telephone have not been as thorough and accurate as ones conducted in-person. Before allowing telehealth for the IA assessments, the Department should first conduct a clinical evidence-based study to determine the efficacy, validity, and availability of using telehealth for conducting the CHA, rather than rely on anecdotes.

We note that "telehealth" is not defined in the proposed regulation nor elsewhere in state regulations to require synchronous audiovisual technology. This concept only appears in the Department's responses to the comments in the notice of proposed rulemaking. The regulation must define telehealth to require audiovisual technology directly or by cross-reference to other regulations, and should specifically prohibit telephone-only assessments, at least for the IA CHA.

B. Scheduling of Various Assessments and Development of Plan of Care

As said above in the section about delays, the sole reference in the regulations regarding when the myriad assessments must be scheduled is inadequate:

> 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) 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.

505.14(b)(2)(iv)(a)-(b); 505.23(d)(4)(i). Time limits must be added for the LDSS and MMCO to refer a consumer for the IA nurse assessment, for that assessment to be conducted and a referral made for the IPP medical assessment, for that assessment to be conducted and transmitted to the LDSS or MMCO, and when the LDSS or MMCO must develop a plan of care and make a referral for the high-needs review.

We question the need for the last clause in subpar. (iv)(b) quoted above – if an individual has contacted an LDSS or MMCO requesting services, there is no need for a caution against pressuring the individual to request an assessment unwillingly. This language could deter plans and LDSS from providing the assistance needed to a consumer who has requested services.

C. Independent Assessment by Nurse – Concerns

1. <u>IA Must assess Frequency of ADL Needs Especially at Night and Sleeping Accommodations for Aide</u>**.**

The Department has maintained the "…responsibility to assess frequency of needs [lies] 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…" Reg. p. 185 (emphasis added). The IA CHA assessment is the foundation for the entire process, including the MMCO/LDSS determination of whether the consumer requires more than 12 hours/day so must be referred for the IRP. It simply makes no sense for this assessment to be done without assessing frequency of ADL needs, especially at night, and assessing sleeping accommodations for a 24-hour aide if needed. Until now, since the LDSS or MMCO nurse conduct the CHA assessments, the MMCO and LDSS arguably can ask these assessors to assess frequency of needs, especially at night, and sleeping accommodations for a live-in aide. This work-around is wholly inadequate because the questions are not methodically asked through the CHA tool, and advocates repeatedly see assessments lacking any information about frequency of needs especially at night. However, at least the entity charged with assessing these needs has eyes and ears in the home, through the nurse doing the CHA. Now that the CHA is delegated to an independent assessor, it would be a wasteful duplication of effort for the MMCO and LDSS to send a nurse into the home solely to assess these needs and sleeping accommodations, which are so logically part of what the IA is designed for. The failure to incorporate these factors in

the CHA will hurt consumers; if the question is not asked about night-time needs, it is not answered.

RECOMMENDATION: The delegation to an independent assessor should be delayed until the CHA tool is modified to include assessment of frequency of ADL needs, especially at night, and sleeping accommodations.

2. Informal Caregiver Availability - We support the proposed regulatory language imported from the former social assessment, requiring the assessor to elicit the number and kind of informal caregivers available, their ability and motivation to assist, extent of their potential involvement and availability or future assistance; and acceptability to the individual of their involvement in his/her care. 505.14(b)(2)(i)(b)(3). Since these factors were previously part of the social assessment, the CHA nurse assessment form does not elicit this information with the needed detail. In the UAS section on "Social Supports," the assessor must indicate if a listed informal caregiver gave, in the prior three days, help with IADLs or ADLs, with room for a YES or NO answer for each, but must elicit more detail about days and times of availability. The UAS-NY does ask "yes" or "no" whether the consumer is accepting of the caregiver's help, and if the caregiver is unable or unwilling to continue helping. This is important but is not enough.

