April 27, 2015

American Clinical Laboratory Association

Mr. Daniel Levinson, Inspector General
Office of the Inspector General
U.S. Department of Health and Human Services
300 Independence Avenue, S.W.
Washington, DC 20201

Dear Mr. Levinson:

We are writing to express our deep concern about a recently-published Advisory Opinion from the Office of the Inspector General that addresses the permissibility of an arrangement between a clinical laboratory and physician offices for the provision of clinical laboratory services.[1] The American Clinical Laboratory Association ("ACLA") is an association representing clinical laboratories throughout the country, including local, regional, and national laboratories. We believe that the Advisory Opinion contradicts long-standing guidance from the OIG and from courts, and it has the potential to undermine federal policies aimed at promoting cost savings and efficiencies in health care delivery.

We ask that the OIG withdraw the Advisory Opinion in its entirety. We are aware that an Advisory Opinion may be relied on only by the entity that requested it, but Congress directed the OIG to publish its advisory opinions in order to provide guidance to interested stakeholders other than the requestor.[2] These interested stakeholders include not only clinical laboratories, but also physicians, hospitals, and payors. We have serious reservations about the novel theories that the OIG appears to have advanced in the Advisory Opinion, their potential breadth, and their possible misapplication to otherwise permissible arrangements. We would welcome an opportunity to discuss our concerns with you and your staff as soon as possible.

A. Background

1. Advisory Opinion

The Requestor is a laboratory that furnishes clinical laboratory, anatomic pathology, and other laboratory services for physicians, hospitals, assisted living facilities, and government entities. It operates a number of patient service centers where it collects specimens from patients, and it performs testing services at a main laboratory facility and transmits test results to physicians, in some cases using a laboratory information system ("LIS") interface that it provides to the physicians. The Requestor has heard from some physicians that they would prefer to work with a single laboratory to facilitate communication about test results and because of the consistency of reference ranges for test results when working with just one laboratory. About 70 percent of the Requestor's clients have some patients enrolled in "Exclusive Plans" that require enrollees to use a designated laboratory other than the Requestor. Of those clients, it is estimated that between 10 percent and 40 percent of the clients' patients are enrolled in Exclusive Plans.

[1] Advisory Opinion No. 15-04 (March 18, 2015).
[2] *See* 42 U.S.C. § 1320a-7d(b)(5)(A)(v).

The Requestor proposed that it would agree with physicians or physician groups to furnish all laboratory services to patients, regardless of a patient's insurance status. If a patient is enrolled in an Exclusive Plan, the Requestor would not bill anyone for the services. The Requestor would bill for services furnished to all other patients, including those enrolled in the Federal health care programs. The physicians and physician groups would represent that neither would receive any financial benefit as a result of the proposed arrangement (such as incentive bonuses), and the Requestor would not provide anything of value to the physicians or physician groups other than the LIS interface.

2. OIG's Analysis of the Proposed Arrangement

The OIG determined that the proposed arrangement potentially could violate the Federal Anti-Kickback Statute and the OIG's permissive exclusion authority.[3] It said that, although the physicians and physician groups would receive no direct payments under the proposed arrangements, other facts in combination could be construed as "remuneration" for purposes of the Anti-Kickback Statute. First, it said the physicians or physician groups would stand to benefit from the convenience and administrative efficiency of working with just one laboratory, one consistent reference range for test results, and maintenance of one LIS interface.[4] Second, the physicians or groups potentially could be relieved of the fees sometimes charged by their electronic health record ("EHR") vendors to maintain various interfaces with LISs. Thus, physicians hypothetically could benefit from the absence of fees. Third, the OIG said the Requestor did not present any discernible quality or safety improvements that would result from the proposed arrangement, nor did it describe any safeguards that would reduce the risk of a violation of the Anti-Kickback Statute.

