December 23, 2019

Ms. Seema Verma, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building, Rm. 445-G
200 Independence Avenue SW
Washington, DC 20201

American Clinical Laboratory Association

**RE: Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations (CMS-1720-P)**

Dear Administrator Verma,

The American Clinical Laboratory Association (ACLA) is pleased to submit these comments on the proposed rule "Modernizing and Clarifying the Physician Self-Referral Regulations" (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 Centers for Medicare and Medicaid Services (CMS) 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 exception for donations of cybersecurity technology and related services, the proposed exception for limited remuneration to a physician, and the proposed new definition of "commercially reasonable." Finally, we have commented on certain aspects of the agency's efforts to recalibrate the scope and application of Physician Self-Referral regulations.

## A. Proposed Definition of Value-Based Enterprise Participant

Laboratories should not be excluded from the proposed definition of "value-based enterprise participant," nor should CMS finalize an exception for arrangements that facilitate value-based health care delivery and payment that stipulates that the arrangement may not be

[1] 84 Fed. Reg. 55766 (Oct. 17, 2019).

between a physician and a laboratory. ACLA strongly encourages CMS to reconsider its assumption that laboratories do not participate in value-based arrangements in a way that would "justify their inclusion as parties working under a protected value-based arrangement to achieve the type of patient-centered care that is a core tenet of care coordination and a value-based health care system."[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, CMS 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 "reduction of orders for duplicative items and services" and "sharing of medical records and other important health data across care settings and among a patient's providers,"[3] which laboratories are engaged in daily. The agency's proposed definition of "coordinating and managing care" in the final rule includes "sharing of information between two or more VBE participants, tailored to improving the health outcomes of the target patient population"—again, 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 hospitalization 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

[2] *Id*. at 55775.
[3] *Id*. at 55774.

test order that contradicts the ordering rules requires prior authorization from the payor. The arrangement may result in the laboratory not performing tests for patients because they are duplicative or not indicated for those patients, and it results in 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 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 CMS pursuant to Sec. 1115A(d)(1) of the Social Security Act, indicating that the agency 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

CMS must 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 exceptions at 42 C.F.R. § 411.357(aa), coupled with exclusion from participation in arrangements addressed in proposed Anti-Kickback Statute safe harbor regulations, 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. CMS'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 CMS 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 <u>all</u> parts of the health care system provide value-based care and control costs.

### 3. Clarification of Statement about Excluded Entities' Participation in a Value-Based Enterprise

We are confused by the following statement in the Proposed Rule's preamble: "We note that, regardless of whether we exclude these suppliers (or any other providers or suppliers) from the definition of "VBE participant," they may nevertheless be part of a value-based enterprise. A "value based enterprise" would be defined as "two or more VBE participants—(1) Collaborating to achieve at least one value-based purpose; (2) Each of which is a party to a value-based arrangement with the other or at least one other VBE participant in the value-based enterprise; (3) That have an accountable body or person responsible for financial and operational oversight of the value-based enterprise; and (4) That have a governing document that describes the value-based enterprise and how the VBE participants intend to achieve its value-based purpose(s)."[4] This does not appear to leave room for an entity that is not a VBE participant to "be part of" a value-based enterprise. We ask the agency to clarify its statement.

[4] *Id*. at 55841.

### B. Proposed Exception for Donations of Cybersecurity Technology and Related Services

CMS proposes a new exception at 42 C.F.R. § 411.357(bb) to protect arrangements involving the donation of certain cybersecurity technology and related services. The agency believes that "the fraud and abuse risks associated with cybersecurity are different than donations of other valuable technology, such as EHR items and services," but it seeks comment on whether it should restrict the types of entities that may make donations under this exception.[5]

A donation exception of this kind is bound to be abused, regardless of the types of safeguards CMS would implement, and even as the exception purports to solve other problems. ACLA urges the agency not to finalize an exception that allows a donation of cybersecurity technology and related services from any DHS entity to a physician. However, if CMS proceeds with implementing such an exception, then for the same reasons that ACLA urged CMS 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 CMS on its proposals to extend the applicability of the EHR donation exception 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 CMS 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 CMS 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

[5] *Id*. at 55833.
[6] ACLA's comments are available here: https://www.regulations.gov/document?D=CMS-2013-0065-0070.

