December 23, 2019

American Clinical Laboratory Association

Ms. Joanne Chiedi, Acting Inspector General
Office of Inspector General
Department of Health and Human Services
Cohen Building, Room 5521
330 Independence Avenue SW
Washington, DC 20201

RE: Medicare and State Healthcare Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements (OIG-0936-AA10-P)

Dear Acting Inspector General Chiedi,

The American Clinical Laboratory Association (ACLA) is pleased to submit these comments on the proposed rule "Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements" (Proposed Rule).[1] ACLA is a not-for-profit association representing the nation's leading clinical and anatomic pathology laboratories, including national, regional, specialty, end-stage renal disease, and nursing home laboratories. The clinical laboratory industry is at the forefront of precision medicine, driving diagnostic innovation and contributing more than $100 billion to the nation's economy annually. ACLA member companies have a direct stake in ensuring that laboratories have the opportunity to participate meaningfully and fully in the nation's transition toward value-based care.

In summary, ACLA encourages the Office of Inspector General (OIG) to include laboratories among those entities that may be "value-based enterprise participants" in order to ensure that they can contribute important informational, analytical, and care management assets to existing and newly-developed value-based arrangements. Laboratories already play an important role in a wide variety of value-based arrangements, some operating under waivers conferred by the agency itself, and they should be encouraged to be active contributors to value-based care models. Diagnostic testing provides great value in healthcare and impacts the majority of healthcare decisions, despite representing less than 3 percent of health care spending. In addition to comments on proposals to facilitate the transition to value-based care and fostering care coordination, we also have provided comments on the proposed safe harbor for donations of cybersecurity technology and related services and on proposed amendments to the personal services safe harbor.

A. Proposed Definition of Value-Based Enterprise Participant

Laboratories should not be excluded from the proposed definition of "value-based enterprise participant," nor should the OIG finalize safe harbors for arrangements that facilitate value-based health care delivery and payment that stipulate that the arrangements may not include a laboratory as a participant. ACLA strongly encourages the OIG to reconsider its assumption that laboratories would seek to participate in value-based arrangements primarily as "a means of

[1] 84 Fed. Reg. 55694 (Oct. 17, 2019).

offering remuneration to practitioners and patients to market their products, rather than as a means to create value for patients and payors by improving the coordination and management of patient care."[2] Today, laboratories are active participants in a variety of value-based arrangements with other health care providers and suppliers, both for patients covered by the Federal health care programs and those covered by commercial payors. For the agency to realize the goal of migrating from paying for volume toward paying for value, laboratories must be included.

1. Role of Laboratories in Care Coordination and Value-Based Delivery and Payment Models

In its discussion of patient care coordination and management activities, the OIG unwittingly includes examples of what laboratories do each day in partnership and collaboration with other health care providers and suppliers. "Care coordination" is described to include "sharing information between two or more VBE participants or VBE participants and patients, tailored to improving the health outcomes of the target patient population,"[3] activities that laboratories are engaged in daily. The definition would include "sharing or use of health information technology and data to identify a target patient population, coordinate care, or measure outcomes"[4]—also activities that laboratories do regularly in partnership with others in the health care system. Laboratories' participation in value-based arrangements is part of what enables providers and suppliers to undertake "value-based activities" such as "taking of an action" (*e.g.*, ordering a laboratory test at recommended intervals) or "refraining from taking an action" (*e.g.*, not ordering a laboratory test that has been furnished to a patient recently pursuant to an order from another physician).

