American
Clinical Laboratory
Association

January 16, 2018

Ms. Seema Verma, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-4182-P
7500 Security Boulevard
Baltimore, Maryland 21244

Submitted electronically to http://www/regulations.gov

RE: Proposed Rule - Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program, CMS-4182-P

Dear Administrator Verma,

The American Clinical Laboratory Association (ACLA) respectfully submits these comments on the Proposed Rule - Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program ("2019 Medicare Proposed Rule"). ACLA is a not-for-profit association representing the nation's leading clinical and anatomic pathology laboratories, including national, regional, specialty, ESRD, and nursing home laboratories. The clinical laboratory industry is at the forefront of personalized medicine, driving diagnostic innovation and contributing more than $100 billion to the nation's economy annually.

ACLA's comments are specific to the provisions in the Reducing the Burden of the Compliance Program Requirements section of the 2019 Medicare Proposed Rule and proposed revisions to the Medicare Advantage ("MA") compliance training requirements applicable to "first tier, downstream, and related entities" ("FDRs") (§§ 422.503 and 423.504). ACLA applauds the agency's recognition of both the burden and difficulties faced by FDRs in adhering to the current Centers for Medicaid and Medicare Services ("CMS") compliance training requirements. We also appreciate the acknowledgement by CMS that it is possible to fulfill the statutory requirements for MA compliance training through other more efficient and effective means, and that it put forth a solution consistent with these means in the 2019 Medicare Proposed Rule.

Over the course of several years, ACLA, on behalf of its members, many of whom are FDRs, has expressed our concerns to the CMS Medicare Parts C and D Oversight and Enforcement Group ("OEG") regarding the MA compliance training program requirements. As recently as July 2017, ACLA reiterated to OEG in writing that large portions of the CMS mandatory compliance training program are wholly irrelevant to laboratories, including information regarding prescription drug plans and scenarios relating to beneficiary appeals and beneficiary enrollment

issues. The training is also oftentimes duplicative of training FDRs already provide for their employees.

ACLA sincerely appreciated efforts by CMS in February 2016 to provide clarifying guidance to Medicare Advantage Organizations ("MAOs") and Prescription Drug Plan Sponsors regarding how FDRs may administer the MA compliance training, which FDR employees must complete the training, and when the training must be completed.[1] Despite the CMS guidance, ACLA members found little relief and still are subject to onerous training requirements. Also, contrary to the guidance, many MAOs continue to insist that all FDR employees complete the training, rather than only those with critical positions within the FDR. Finally, ACLA members continue to struggle with the static nature of the generic MA compliance training and the redundancies between it and their own compliance program trainings. Requiring training that is irrelevant and duplicative of existing programs not only increases burden and costs, but also proves counterproductive for health care organizations that are FDRs to provide for their employees, leading them to tune out or ignore the training.

ACLA members are committed to fostering a culture of compliance and to providing efficient and effective compliance training to their employees at least annually. As such, ACLA appreciates that CMS recognizes implementation of the mandatory CMS-developed training, and the requirement that it be used by MAOs, has not achieved its intended goals or promoted effective administration of the MA program. ACLA strongly supports CMS's proposal to delete the provisions from the Part C and D regulations that require the use of the CMS-developed training. ACLA also concurs that an MAO can ensure compliance with program requirements through routine monitoring and implementing corrective action when non-compliance is identified. As CMS acknowledged in the Proposed 2019 Medicare Rule, given the current MA climate and sophistication of the industry, the CMS training requirement is not the driver of performance improvements or FDR compliance with key CMS requirements. ACLA agrees and applauds CMS for proposing to remove the reference to FDRs in the compliance training requirements codified at §§ 422.503(b)(4)(vi)(C) and 423.504(b)(4)(vi)(C). Such a solution preserves the integrity and the spirit of MA compliance training while alleviating the unnecessary burden borne by FDRs under the current requirements.

If CMS does not adopt the revisions to the Medicare compliance training requirement set forth in the proposed rule, ACLA urges CMS, at a minimum, to clarify that FDRs are permitted to determine which of their employees are subject to any mandated CMS-developed training based on factors such as relevance to their job functions and the extent of their involvement with

[1] Additional Guidance – Compliance Program Training Requirements and Audit Process Update, Medicare Part C and D Oversight Enforcement Group (Feb. 10, 2016), *available at* https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/Downloads/2016_Complaince_and_-FWA_Training_Requirement_Update.pdf.

MAOs. Simply put, the generic training is not relevant to many laboratory employees. There is no justification for all laboratory employees to be required to complete the training.

Once again, we appreciate the revisions in the 2019 Proposed Medicare Rule to the MA compliance training requirements and the focus by CMS on reducing the burden of the MA compliance program training requirements. We strongly encourage their adoption and thank you for your consideration of ACLA's comments.

Sincerely,

Sharon L. West
Vice President, Legal and Regulatory Affairs
American Clinical Laboratory Association