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 exception still was applicable to laboratories.

In theory, the exception 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 CMS has proposed a number of safeguards designed to discourage abuse of the exception. 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 CMS to reconsider the exception in its entirety, but at a minimum we urge CMS to exclude laboratories from the types of entities allowed to donate cybersecurity technology and related services under the proposed exception.

### C. Proposed Exception for Limited Remuneration to a Physician

ACLA supports CMS's proposed exception for limited remuneration to a physician (proposed 42 C.F.R. § 411.357(z)). We agree with the agency that arrangements with physicians who provide items or services only sporadically or for minimal compensation, or that are for a short period of time to fill a specific business need, are unlikely to pose a risk of program or patient abuse. This proposal would provide flexibility to engage in non-abusive business arrangements with physicians.

The exception would be helpful to laboratories in a variety of situations. One example is engaging a physician to act as the laboratory director for a high-complexity CLIA-certified laboratory on a short-term basis. Under CMS's regulations, the laboratory must have a laboratory director to operate compliantly, and the laboratory director must be a doctor of medicine, osteopathy, or podiatric medicine (or hold an earned doctoral degree).[7] This condition is not met when the position is not filled or when the laboratory director does not fulfill his or her responsibilities.[8] In the event that a laboratory's usual laboratory director suddenly is unable to serve in that capacity (*e.g.*, due to a serious illness), a laboratory may need to engage an individual who meets the definition of "physician" at 42 CF.R. § 411.351 as the laboratory director, quickly and on a short-term basis to remain in compliance with the regulations. It may not be possible to reduce all of the terms of the engagement to a written instrument signed by

[7] 42 C.F.R. §§ 493.1441, 493.1443.
[8] *See* State Operations Manual, Pub. No. 100-07, Appendix C—Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services, *available at* https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107ap_c_lab.pdf.

both parties in time for the physician to step into the role quickly. Such an engagement would meet the elements of this proposed exception: it would be for services actually provided by the physician and would further a legitimate business purpose (continuing to operate the laboratory), the remuneration would be limited, and fair market value could be determined easily. It also would be useful in this situation to use the exception in conjunction with the personal services exception at 42 C.F.R. § 411.357(d), in the event that interim laboratory director needs to be engaged on a long-term basis.

We do not believe that it is necessary for CMS to include in the proposed exception a requirement that the arrangement must not violate the anti-kickback statute or other Federal or State law or regulation governing billing or items or services provided by the physician.[9] Of course, each physician must act in compliance with the anti-kickback statute and not solicit the remuneration in return for a referral, and each entity paying remuneration to a physician must not offer or pay cash to a physician to induce referrals. But including such a requirement could have the effect of limiting the usefulness and flexibility of the exception, as it may lead some to believe that the arrangement for limited remuneration to a physician must comply in all respects with an anti-kickback statute safe harbor. Rather, the arrangement would comply with the anti-kickback statute when neither party intends that the arrangement is entered into in return for referrals.

### D. Proposed Definition of "Commercially Reasonable"

CMS proposes a new definition of "commercially reasonable":

> *Commercially reasonable* means that a particular arrangement furthers a legitimate business purpose of the parties and is on similar terms and conditions as like arrangements. An arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties.

