May 2, 2016

Mr. Daniel Levinson
Inspector General
U.S. Department of Health and Human Services
330 Independence Avenue, SW
Washington, DC 20201

Dear Mr. Levinson:

On behalf of the American Clinical Laboratory Association (ACLA), I am writing to express our concerns regarding the unimplemented recommendation focused on clinical laboratories included in the Appendix of the HHS/OIG Compendium of Unimplemented Recommendations, April 2016 Edition[1]. ACLA is an association representing clinical laboratories throughout the country, including national, regional, hospital, and esoteric laboratories. As providers of millions of clinical diagnostic laboratory services for Medicare beneficiaries each year, ACLA member companies are deeply invested in ensuring appropriate utilization of laboratory services.

ACLA strongly supports efforts to eliminate fraud and abuse in the health care system, particularly in the laboratory sector. However, we are troubled by the OIG's attention to the Clinical Laboratory Fee Schedule (CLFS) in the Appendix to the April 2016 edition of the Compendium of Unimplemented Recommendations. In particular, ACLA is concerned about your recommendations not only to apply beneficiary coinsurance and deductibles for clinical laboratory services provided under Medicare Parts A and B, but also to reassess from time to time the prices for individual tests on the CLFS.

Cost-Sharing

ACLA disagrees with your recommendation to apply beneficiary coinsurance and deductibles under Parts A and B. This policy change would not reduce the utilization of laboratory services. To truly impact utilization, one needs to address prescriber behavior, since all CLFS services must be ordered by a licensed clinician.

The Institute of Medicine has stated: "[c]ost sharing is unlikely to significantly reduce overuse or increase the detection of fraud and abuse; it could create barriers to access for the most vulnerable Medicare beneficiaries; and it would be financially and administratively burdensome for laboratories, patients, and the Medicare program."[2] Collecting coinsurance is uniquely difficult for labs because, unlike all other health care providers, labs typically do not have face-to-face encounters with patients. Most of the time, a Medicare beneficiary's specimen is obtained somewhere else, such as a physician's office, and sent to the lab, which then performs the prescribed testing. As such, labs must rely on billing and collections to obtain the cost-sharing amount from beneficiaries. If those good faith efforts do not succeed, laboratories must absorb those losses along with the added costs of collecting the cost-sharing.

[1] Available at http://oig.hhs.gov/reports-and-publications/compendium/files/compendium2016.pdf

[2] Available at http://www.nap.edu/read/9997/chapter/1

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ACLA has estimated that the application of Medicare cost-sharing would result in over 143 million new Medicare claims each year, of which 50 percent will be for $5.00 or less, with approximately 73 percent for $10 or less. About 14 million of the new claims would be for $1 or less. Indeed, for almost 40 percent of the new claims, the $3.50 cost of collecting and processing the coinsurance would exceed the coinsurance liability. Putting this in perspective, for every net dollar in savings generated for the Medicare program through implementation of cost-sharing for Part B laboratory services, laboratories will pay nearly $0.50 in costs.

In addition, we are concerned that cost-sharing will disproportionately affect access to vital diagnostic lab services for Medicare's most vulnerable beneficiaries, namely those receiving skilled nursing or home health services. A George Washington University study found for the labs that primarily provide rush (STAT) and same-day testing services to skilled nursing facilities, 71 percent had low profit margins[3]. If cost-sharing is imposed, these labs may no longer be able to serve these beneficiaries, forcing hospitals to serve them instead, which increases program costs.

Periodic Re-evaluation of the CLFS

ACLA also disagrees with the recommendation to "[p]eriodically evaluate the national fee schedule to ensure that reimbursement is aligned with the prices physicians pay for clinical laboratory tests." The CLFS is in the midst of significant reform, as required by the Protecting Access to Medicare Act of 2014 (PAMA) (P.L. 113-93). Section 216 of PAMA directs the Department of Health and Human Services to set new prices for every clinical laboratory test on the CLFS, based on a weighted median of private payor rates. These prices are recalculated either annually or every three years, depending on the type of laboratory test. Additional review of the CLFS is not necessary. PAMA also directs the OIG to "conduct analyses the Inspector General determines appropriate with respect to the implementation and effect of the new payment system for laboratory tests under section 1834A of the Social Security Act, as added by subsection (a)."

Thank you for the opportunity to share our views. Please contact Francesca Fierro O'Reilly at either (202) 637-9466 or foreilly@acla.com, if you have questions or if you would like to schedule a meeting to discuss these issues in more detail.

Sincerely,

Alan Mertz
President

[3] Available at: https://www.aab.org/images/aab/pdf/2013/Lab%20Survey%20by%20GWU.PDF