The OIG also found that it is possible that some of the agreements into which the Requestor would enter potentially could violate the "substantially in excess" provision, which is designed to prevent entities from charging the Medicare and Medicaid programs more than their "usual charges" to other payors for the same items and services.[5] Under the arrangement, the Requestor might provide free services to a large portion of the non-Medicare/Medicaid business referred to it, because up to 70 percent of its clients indicated that between 10 percent and 40 percent of patients are enrollees of exclusive plans. Therefore, it is possible that more than half of non-Medicare/Medicaid patients would be receiving free services, while Medicare and Medicaid would be charged the regular rate. Thus, the OIG said, the proposed arrangement potentially could "result in a two-tiered pricing structure." The OIG did say that the "substantially in excess" provision is not intended to prevent providers and suppliers from negotiating rates with private plans that may be below the Medicare/Medicaid rates.

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[3] 42 U.S.C. § 1320a-7(b)(6)(A).

[4] The Requestor noted that the OIG has acknowledged that a limited-use interface like the LIS here is not in itself "remuneration." In the Advisory Opinion, the OIG said that it was not asked to opine, and expressed no opinion, on the LIS provided by the Requestor.

[5] 42 U.S.C. § 1320a-7(b)(6)(A).

B. The Advisory Opinion directly contradicts a 1994 OIG Special Fraud Alert on the same topic.

Curiously, in the Advisory Opinion, the OIG did not make any reference to a Special Fraud Alert it issued in 1994 about waiving charges for managed care patients – guidance that is directly contradicted by the Advisory Opinion.[6] There, the OIG addressed a similar situation in which a managed care plan requires a physician to use only the laboratory with which the plan has negotiated a fee schedule and generally refuses to pay claims submitted by any other laboratory, and "[i]n order to retain the provider as a client, the laboratory that does not have the managed care contract may agree to perform the managed care work free of charge." The OIG said of such an arrangement: "the status of such agreements under the Anti-Kickback Statute depends in part on the nature of the contractual relationship between the managed care plan and its providers." If a physician receives a bonus for keeping utilization of laboratory services below a particular threshold (or is penalized if utilization exceeded a threshold), then a laboratory's waiver of all charges for those managed care patients potentially could confer a financial benefit on the physician and be considered "remuneration" in exchange for referrals of Federal health care program business. On the other hand, if a physician received no financial benefit from such an arrangement, as with the physicians in the Advisory Opinion, then there would be no "remuneration" for purposes of the Anti-Kickback Statute. Thus, the OIG's position in the recent Advisory Opinion is inconsistent with its position in the 1994 Special Fraud Alert. Like the situation in the 1994 Special Fraud Alert, the physicians here would not receive any financial benefit, yet the OIG reached the opposite conclusion.

It is surprising that the OIG would issue an opinion that appears to be so at odds with its prior guidance, without any explanation or discussion (or even a mention of the Special Fraud Alert). The Requestor appears to have designed the proposed arrangement with this prior guidance in mind. At a minimum, the OIG should explain whether and how it would reconcile its position in the Advisory Opinion with its position in the Special Fraud Alert. We believe that the 1994 Special Fraud Alert is the sounder position.

C. The Advisory Opinion advances several novel theories about what constitutes "remuneration."

The Advisory Opinion advances several previously unarticulated theories about what is "remuneration" for purposes of the federal Anti-Kickback Statute. The confusion about these new theories is compounded by the fact that the OIG did not say that any one of the factors results in "remuneration"; rather, it was the combination of factors that led the OIG to conclude that the proposed arrangement potentially constituted "remuneration." As a result, readers of the Advisory Opinion are left to wonder whether any one of the factors in isolation also would be suspect, whether some different combination of factors would lead the OIG to a different conclusion, and whether there are ways to mitigate the OIG's concerns. For these reasons and others, we do not believe that an advisory opinion is the proper vehicle for the OIG to set forth these new interpretations of the Anti-Kickback Statute.

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[6] http://oig.hhs.gov/fraud/docs/alertsandbulletins/121994.html.

