LeadingAge New York

September 12, 2022

Michael T. D'Allaird
Office of the Medicaid Inspector General,
800 North Pearl Street, 2nd Floor
Albany, New York 12204,

Via E-Mail

Re: Medicaid Program Fraud, Waste and Abuse Prevention (I.D. No. MED-28-22-00016-P)

Dear Mr. D'Allaird:

I am writing on behalf of the members of LeadingAge New York -- non-profit and public providers of long-term/post-acute care and aging services and provider-sponsored managed long term care (MLTC) plans and PACE programs -- to offer comments on the above-referenced proposed regulation.

As an initial matter, I want to emphasize that long-term care providers, including provider-sponsored MLTC plans and PACE programs, remain in crisis mode as result of the pandemic. While the rest of state and the nation seem to be returning to normal, long-term care providers and MLTC plans continue to struggle with unprecedented staffing shortages, ongoing outbreaks, and a deluge of new regulatory, notification, workforce, reporting, and clinical requirements. The staffing challenges extend not only to the direct care positions, but also to administrative roles. And, in many organizations, employees in administrative roles are frequently called upon to pitch in on the frontlines when there are insufficient staff to provide essential services. Turnover is high among administrative staff, as well as direct care staff, due to the stresses of the pandemic and the heavy toll of a vast array of often confusing new requirements.

In this environment, any new administrative requirements imposed upon long-term care providers and MLTC plans must be carefully assessed based on the value they add versus the extent to which they divert resources from the delivery of care. These proposed regulations will require providers and plans to restructure their compliance programs, hire additional personnel, develop new policies and procedures, re-train their staff and their contractors, and implement new oversight processes for contractors. We question whether the benefits of these new requirements outweigh the potential negative impact they will have on the ability of providers and plans to carry out their core mission of delivering or arranging for high quality care. **At a minimum, the effective dates of the various sub-parts should be delayed until 12 months after the termination of the federal COVID Public Health Emergency.**

With that context and our request for a delay in implementation in mind, I would like to raise the following more targeted concerns:

Subpart 521-1 Compliance Programs

The proposed regulation broadly defines "Affected Individuals" to include "all persons who are affected by the required provider's risk areas," including (among others) the Required Provider's contractors. Required Providers include not only health care providers, but also managed care plans. Under the

proposed regulations, Affected Individuals that are contractors are subject to the same oversight, training, documentation, and other requirements as those who are employees. Since virtually every health care provider also contracts with multiple managed care plans, every provider will be both a Required Provider and an Affected Individual for multiple plans. Each provider's employees will be subject to both its own compliance program and the compliance programs of every managed care plan with which it contracts. Employees of providers will be required to be trained in potentially dozens of compliance programs. This is infeasible. The term "Affected Individuals" should be more narrowly defined, and Affected Individuals should be permitted to rely on their own compliance programs to satisfy the requirements of the regulation.

The proposed regulation requires Required Providers to provide Affected Individuals with the compliance program's policies and procedures, including documentation of implementation of each of the applicable regulatory provisions, the ongoing operation of the compliance program, and how potential compliance issues are investigated and resolved. This provision could require the disclosure of proprietary information to contractors, including utilization review policies and fraud detection procedures. Such disclosures of proprietary or sensitive information could have unintended consequences that impede the goals of the regulations. This provision should also be more narrowly tailored to achieve its intended purpose.

521-1.4 Compliance Program Requirements

The proposed regulation eliminates the existing threshold of at least $5 million in Medicaid receipts or payments that triggers the requirement to have written policies that provide detailed information about the False Claims Act and any analogous state laws and whistleblower protections. Organizations that receive less than $5 million in Medicaid revenue tend to be very small and are particularly stressed in the current public health emergency. The federal government has apparently determined that a $5 million floor for this requirement is justified. New York has not presented a compelling rationale for imposing this requirement on smaller organizations.