Following are concrete examples of value-based arrangements in which laboratories participate today:

- A laboratory works with an accountable care organization (ACO) that wishes to decrease emergency room visits and hospitalizations by a target patient population and encourage care in a lower-cost setting. The laboratory reaches out to the patients on behalf of the ACO's physicians to remind the patients that they are overdue for follow-up appointments. The laboratory also facilitates appropriate laboratory testing prior to those appointments so the results can be used by the ACO's physicians to guide medical decision-making during the appointments. This results in more preventive care, better education of patients about their own health care, fewer needless trips to the emergency room, and cost savings overall.
- A laboratory assumes financial risk on behalf of a payor for laboratory testing performed for a defined patient population. In partnership with the payor, it develops a clinical decision support tool that reflects the payor's ordering rules and facilitates its integration into participating physicians' EMRs. A laboratory test order that contradicts the ordering rules requires prior authorization from the payor. The arrangement may result in the laboratory <u>not</u> performing tests for patients because they are duplicative or not indicated for those patients, and it results in

[2] *Id.* at 55704.
[3] *Id.* at 55707.
[4] *Id.*

fewer unnecessary blood draws as well. The laboratory shares with the payor any savings from avoidance of testing that is not medically indicated.

- A payor identifies patients diagnosed with a certain chronic disease (*e.g.*, diabetes). On behalf of the payor, a laboratory educates treating physicians about what tests are appropriate for the patient, based on the diagnosis and industry guidelines, and the laboratory receives a bundled payment for all appropriate laboratory testing relevant to the diagnosis, regardless what tests physicians ultimately order.
- A laboratory works with an accountable care organization to identify physicians with test ordering patterns that are outside the industry recommendations and to educate those physicians about appropriate test ordering. This ensures the right tests are ordered at the right time and ultimately saves money.
- Under an arrangement with a payor, a laboratory reviews historical test results for a patient population to identify those likely to have a condition such as diabetes or chronic kidney disease and facilitates their enrollment in evidence-based disease management programs designed to decrease the incidence of disease complications.
- The FDA-approved label for a blood thinner states that a patient with two non-functional copies of a certain gene is unable to process the drug, meaning the drug will be ineffective in reducing the risk of myocardial infarction and stroke in that patient. Working as part of an integrated health system, a laboratory notifies a physician prescribing the blood thinner when the laboratory has no results on file for the genetic test for that patient and that the physician should consider canceling the prescription until the test has been performed. Since the laboratory began implementing this intervention, the intervention is estimated to have prevented 86 adverse events and saved approximately $40,000 per 100,000 lives annually.
- In consultation with clinical pathologists and treating clinicians, a laboratory developed a "same day hard stop" clinical decision support tool to prevent orders for laboratory tests that are never needed more than one time in 24 hours. In seven years, it has prevented approximately 330,000 unnecessary tests and saved more than a half million dollars, and less than 10 percent of ordering physicians contacted the laboratory to override the hard stop.

The foregoing examples show how laboratories already are engaged with other sectors of the health care system to improve care, lower costs, and ensure that patients receive the right care at the right time and in the proper setting. We note that laboratories have been included in certain of these value-based arrangements under waivers granted by the Centers for Medicare and Medicaid Services pursuant to Sec. 1115A(d)(1) of the Social Security Act, indicating that the Department of Health and Human Services already recognizes the vital role that laboratories can play in the transition from paying for volume to paying for value.

2. Unintended Consequences of Excluding Laboratories from the Definition of Value-Based Enterprise Participant

We urge the OIG to consider the unintended consequences that could arise from excluding laboratories from the definition of "value-based enterprise participant." Laboratories currently

participate in value-based arrangements involving patients covered by commercial payors and the Federal health care programs alike. Effective exclusion from value-based arrangements that are protected under the proposed safe harbors for value-based arrangements, coupled with exclusion from participation in arrangements addressed in the proposed Physician Self-Referral regulations exception, likely would send a strong signal to other types of health care providers and suppliers that they should steer clear of including laboratories in value-based arrangements or terminate existing arrangements, even those involving only patients covered by commercial payors. The OIG's exclusion of laboratories would slow laboratories' momentum as they integrate themselves in more value-based care arrangements. Furthermore, it would impede the already difficult task of educating health care systems and payors about how much care is driven by laboratory testing and the considerable role that laboratories can play in value-based arrangements.