We appreciate that new language added on the second round of proposed regulations requiring that the LDSS or MMCO "must confirm the caregiver's willingness to meet the identified needs in the plan of care for which they will provide assistance" before including their assistance in the plan of care." 505.14(b)(2)(iii)(b)(2). 505.28(d0(3)(ii)(b). However, unless the caregiver's exact daily schedule of availability is ascertained by the IA, the LDSS or MMCO will not have this information. Like assessing night-time needs and sleeping accommodations, all of these vital factors should be included in the IA to avoid duplication with the LDSS and MMCO, and to prevent these factors from being overlooked. Otherwise, the consumer is hurt when assumptions are made about caregiver availability.

3. Under Person-Centered Service Plan Requirements, IA Must Elicit Consumer Preferences. We appreciate that the Department has, in this second round, now required the LDSS and MMCO to consider "… the individual´s preferences and social and cultural considerations for the receipt of care" in determining the plan of care. 505.14(b)(2)(iii)(a)(3); 505.28(d)(3)(i)(c). These preferences should be ascertained in the IA CHA since it is the most comprehensive assessment and, as we request above, should be conducted in-person. While the independent assessment must include "a discussion with the individual to determine the individual´s perception of his/her circumstances and preferences," 505.14(b)(2)(i)(b)(2); 505.28(d)(1)(ii)(b), the regulation should more specifically require that consumer's preferences must be elicited as to their requested schedule of personal care or CDPAP services, their preferences about other services in the MMCO benefit package (adult day care, PERS, nursing, etc.), and, as discussed above, the acceptability of informal care. This is required under federal rules: "The person-centered service plan [PCSP] must reflect …what is important to the individual with regard to preferences for the delivery of such services and supports." 42 CFR § 441.301(c)(1) and (2), incorporated by cross reference from 438.208(c)(3)(ii). Unless these preferences are elicited in the IA, it either requires duplication of effort for the MMCO and LDSS to separately assess them, or they will simply not be assessed.

Declining "to specifically incorporate federal [PCSP and CFCO] requirements," the Department reasoned that they "…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." Reg. p. 179. The Department is essentially saying it is too much trouble to incorporate federal requirements that it is legally obligated to ensure are followed by LDSS and MMCO's, just because these federal regulations may change. This is a gross abdication of responsibility. These federal regulations are not readily available to providers, plans, LDSS, hearing officers, and consumers. It is the Department's responsibility as "single state agency" to bring together the myriad authorities that govern these services and provide clear guidance to all parties on their duties to comply.

D. Concerns About Independent Medical Exam and Physician's Order

1. The consumer's representative – whether family member, social worker or other person – must be given the opportunity to be present for this examination. (Dept. response at Reg. 237, 260) Under federal person-centered planning requirements, the "representative should have a participatory role, as needed and as defined by the individual…." 42 CFR § 441.301(c)(1) and (2), as cross referenced from § 438.208(c)(3)(ii). Although this set of regulations contains no prohibition against a Consumer's representative participating during in person assessments, ELSN believes that the regulations should provide an affirmative right to such participation to assure adherence to federal law. This right should apply equally to self-directing and non-self-directing individuals. Inclusion of reference to a representative in a telehealth appointment is insufficient to address this concern.

2. State law does not authorize substitution of nurse practitioner or physician assistant for a physician. In this second version of the proposed regulation, a physician assistant, specialist assistant, or nurse practitioner – rather than a physician -- may conduct the medical exam, prepare and sign the medical orders, now called "practitioner" orders. The state statute, however, requires personal care services to be "…prescribed by **a** qualified independent physician selected or approved by the department of health." N.Y. Soc. Serv. Law §365-a, subd. 2(e); 505.14(b)(2)(ii)(b); 505.28(d)(2)(ii). As stated above, we question the Department's discretion to permit this substitution, when the Department claims it lacks any flexibility to define the minimum ADL requirement in a way that does not violate Medicaid law. If non-physicians are permitted to do the examination, both the medical examiner and the prescribing physician, like the nurse conducting the independent assessment, must have two years of "satisfactory recent experience in home health care," which should be in geriatrics, rehabilitation medicine, or a related field. 505.14(b)(2)(i)(a)(2), 505.28(d)(1)(i).