The agency also seeks stakeholder input on possible definitions that "would provide clear guidance to enable parties to structure their arrangements in a manner that ensures compliance with the requirement that their particular arrangement is commercially reasonable."[10]

ACLA is concerned that the proposed definition potentially could be interpreted by unscrupulous actors as permission to enter into unprofitable arrangements with potential referral sources, reasoning that "the arrangement makes sense as a means to accomplish" the goal of attracting their business. The proposed definition does not provide enough guidance regarding what is a "legitimate business purpose," particularly in the absence of profit for one or more of the parties. One way that CMS could mitigate this unintended consequence is to include examples of legitimate business purposes in the preamble of the final rule that emphasize that the rule is meant only to address situations where parties can point to discrete and well-documented factors establishing that an unprofitable arrangement furthers a legitimate business purpose (*e.g.*, a regulatory or licensure requirement or a patient access issue). Alternatively, CMS could

[9] 84 Fed. Reg. 55829.
[10] *Id*. at 55790.

eliminate the second sentence from the proposed definition and address commercially reasonable unprofitable arrangements on a case-by-case basis via guidance.

### E. Recalibrating the Scope and Application of the Regulations

#### 1. Definition of "Remuneration"

ACLA disagrees with CMS's proposal to revise the definition of "remuneration" with respect to surgical items, devices, and supplies, and we urge the agency not to finalize it. Currently, subparagraph (2) of the regulatory definition of "remuneration" exempts from the definition "the furnishing of items, devices, or supplies (not including surgical items, devices, or supplies) that are used solely" to collect, transport, process, or store specimens or to order tests or communicate test results.[11] CMS proposes to remove the parenthetical phrase "not including surgical items, devices, or supplies" and, through revised regulatory text, to focus on whether the items, devices, or supplies "in fact" were used solely for one or more of those purposes and no others.

We question why it is necessary to remove the parenthetical phrase, which has provided a bright-line rule to laboratories and physicians since 2001, and certainly since CMS issued a pair of advisory opinions in 2013 about the types of items, devices, and supplies that do and that do not constitute remuneration.[12] In the Proposed Rule, the agency did not provide any examples of a surgical item, device, or supply that a laboratory should be able to provide to a physician for free that currently it is prohibited from providing, or what problem the proposed change would solve.

It is a relatively straightforward exercise for a laboratory to determine whether or not an item is classified as "surgical"; if it is, it is not excluded from the definition of "remuneration" and cannot be given to a physician unless the donation meets an applicable exception. It is far more difficult—if not impossible—for a laboratory to determine whether a surgical item, device, or supply "in fact" was used solely to collect, transport, process, or store a specimen. As the agency notes with respect to the provision of surgical gloves, which it says remain within the definition of "remuneration": "we continue to believe it would be impractical for parties to monitor the use of the gloves to ensure they are used solely for one or more of the purposes" set forth in the statute and in the regulation.[13] But neither a laboratory nor CMS could monitor how a physician uses a device that could be used both for a surgical purpose and for specimen collection, transport, processing, and/or storage.

We are concerned that removal of the parenthetical phrase could create a "slippery slope" that eventually would embolden unscrupulous actors to provide items, devices or supplies that are used routinely as part of a surgical procedure, rather than for purposes of specimen collection, transport, processing, or storage. Given how difficult it would be to monitor their use, we do not believe it would be prudent to modify the exception in this way.

[11] 42 C.F.R. § 411.351.
[12] *See* CMS-AO-2013-01 and CMS-AO-2013-02.
[13] 84 Fed. Reg. 55807.

### 2. Denial of Payment for Services Furnished Under a Prohibited Referral—Period of Disallowance

ACLA supports most aspects of CMS's proposal to eliminate regulatory text at 42 C.F.R 411.351(c)(3) regarding when a period of disallowance ends.[14] We understand that this would not affect the basic principle that a physician may not make a referral for designated health services to an entity with whom he or she has a financial relationship, and the entity may not bill Medicare for the services if the financial relationship does not meet all requirements of an applicable exception. Rather, the purpose of the agency's proposal is to allow the parties to use whatever method is reasonable and practical, based on the facts and circumstances, to determine when a period of disallowance is over. Given the diversity of facts and circumstances surrounding financial relationships between laboratories and referring physicians, it makes the most sense to allow flexibility regarding how to bring any period of noncompliance to a close.