In several areas pertaining to governance and staffing, the regulations are highly proscriptive, eliminating provider and plan discretion to design their compliance program to align with the size, structure, and focus of the organization. For example, the requirements that the compliance committee meet no less than quarterly and update the committee charter annually is unnecessarily inflexible. Likewise, the requirement that the *committee* report directly to the CEO and board is unnecessary and may be infeasible. The compliance officer, not the entire committee, should be in a reporting line to the CEO and the governing body.

521-2.1 Medicaid Managed Care Fraud, Waste and Abuse Prevention: Scope

The proposed regulation is unclear in its applicability to PACE programs which are both providers and MLTC plans and are subject to extensive PACE-specific federal regulations (42 CFR Part 460), including regulations governing the prevention, detection, and correction of fraud, waste and abuse. Given the size and structure of PACE programs, and their unique regulatory structure, they should not be subject to the managed care provisions of the regulations. PACE programs tend to be much smaller entities than other MLTC plans because they must deliver certain services at a PACE center. They also deliver much of their services directly or through affiliated entities, which reduces the likelihood of

many types of fraud, waste, and abuse. In particular, the SIU requirements would be excessive if applied to PACE programs and should not be imposed on them.

521-2.3 MMCO Duties- SIU Requirements

Many of the managed care plan SIU provisions are unnecessarily proscriptive. For example, in proposed 18 NYCRR §521-2.4, the regulation specifies staffing requirements for managed care plan special investigation units (SIUs) of at least one full-time investigator per 60,000 enrollees, except in the case of an MLTC plan, which must employ at least one full-time investigator per 6,000 enrollees. The regulation provides no justification for the much higher ratio of investigators per enrolled population for MLTC plans. This disparity is counter-intuitive, as MLTC plans generally have smaller enrollments, smaller networks, and fewer employees than mainstream Medicaid managed care plans. They should not be subject to more rigorous SIU requirements than other plans. The ability to seek OMIG approval of alternate staffing arrangements offers little reassurance The regulations do not provide any standards for approving such waivers, suggesting that the process is ill-defined and the likelihood of receiving approval is unpredictable.

Similarly, in proposed 18 NYCRR §521-2.4(b), the requirements related to investigator qualifications and the minimum size of SIU audits (i.e., 1% of the aggregate Medicaid managed care program claims paid) are overly proscriptive. Plans should have the discretion to design their SIUs, hire investigators, and develop audit processes in accordance with their risk areas and the needs of their organizations.

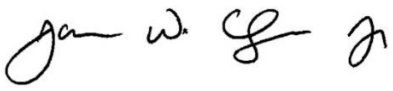
521-3.4 Self-Disclosure Program

The Self-Disclosure Program provisions require that even if the "person" is ineligible to participate in self-disclosure, they must submit a Self-Disclosure Statement if they determine that they have received an overpayment. A person may be ineligible for self-disclosure if the entity is under investigation or audit by OMIG or under any criminal investigation pertaining to their participation in the Medicaid program. Thus, under the regulations, Medicaid providers or managed care plans must disclose overpayments even if they are under a civil or criminal investigation by OMIG or another law enforcement agency. The requirement of self-disclosure under these circumstances appears to violate due process protections, and in the context of a criminal inquiry, the privilege against self-incrimination.

The Self-Disclosure Program regulation also requires all disclosing persons to not only repay the overpayment, but also to enter into a Self-Disclosure and Compliance Agreement imposing prospective obligations. Overpayments that lead to self-disclosures typically arise out of inadvertent errors, not intentional fraud. Providers and plans that self-disclose overpayments have complied with their obligations under the law by reporting and correcting the error. A requirement that every self-disclosing entity execute compliance agreement with prospective obligations is unnecessary and may have a chilling effect on self-disclosures.

Thank you very much for your consideration of these issues.

Sincerely yours,



James W. Clyne, Jr.
President and CEO