3. In the second round of the proposed regulation, the independent medical practitioner determines whether the consumer is self-directing. The Department's commentary says that the medical practitioner will have the benefit of the independent assessment to make this determination, but this question is not specifically asked on the IA. Reg. pp. 193, 237-239. The IA is in the best position to assess the consumer's ability to self-direct, identify the person or entity that will direct care if the consumer is not self-directing, and describe their availability and the tasks to be performed. Without this information, the physician assessor could not make this determination. Now that the

Department has substituted a nurse practitioner or a physician assistant for a physician to do the IPP, the claim that the determination of self-directing may only be done by a physician falls apart. At the very least, the nurse doing the IA should be asked for her opinion on whether the consumer is self-directing, which can then be reviewed in the IPP.

4. Consumer right to receive copy of assessment. A copy should be provided to the consumer, who must have the right to review it and point out any incorrect or missing information to the plan or LDSS. Requiring the assessment to be provided only after a request for a Fair Hearing delays the process. Provision of the assessment in real time, would allow the consumer to immediately correct any inaccuracy potentially eliminating the need for any Fair Hearing. To require an appeal request in order to secure a copy of the assessment leads to delay and unnecessary administrative waste. Reg. p. 197.

E. LDSS/MMCO Responsibilities for Developing a Plan of Care

1. We appreciate the change made in the second round requiring the LDSS or MMCO to review the independent practitioner's order, and not only the IA CHA in developing the plan of care. However, we question why the limitation was added that now only requires review of the "most recent" assessments." 505.14(b)(2)(iii)(a); 505.28(d)(3)(i). In many situation, it may be necessary or at least advisable to review a previous assessment, such as where the individual has transitioned from another plan or from the LDSS to a plan, or if the plan or LDSS is contemplating a reduction in services.
2. The regulations make it optional for the LDSS or MMCO to assess the individual. 505.14(b)(2)(iii)(a); 505.28(d)(3)(i). If the regulation does not does not require the IA and IPP to specifically assess frequency of needs, especially at night, and sleeping accommodations, with an updated CHA tool as recommended above, the LDSS or MMCO must assess the individual in order to assess these factors.
3. Changes made in the second round that are puzzling -- the requirements for the LDSS or MMCO to assess whether the consumer's needs can be met by alternate services. The Department added language requiring the LDSS or MMCO to "consider the use of such services in accordance with … the individual´s identified preferences and social and cultural considerations…." 505.14(b)(2)(iii)(b)(1). However, that requirement only applies to alternative services listed in paragraphs 505.14(b)(2)(iii)(a)(4) – (a)(10) not to (a)(11) – (a)(13). This means that the individual's *preferences need not be considered* when the deciding whether needs can be met with

   > (a)(11) adaptive or specialized medical equipment or supplies … including, but not limited to, bedside commodes, urinals, walkers, wheelchairs and insulin pens;
   >
   > (a)(12) formal services provided or funded by an entity, agency or program other than Medicaid, and
   >
   > (a)(13) voluntary assistance available from informal caregivers

   There is no explanation for distinguishing these services from others – such as adult day care, assisted living program, CDPAP, in which the individual's preferences must be considered. Distinguishing these three types of services seems to be very purposeful, but it is not permitted by PCSP and CFCO and other requirements. This

distinction must be eliminated and consumer preference considered for considering all alternate services.

F. Problematic Requirement of a Review of High Need Cases

Generally, the NYSBA ELSN remains concerned that automatic referral for a second review of recommendations for more than 12 hours of care will unnecessarily cause delay in the delivery of services, forcing applicants into institutional settings in violation of Olmstead v. LC, 527 US 581 (1999). 18 NYCRR 505.14(b)(2)(iii)(f) 505.28(d)(3)(vi); Reg. at 167-168, 179, 242. Authorizing MCCO and LDSS to implement temporary care plans while the IRP convenes is a stride in the right direction and we request that these provisions be clarified to require, rather than merely permit, such temporary care plans. See Section V..B. on delays above.

Further, ELSN understands that DOH is bound by the statute promulgated by the legislature, but believes that the regulations could minimize delays by outlining procedure and time frames under which this second level of review must be completed. We do not believe that the simple consolidation of the IA and IRP to a single point of contact alleviates this concern. To the contrary, we are concerned that dependence upon a single State-contracted IA will create a bottle-neck in high utility reviews, placing the most vulnerable New Yorkers' at risk of not receiving timely services. Below is a summary of the specific remaining concerns.

