



American
Clinical Laboratory
Association

July 14, 2015

Mr. Greg Demske, Chief Counsel to the Inspector General
Office of the Inspector General
U.S. Department of Health and Human Services
330 Independence Avenue SW
Washington, DC 20201

Dear Mr. Demske,

Thank you very much for taking the time to meet with members of the American Clinical Laboratory Association on June 16, 2015 to discuss Advisory Opinion 15-04. We found it to be an informative and productive discussion.

As we mentioned in our meeting, the Advisory Opinion has created a fair amount of confusion in the laboratory industry, particularly with respect to the issue of when the OIG might consider “convenience” and “efficiency” to constitute remuneration under the Anti-Kickback Statute. Physicians, laboratories, and other Medicare suppliers and providers constantly look for ways to increase the efficiency and speed with which they perform services and to coordinate care. Our understanding from the meeting is that it is not the OIG’s position that convenience or efficiency alone constitute remuneration; it is only when the convenience or efficiency is accompanied by some kind of impermissible financial benefit to a referral source (and the requisite intent to influence referrals) that the OIG potentially would consider convenience or efficiency to constitute remuneration.

The facts supplied to the OIG by the Requestor are very specific and, in some regards, they also are highly unusual. (As an example, based on the facts provided by the Requestor, the OIG viewed the “financial benefit” to a physician as relief from monthly fees for maintenance of an interface between an electronic health record and a laboratory information system.) In addition, in our discussion, you noted that the arrangement was being pursued in part to obtain Medicare referrals. We understand that, based on the facts provided to it, the OIG felt that it was unable to sanction the arrangement, but it could reach a different conclusion if presented with different facts.

Regardless of the narrow application of the Advisory Opinion, we do believe that laboratories and other suppliers and providers would benefit from clearer guidance from the OIG on the standard it would use to determine the circumstances in which it potentially could consider convenience or efficiency to raise the specter of a violation of the Anti-Kickback Statute. We hope to continue our dialogue with your office about this issue, and ACLA is happy to serve as a resource to your staff on matters that concern laboratory operations. Thank you again for your time.

Sincerely,

A handwritten signature in black ink, consisting of a large, stylized loop followed by a long horizontal stroke that tapers to the right.

JoAnne Glisson, Senior Vice President
American Clinical Laboratory Association

CC: Ms. Martha Talley, Chief, Industry Guidance Branch
Ms. Heather Westphal, Senior Counsel