We believe that the Department of Health and Human Services is committed to accelerating the transformation of the health care system into one that better pays for value and promotes care coordination, and to do so, it has to include laboratories in that vision. If laboratories cannot participate fully in value-based arrangements, they will not be able to make important contributions to the arrangements: information that helps define target patient populations needing specific interventions, educational resources for physicians about appropriate and inappropriate test ordering, test utilization data, identification of at-risk patients, and so on. This is information that helps all parts of the health care system provide value-based care and control costs.

3. Additional Safeguards to Prevent Abusive Practices

The OIG seeks comment on additional safeguards it could include to prevent abusive marketing practices, protect clinical decision-making, and reduce the risk of inappropriate cost-shifting to Federal health care programs. Specifically, the OIG is considering whether to include a safeguard that would preclude protection for a value-based arrangement with a requirement that the VBE participant is the exclusive provider of care coordination items or services or the exclusive provider of a reimbursable item or service, or whether to impose heightened standards and conditions on certain entities that would receive safe harbor protection, such as enhanced monitoring, reporting, or data submission requirements. ACLA supports precluding protection for exclusivity requirements, particularly those that would require a VBE participant to be the exclusive provider of a reimbursable item or service. Such an arrangement does not bear any reasonable connection to the goals of value-based care and could create perverse incentives to use VBE arrangements as a means to secure referrals. ACLA also supports the enhanced transparency measures the OIG is considering and recommends that the OIG implement a public disclosure requirement similar to those required under ACO waivers in the Medicare Shared Savings Program. Such a requirement would serve to deter bad actors with only minimal additional compliance burden.

B. Proposed Safe Harbor for Donations of Cybersecurity Technology and Related Services

The OIG proposes a new safe harbor at 42 C.F.R. § 1001.952(jj) to protect arrangements involving the donation of certain cybersecurity technology and related services. In part, the agency

seeks comment on whether it should restrict the types of entities that may make donations under this safe harbor.[5]

A donation safe harbor of this kind is bound to be abused, regardless of the types of safeguards the OIG would implement, and even as the safe harbor purports to solve other problems. ACLA urges the agency not to finalize a safe harbor that allows a donation of cybersecurity technology and related services from any entity. However, if the OIG proceeds with implementing such a safe harbor, then for the same reasons that ACLA urged the OIG to exclude laboratories from the types of entities allowed to donate EHRs to physicians, we urge the agency now to exclude laboratories from the types of entities allowed to donate cybersecurity technology and related services. In our June 8, 2013 letter to the OIG on its proposals to extend the applicability of the EHR donation safe harbor and to exclude laboratories from the class of protected donors, we explained the untenable position labs were put in by physicians who implicitly or explicitly conditioned referrals on EHR donations and by EHR vendors that encouraged physicians to request ever-more costly EHR software and services from laboratories.[6] We are concerned that the same situations would arise if laboratories were allowed to donate cybersecurity technology and related services to physicians.

We believe that most laboratories would be careful not to make a donation of cybersecurity technology and services contingent on the receipt of referrals from a physician. However, based on our experience with EHR donations, we are concerned that in some cases a physician may demand that a laboratory make a donation of cybersecurity technology and services if the laboratory wishes to keep the physician's business, or build a new relationship with the physician. We also are concerned about a physician starting or encouraging a "bidding war" between laboratories, insinuating that the laboratory that makes the most generous donation will get the physician's referrals. We are aware that some laboratories in fact may act inappropriately and promise a donation in exchange for future referrals, but we urge the OIG to be mindful that oftentimes it will be the physician, rather than the laboratory, that conditions referrals on a donation.