1. Prohibition Against Referral of High Needs Cases to IRP absent MMCO Enrollment

The prohibition against referral of high needs cases to the IRP until an "individual is enrolled or scheduled for enrollment in the MMCO" raises serious concerns regarding delays. 505.14(b)(2)(iii)(f); 505.28(d)(3)(vi). Under the current system, MMCO enrollments must be submitted by the 19th of the month to be processed within that calendar month. The enrollment is often agreed upon early in the month, but the consumer must wait nearly a month til it is effective the next month. During that lag time, the IA and IPP can and should all be completed and transmitted to the MMCO before enrollment. If the MMCO develops a plan of care prior to enrollment that authorizes more than 12 hours/day, the referral to the IRP should be permitted before the enrollment begins on the 1st of the month. To require enrollment into the MMCO before the high needs case is even referred to IRP will unnecessarily delay the provision of services.

2. The IRP Must Not Be Prohibited From Recommending Specific Hours of Services or an Alternative Plan of Care.

ELSN strongly opposes prohibiting the IRP from recommending specific hours of service or an alternate plan of care. 505.14(b)(2)(v)(f); 505.28(b)(5)(vii); DOH comments at Reg. pp. 222, 223-224. The purpose of this review is to determine whether the consumer needs more than 12 hours/day, and if so, whether the proposed care plan reasonably maintains their health and safety. The IRP must be able to recommend that 24-hour live-in or 24-hour split-shift care is necessary to maintain the consumer's health and safety. Although this prohibition seems to echo the current regulation's ban on a treating physician making a recommendation of a specific number of hours, it is not applicable here because there is no risk of bias in the context of an *independent* review.

The Department's concern that recommendations of a specific care plan would "usurp" the care planning function of the MCCO or LDSS is without merit. Indeed, the comment that the IRP may recommend reduction of services only heightens ELSN's concern that for fiscal reasons only, assessors will not recommend high hours for high needs consumers. Moreover, DOH's assertion that the IRP have special qualifications to assess the reasonable needs of the consumer is unsupported by the regulations. As the regulation is now proposed, there are no requirements that the IRP have even one member with any such specialty or concentration. *See*, A.1 *infra.*

3. Clarification is Required Regarding IRP Procedure
505.14(b)(2)(v), 505.28(d)(5); Reg. p. 220

The second draft of the regulation describes a "panel of medical professionals or other clinicians," but remains unclear regarding the composition of such panel. It fails to identify how many medical professionals would participate, or what other professionals would be included on the panel beside physicians. ELSN understands that DOH desires flexibility in comprising the IRP, but this can be achieved within defined parameters. The regulations could include a maximum number of practitioners and provide requirements for the member qualifications. (i.e. a medical professional, medical social worker,). Such broad parameters allow DOH the flexibility it requires, while still assuring that the consumer's care plan is subject to the timely and adequate review contemplated by the statute.

As proposed, "The lead physician may evaluate the individual, or review an evaluation performed by another medical professional on the clinical review panel." 505.14(b)(2)(v)(c); 505.28(d)(5)(iv). We remain concerned about more delay with another evaluation by the lead physician or panel member. The regulation must give a short deadline for the IRP to schedule an evaluation, whether in person or by telehealth/phone, and require that any results be recorded and available to the consumer in any record for appeal.

Similarly, allowing the IRP to "request additional information or documentation, including medical records, case notes, any other material the lead physician deems important to assist the panel's review….." causes concerns regarding delays. 505.14(b)(2)(v)(e); 505.28(d)(5)(vi).

4. Modify Provision that Allows MMCO/LDSS to Authorize More than 12 Hours/Day Without an IRP if Ordered By Fair Hearing or Court

We appreciate the change in the second round of regulations permitting the LDSS/MMCO to authorize more than 12 hours without an IRP review if ordered by a fair hearing decision or court. 505.14(b)(4)(vi); 505.28(e)(4). However, there is still an issue that needs clarification to prevent wrongful denial of services.

