AMERICAN CLINICAL LABORATORY ASSOCIATION

April 16, 2021

Acting Administrator Liz Richter
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-3372-IFC
P.O. Box 8013
Baltimore, Maryland 21244-8013

RE: Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary"; Delay of Effective Date; Public Comment Period

Dear Ms. Richter,

The American Clinical Laboratory Association (ACLA) appreciates the Centers for Medicare and Medicaid Services (CMS) considering our comments on the abovementioned interim final rule.[1] ACLA is the national trade association representing leading laboratories that deliver essential diagnostic health information to patients and providers. ACLA members are at the forefront of driving diagnostic innovation to meet the country's evolving health care needs and provide vital clinical laboratory tests that identify and prevent infectious, acute, and chronic disease. ACLA works to advance the next generation of health care delivery through policies that expand access to lifesaving testing services.

ACLA's comments focus primarily on the procedural inadequacy of the portion of the final rule published January 14, 2021 relating to the codification of the definition of "reasonable and necessary". In particular, we believe CMS did not meet its obligations under the Administrative Procedure Act to respond to several of ACLA's significant comments about the definition that raise points relevant to the agency's decision-making.

We believe that CMS should rescind the portion of the final rule concerning the definition of "reasonable and necessary" because of the rulemaking's procedural defects. Considering that this definition would apply broadly to all items and services furnished to a Medicare beneficiary, not just in the context of devices covered through the MCIT pathway, it warrants more careful consideration than CMS gave it in the final rule. We do support implementation of the MCIT pathway effective May 15, 2021, as currently scheduled.

A. The rulemaking process was not procedurally adequate.

The rulemaking process was not procedurally adequate because CMS did not respond to many of ACLA's substantive comments.[2] The following are examples of ACLA's comments to

[1] 86 Fed. Reg. 15472 (Mar. 17, 2021).
[2] ACLA's comments on the proposed rule may be found here: https://www.acla.com/wp-content/uploads/2021/04/ACLA-Comments-on-MCIT-and-_Reasonable-and-Necessary-Submitted-11.2.2020-2.pdf.

which CMS did not respond in the preamble of the final rule:

- The term "safe and effective," as included in the definition of "reasonable and necessary," does not apply to laboratory-developed tests (LDTs), which are processes and methodologies that are qualitatively different from the tangible goods that the Food and Drug Administration (FDA) might regulate as "devices" and to which the concept "safe and effective" may apply. CMS should acknowledge and clarify that "safe and effective" will not be interpreted to require LDTs to have FDA clearance or approval before Medicare can cover them.[3]

- CMS should strike the criterion "at least as beneficial as an existing and available medically appropriate alternative" from the definition of "reasonable and necessary." To determine whether an item or service is appropriate for a Medicare beneficiary, it is not necessary to determine whether it is more or less beneficial than other available items or services.[4]

- The phrase "one that meets, but that does not exceed, the patient's medical need" could be interpreted to exclude from coverage innovative tests that are designed to provide more complete information to a health care practitioner earlier in the course of a disease. CMS should revise that part of the proposed definition to "one that meets the patient's medical need."[5]

It is insufficient that the agency merely acknowledged that "some commenters" offered input on the foregoing parts of the proposed definition, without actually addressing the legal and policy issues raised by them. As it stands, in many cases, it is not possible for stakeholders to determine what CMS's position is on these and other issues because the agency did not discuss the policy considerations in any substantive way.

B. The agency did not make reasonable judgments about legally relevant policy considerations.

In several places in ACLA's comment letter, we raised the issue of the FDA's approach to regulation of LDTs and sought assurances that different aspects of the proposed rule would not result in any requirement that an LDT must be FDA-cleared or -approved. Given the FDA's history of back-and-forth pronouncements in the past several years – and in the recent past – on its authority to regulate LDTs and its policy of "enforcement discretion," we believe this merited a response from CMS. Yet the agency did not even acknowledge ACLA's comments on these issues.

For ACLA members and the tens of thousands of other laboratories in the U.S. that develop and offer LDTs, it is important to know what judgments CMS has made about this critical policy issue. This is particularly so, since the agency finalized a codified definition of "reasonable and necessary" that includes language typically applied to medical devices regulated by the FDA. This

[3] *See* 86 Fed. Reg. 2995.
[4] *See id*.
[5] *See id.*

is but one example of the agency's failure to explore fully the impact of its policy choices on stakeholders.

C. Conclusion

For the foregoing reasons, we urge CMS to rescind the portion of the final rule that includes the definition of "reasonable and necessary" and to proceed with implementation of the MCIT pathway as planned. Thank you for your consideration of our comments.

Sincerely,

Sharon L. West
Vice President, Legal and Regulatory Affairs