Efficiency and convenience: Perhaps the most confounding theory espoused in the Advisory Opinion is that the OIG might consider convenience and administrative efficiency (in this case, working with a single laboratory, one consistent reference range for test results, and maintenance of one LIS interface) to be "remuneration" paid to a physician. A 2004 federal district court case involving an arrangement similar to the one described in the Advisory Opinion shows the novelty of the OIG's position. In that case, a laboratory initiated a program to furnish all laboratory testing for physicians' offices, and the lab would accept as payment-in-full whatever payments it received from plans with which it was "out of network". Although government attorneys alleged that the agreements resulted in impermissible "remuneration" to physicians in the form of savings of staff time that would be spent packaging and sending specimens to different laboratories, as required by patients' managed care plans, the Court said, "The Government has not cited and the Court has found no case which holds that an incidental savings in time which results to a physician from an agreement with a clinical laboratory (or any other entity) constitutes the payment of 'remuneration, directly or indirectly,…in cash or in kind.'"[7] We are unaware of any federal court cases since this 2004 case in which time savings and efficiency have been considered "remuneration" paid by one health care entity to a physician.

This position also appears to reverse previous guidance from the OIG that intangible "psychic" benefits are not "remuneration" for purposes of the Anti-Kickback Statute. One of the factors the OIG cites in the Advisory Opinion is meeting the physician's preference to work with one lab for the sake of efficiency and convenience. Yet in previous guidance, the OIG has said that in the absence of an actionable economic benefit, a benefit with an "inchoate psychic value"[8] or one where the benefits "are primarily intangible and psychic"[9] would not be considered "remuneration." In this case, the OIG seems to imply that the non-specific "psychic" benefits of efficiency and convenience for a physician may, in fact, constitute "remuneration."

At the same time that the U.S. Department of Health and Human Services is promoting greater efficiencies to lower costs in healthcare across the spectrum,[10] the Advisory Opinion may place health care providers in the difficult position of attempting to determine when convenience or administrative efficiency might be considered illicit remuneration, and could lead health care providers to believe that greater efficiency resulting in lower costs could expose them to sanctions. It is not at all clear from the text of the Advisory Opinion when the OIG might consider this to be the case, or whether efficiency and convenience in isolation could be construed as "remuneration." We are concerned about the many unintended consequences of this line of reasoning being allowed to stand.

Relief from fees levied by a third party: Another theory newly advanced in the Advisory Opinion is that an agreement that incidentally may relieve one of the parties of fees levied by an

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[7] U.S. v. Hagstrom *et al*, No. CR-04-120-R (Dec. 28, 2004).
[8] Advisory Opinion No. 08-05 (Feb. 15, 2008); Advisory Opinion 11-07 (Jun. 1, 2011).
[9] Advisory Opinion No. 00-03 (Apr. 7, 2000).
[10] *See* HHS Strategic Plan, FY 2014 – 2018, *available at* http://www.hhs.gov/strategic-plan/priorities.html. Strategic Plan has four broad strategic goals, the first of which includes reducing the growth of healthcare costs while promoting high-value, effective care, and one of the strategies for achieving that goal is "incentiviz[ing] health care providers to…invest in infrastructure and redesigned care processes for high-quality and efficient service delivery."

unrelated third party potentially could constitute "remuneration" under the Anti-Kickback Statute. The OIG speculated that the proposed arrangement "could relieve physician practices of [monthly EHR maintenance fees] for any interface that the physician practice no longer would maintain." This underscores why any analysis regarding relief from fees or other administrative cost savings must be made on a case-by-case basis. In this case, it is not clear whether any physicians would be relieved of fees at all. Because the facts of each situation are different, there cannot be a bright-line rule that the absence of a payment from a physician to a third party is equal to a payment from a laboratory to a physician. We are not aware of the OIG espousing such an idea in the past, and it may not be the OIG's intention to announce such a rule now. But the Advisory Opinion is sufficiently unclear on this point to warrant further discussion and explanation.