The change that was made clarifies that even if the IRP review was not conducted because the plan or LDSS did not determine that the individual needs more than 12 hours of care, if a hearing or court reverse and order 24/7 care, the LLDS or plan may authorize the ordered 24/7 care. This removes the threat of even more delay for the consumer, if a remand back to the agency was needed to do the IRP.

The change makes it clear that *if* the hearing or court decision orders 24/7 care, the LDSS or MMCO must implement it. It is still unclear, however, that a hearing officer or even a

Court may reverse a denial of more than 12 hours of care and order 24/7 care where the IRP review was not done. The regulation must make clear that the IRP review is not a prerequisite for a reviewer in a hearing, appeal or court to order more than 12 hours/day of care, where the requirements are otherwise met.

Also, the language should be amended to state that more than 12 hours/day authorization may not be authorized "unless such authorization is ordered pursuant to a fair hearing decision, by a decision of the NYS Department of Financial Services (DFS) after an External Appeal, or by another court of competent jurisdiction." DFS decisions, made pursuant to Article 49 of the state Insurance Law, must be included.

5. The IRP Must be Given the Consumer's Requested Plan of Care and Their Other Preferences

The regulation provides, "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." 505.14(b)(2)(v)(b); 505.28(d)(5)(iii). The IRP should be provided not only the LDSS/MMCO's plan of care but also the consumer's requested plan of care. If the IRP is only given the LDSS/MMCO's plan of care, if that plan is inadequate to meet the consumer's needs, the IRP must decide that the plan cannot maintain health and safety. Since the consumer's requested plan of care, however, may be adequate, the IRP should have that available to review. Otherwise the IRP lacks sufficient information needed to determine if a proposed plan of care can maintain the consumer's safety at home.

6. Reauthorizations – Modification Requested About When IRP Required – and Must Align CDPAP and PCS Procedures

The revised PCS regulation states that the IRP review is not required on re-authorization "[w]here an independent review panel previously reviewed a high need case … 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." 505.14(b)(4)(xi)(b). We support omitting the IRP review for cases that were already high needs, but propose two changes in this provision. Also, we note that this provision is not in the CDPAP regulation, which should be the same as the personal care regulation.

First, the Department explains that this change was made in response to comments to clarify that an IRP is not required "…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." Reg. p. 216. However, as the regulation is proposed, those who were previously authorized for high-hours prior to the effective date of these regulations will be required to be reviewed by the IRP on re-authorization because they were not previously reviewed by the IRP. This is contrary to the intended meaning the Department states in its narrative, which is that "the IRP reviews a plan of care only when the consumer crosses the high-hours threshold." Reg. p. 216. To conform the regulation to the expressed intent per the Department's narrative, we recommend the edit marked in **bold**:

> Where ~~an independent review panel previously reviewed a high need case~~ **hours above the high need threshold were previously authorized**,

> reauthorization of services shall not require another panel review for as long as the case remains a high needs.

505.14(b)(4)(xi)(b).

Second, the sentence that follows the sentence quoted above also requires clarification in order to protect consumers. It states, "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." Id. Clarification is needed to ensure that service levels are considered "reduced" under this provision only if proper written notice and appeal rights was provided, and either the time to appeal the adverse notice of reduction expired or the reduction was upheld on appeal or at a fair hearing. Otherwise the consumer may still have the right to win a hearing or appeal reversing the reduction. This would contradict the Department's clarification that high-hour care may be authorized without an IRP if ordered by a fair hearing or on appeal (or we suggest also on external appeal before the Dept. of Financial Services). 505.14(b)(4)(vi). We propose this edit:

> If service levels are reduced below the high needs threshold, <u>after timely and adequate notice, and either the reduction was affirmed upon appeal or fair hearing or the time to request an appeal or fair hearing has expired,</u> and <u>the individual's needs</u> subsequently increased to become a high needs case again, another review by the independent review panel is required.

505.14(b)(4)(vi). Again, the same provision must be added to the CDPAP regulation, with our recommended changes.

Thank you for the opportunity to comment on these regulations.

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