We fear that cybersecurity technology vendors would engage in similar activity as they did with respect to EHR donations by laboratories. This is particularly true if the OIG were to finalize its proposal that a recipient would not be required to make a financial contribution toward the total cost of the cybersecurity technology and services. Our experience with EHR vendors' sales representatives and with federal investigations and settlements regarding EHR donations by laboratories to referring physicians informs our concerns now. A cybersecurity technology vendor's sales representative may urge physicians needing such software and services to direct their requests to laboratories that are more likely to make a contribution. The vendors may use this approach to increase demand for their technology. And, if a physician is not required to donate any portion of the cost of cybersecurity technology and related services, there would be little incentive for a vendor to offer a competitive price for its technology. This is the behavior that our members observed prior to 2013, when the EHR safe harbor still was applicable to laboratories.

[5] *Id.* at 55737.
[6] ACLA's comments are available here: https://www.regulations.gov/document?D=HHSIG-2013-0001-0090.

In theory, the safe harbor would not require any potential donor to donate cybersecurity technology and services, and it would not prohibit donors from requiring a contribution of part of the cost. In reality, whether or not a laboratory makes a donation or requires a physician to contribute a portion of the cost of the cybersecurity technology and services very well could become an additional determinant of where a physician sends referrals, as it did with EHR donations.

We recognize that the OIG has proposed a number of safeguards designed to discourage abuse of the safe harbor. For example, donations of multi-function hardware would not be permitted, donors could not condition donations upon referrals, recipients could not condition referrals upon donations, and the terms of the donation would need to be in writing. We are concerned that these safeguards would be inadequate, as they are difficult to monitor and less stringent than the established safeguards for donations of EHRs. For all of the foregoing reasons, we urge the OIG to reconsider the safe harbor in its entirety, but at a minimum we urge the OIG to exclude laboratories from the types of entities allowed to donate cybersecurity technology and related services under the proposed safe harbor.

C. Modifications to the Personal Services Safe Harbor

1. Elimination of Requirements to Set Aggregate Compensation in Advance and to Specify Schedule of Part-Time Arrangements

ACLA supports the proposed amendment to the personal services safe harbor to eliminate the requirement that aggregate compensation must be set in advance and to allow the arrangement's compensation *methodology* to be set in advance of the initial payment, instead. We also support the proposed amendment that would eliminate the requirement that for periodic, sporadic, or part-time arrangements, the agreement must specify "exactly the schedule of such intervals, their precise length, and the exact charge for such intervals." Both changes would provide much-needed flexibility, particularly for arrangements that are not full-time and it is not possible to determine in advance the schedule or intensity of services needed. We agree that other safeguards in the safe harbor mitigate the risk that payments would be made to reward or induce referrals (*e.g.*, fair market value compensation that does not take into account the volume or value of any referrals, commercial reasonableness, term of at least one year).

2. Exception for Certain Outcomes-Based Payments

The OIG is proposing to amend the personal services safe harbor by excepting from the definition of "remuneration" certain outcomes-based payments, such as to reward an agent for improving population health by achieving one or more outcome measures that demonstrate effective coordinated care across settings, or achieving one or more measures that reduces costs while maintaining quality. Under the proposal, protected outcomes-based payments would not include such payments made by a laboratory, pharmaceutical manufacturer, or DMEPOS supplier or that relate solely to achievement of internal cost savings for the principal. As proposed, the safe harbor does not appear to preclude, for example, a payment made to a laboratory that is a downstream agent to a principal that has a shared savings agreement with a payor, as generally a laboratory is not in a position to be induced to make referrals after receiving remuneration. While ACLA supports the OIG's tailoring of the safe harbor to promote value-based care while

minimizing the potential for fraud and abuse, ACLA urges the OIG to consider including laboratories in the safe harbor to protect innovative payment models. For example, a laboratory might make an outcomes-based payment to a hospital or health system under an arrangement that includes payment of shared losses, which is not a circumstance likely to present a risk of fraud or abuse by the laboratory.

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Thank you for your consideration of ACLA's comments on the Proposed Rule.

Sincerely,

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