Safety and quality improvements: We also were surprised to read that another factor in the OIG's decision-making was that the arrangement was devoid of "discernible safety or quality improvements" gained by sending all testing to one laboratory. As you are aware, quality and safety benefits are not an element of the Anti-Kickback Statute, nor of any of the relevant statutory or regulatory safe harbors. Furthermore, there in fact may be quality and safety improvements as a result of having just one set of reference ranges from one laboratory. Regardless, a reader of the Advisory Opinion is left to wonder what place such a factor has in an analysis of the present arrangement.

We disagree with the OIG's conclusion that the application of these new ideas, singularly or in combination, potentially results in "remuneration" to the physician or groups. More than that, we disagree that an Advisory Opinion is the proper place for the OIG to articulate new policies that are so completely at odds with previously-stated positions, if that is in fact what the OIG has done here. In part because of the format of an Advisory Opinion, the OIG has not explained to stakeholders why it has changed certain of its positions, whether it believes any of the factors has more weight than others, and how a laboratory might mitigate any of the OIG's concerns.

D. The "substantially in excess" doctrine is ill-defined and should not be determinative.

The "substantially in excess" provision to this day remains amorphous, and we believe that the OIG's reliance on it in its analysis of the arrangement described in the Advisory Opinion is misguided. In the Advisory Opinion, the OIG acknowledges that it has "attempted on numerous occasions to provide definitive guidance" on the contours of the "substantially in excess" provision of the Social Security Act but that it has never finalized definitions for "substantially in excess" or "usual charges." The OIG first considered defining the terms in a 1990 proposed rule, but later it declined to.[11] It published another rulemaking with related proposals in 1997, but the relevant portions were not finalized.[12] The OIG then published a proposed rule in 2003 in which it floated definitions for "usual charge" and "substantially in

[11] *See* 55 Fed. Reg. 12205, 12215 (Apr. 2, 1990).
[12] 62 Fed. Reg. 47182, 47186 (Sept. 8, 1997).

excess", a rule that it ultimately withdrew in 2007.[13] The OIG said in the preamble to the withdrawn rule that it could not "establish a single, fixed numerical benchmark for 'substantially in excess' that could be applied equitably across health care sectors and across items and services."[14]

We were surprised, then, to see that this portion of the Advisory Opinion's analysis rested on a few sentences in a single letter written in 2000 by the Chief of the OIG's Industry Guidance Branch in response to a question about the application of the "substantially in excess" provision. In that letter, the then-branch chief wrote that the OIG's belief is that the permissive exclusion authority is not implicated "unless a provider's charge to Medicare is substantially in excess of its median non-Medicare/Medicaid charge. In other words, a provider need not even worry about [the "substantially in excess" provision] unless it is discounting close to half of its non-Medicare/Medicaid business." Three and a half years later, the OIG proposed that "usual and customary" could mean the provider's median charge, but this rule was withdrawn in 2007 because of difficulties with establishing workable and widely-applicable standards.

The OIG rejected the "median" approach for good reason. But fifteen years later, the OIG has based this portion of the analysis on the possibility that the arrangement might cross the "median" threshold in some instances. This is extremely confusing, especially because the Advisory Opinion suggests that the "median" concept has been resurrected, when the withdrawal of the 2003 proposed rule said otherwise. We continue to believe that the "median" approach is unworkable and unwise, and we do not believe that it should serve as the basis for the OIG's conclusion in this instance.

E. Conclusion

We would like the opportunity to meet with you and your staff at your earliest convenience to share our concerns about the Advisory Opinion in more detail and to discuss the unintended consequences that may flow from it. Thank you for your consideration, and we look forward to speaking with you.

Sincerely,

Alan Mertz, President
American Clinical Laboratory Association

[13] 68 Fed. Reg. 53939 (Sept. 15, 2003); 72 Fed. Reg. 33430 (Jun. 18, 2007).
[14] 72 Fed. Reg. 33432.