While we support CMS's proposal on the whole, we are concerned that the Proposed Rule's preamble simultaneously wipes away one set of "bright line" rules and establishes another: that parties may "cure" noncompliance on the day before an arrangement is set to expire, but they may not "cure" noncompliance the day after an arrangement expires. In the preamble, the agency says:

> Any entity that detects a problem in an active financial relationship and corrects the problem while the financial relationship is still active is addressing a current problem and is not "turning back the clock" to fix past noncompliance. On the other hand, once a financial relationship has ended, we believe that parties cannot retroactively "cure" previous noncompliance by recovering or repaying problematic compensation…We believe this policy encourages active, ongoing review of arrangements for compliance with the physician self-referral law.[15]

ACLA supports the agency's goal of every health care entity developing and maintaining a robust compliance program that has buy-in from all parts of the organization and that is equipped to detect actual or suspected non-compliance and rectify problems. In theory, a laboratory with a well-functioning compliance program can promptly identify non-compliance with a requirement of an applicable regulatory exception and rectify the error swiftly and prior to the conclusion of the arrangement (*e.g.*, through repayment by the referring physician of compensation that exceeds fair market value). In practice, it may be that, using its active compliance program, the laboratory identifies the non-compliance before the expiration of an arrangement, but it cannot complete steps to correct the problem before the arrangement expires (*e.g.*, because the referring physician does not repay excess compensation before the expiration or refuses to modify the written contract to bring the arrangement into compliance). Thus, a laboratory either will be entitled to bill for all Medicare services it furnishes pursuant to that physician's referrals for the term of the agreement, or none of those Medicare services, depending on when during the term of the agreement it reviewed its arrangement with the physician and/or when the physician repaid any excess compensation.

[14] *Id*. at 55808.
[15] *Id*. at 55811.

Instead of its proposed approach, CMS should allow an entity with a functioning compliance program a set amount of time after the end of a financial relationship with a physician to cure noncompliance with a requirement of an applicable exception. This approach would not absolve an entity of its responsibility to structure its financial relationships with physicians to comply with the requirements of applicable exceptions or to monitor its administration of those agreements. Rather, the approach would acknowledge the realities of the rhythms of compliance programs and recognize that it can take some time to identify, quantify, and cure defects in a financial relationship with a referring physician. It also would be in keeping with the agency's "facts and circumstances" approach to determining the end of a period of disallowance.

### 3. Exceptions for Rental of Office Space and Rental of Equipment

ACLA supports CMS's proposed amendments to the regulatory text at 42 C.F.R. §§ 411.357(a)(3) and 411.357(b)(2) to clarify that space or equipment may be used by more than one lessee concurrently, so long as the space or equipment is not shared with the lessor when it is being used or rented by the lessee (or a sublessee).[16] We agree with the agency that it would not pose a risk of program or patient abuse for more than one lessee to use space or equipment concurrently when the arrangement satisfies all requirements of the applicable exception.

### 4. Exception for Fair Market Value Compensation

ACLA supports CMS's proposal to make the existing exception at 42 C.F.R. § 411.357(l) for fair market value compensation available to protect arrangements for rental or lease of office space. This would be useful in situations such as when a laboratory leases space from a physician for a temporary patient service center for specimen collections while a permanent location is renovated or constructed. It is particularly useful because it would not require the duration of the lease to be for at least one year, thereby accommodating legitimate short-term arrangements. Other safeguards in the exception would mitigate the risk of abuse to the Medicare program stemming from allowing it to be used to protect short-term leases (*e.g.*, fair market value, does not take into account the volume or value of referrals or other business generated by the referring physician, compensation is not based on a percentage of revenue attributable to business generated in the office space, etc.).

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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

[16] *Id*. at 55815.