American
Clinical Laboratory
Association

October 25, 2018

Mr. Daniel R. Levinson, Inspector General
Office of the Inspector General
Department of Health and Human Services
Attn: OIG-0803-N
Cohen Building, Room 5513
330 Independence Avenue SW
Washington, DC 20201

RE: Medicare and State Health Care Programs: Fraud and Abuse; Request for Information Regarding the Anti-Kickback Statute and Beneficiary Inducement CMP

Dear Mr. Levinson,

Please accept the comments of the American Clinical Laboratory Association (ACLA) on the above-referenced Request for Information (RFI). ACLA is a non-profit association representing the nation's leading clinical and anatomic pathology laboratories, including national, regional specialty, end-stage renal disease, hospital, and nursing home laboratories. The clinical laboratory industry employs nearly 277,000 people directly and generates over 115,000 additional jobs in supplier industries. Clinical laboratories are at the forefront of personalized medicine, driving diagnostic innovation and contributing more than $100 billion annually to the nation's economy.

The Office of Inspector General (OIG) seeks to find ways to modify existing anti-kickback statute safe harbors and/or add new safe harbors to foster arrangements that would promote care coordination and advance the delivery of value-based care, while protecting against harms caused by fraud and abuse.[1] ACLA would not oppose new or modified safe harbors that encourage coordinated care arrangements, so long as those safe harbors are accompanied by appropriate safeguards against fraud and abuse.

If the OIG proposes changes to the anti-kickback statute's regulatory safe harbors, we ask that it also amend the prefatory language in the regulation to add the italicized language: "The following payment practices shall not be treated as a criminal offense under section 1128B of the Act *or under any federal law addressing remuneration in return for or to induce referrals* and shall not serve as the basis for an exclusion…"[2] The purpose of the additional language is to ensure that health care providers and suppliers and law enforcement agencies are clear that conduct protected by a current anti-kickback statute safe harbor would not be treated as a criminal offense under a different federal law.

Our request is motivated in part by section 8122 of the "SUPPORT for Patients and Communities Act" recently passed by Congress and signed into law.[3] The legislation adds a new section 220 to the U.S. Criminal Code, entitled "Illegal remunerations for referrals to recovery homes, clinical treatment facilities, and laboratories," that would authorize the imposition of

[1] 83 Fed. Reg. 43607, 43608 (Aug. 27, 2018).
[2] This prefatory language appears at 42 C.F.R. § 1001.952.
[3] H.R. 6, 115th Cong. (2018).

criminal penalties for some conduct that currently is permissible under anti-kickback statute safe harbors. (The section is included in Subtitle J, "Eliminating Kickbacks in Recovery".) As written, section 8122 of the legislation applies to all laboratories, not merely laboratories who perform testing for recovery homes and clinical treatment facilities, and to all services covered by all payors, rather than only items and services covered by the Federal health care programs.[4]

The new legislation includes rule of construction language addressing the provision's relationship to other federal laws, but we do not believe it will be effective to protect conduct that currently is permissible. The rule of construction language reads: "This section shall not apply to conduct that is prohibited under section 1128B of the Social Security Act (42 U.S.C. 1320a-7b(b)." It does not address conduct that currently is protected under an existing safe harbor or implementing guidance such as a fraud alert. It is not clear, for example, how a law enforcement agency would reconcile the current anti-kickback statute's exception that protects the payment and receipt of remuneration under certain employer-employee arrangements with the employer-employee exception in the legislation. While similar, they contain critical differences. The anti-kickback statute does not apply to:

> any amount paid by an employer to an employee (who has a bona fide employment relationship with such employer) for employment in the provision of covered items or services…[5]

The new legislation, on the other hand, would not apply to:

> a payment made by an employer to an employee or independent contractor (who has a bona fide employment or contractual relationship with such employer) for employment, if the employee's payment is not determined by or does not vary by—
>
> > (A) the number of individuals referred to a particular recovery home, clinical treatment facility, or laboratory;
> >
> > (B) the number of tests or procedures performed; or
> >
> > (C) the amount billed to or received from, in part or in whole, the health care benefit program from the individuals referred to a particular home, clinical treatment facility, or laboratory…

It is not evident which law would apply to compensation paid to a laboratory employee that is based, in part, on the amount of business generated by the employee. Would it be the current anti-

[4] The definition of "laboratory" in the legislation cross-references the definition of laboratory found in the Clinical Laboratory Improvement Amendments (CLIA), 42 U.S.C. § 263a. A "health care benefit program" is defined as "any public or private plan or contract, affecting commerce, under which any medical benefit, item, or service is provided to any individual, and includes any individual or entity who is providing a medical benefit, item, or service for which payment may be made under the plan or contract."

[5] 42 U.S.C. § 1320a-7b(b)(3)(B).

kickback statute exception because the new legislation is not to be interpreted to "supersede or preempt" the law, or is it the more restrictive exception in the new legislation?

Another circumstance currently permitted by the existing safe harbor at 42 C.F.R. § 1001.952(j) is payment of an administrative fee by a laboratory to a group purchasing organization (GPO) in return for marketing the laboratory's services to the GPO's members. Under the new legislative text, the administrative fee could be construed as the GPO receiving or soliciting remuneration "in return for referring…patronage…to a lab" or as a laboratory paying remuneration "in exchange for an individual using the services of…a lab." The GPO safe harbor has been in place since 1991, and the new legislation potentially could prohibit well-established marketing arrangements. It is important that the OIG act to protect these and other existing arrangements between health care providers and suppliers and remove uncertainty about what law would apply to them.

Given the foregoing, the OIG should make clear in the safe harbor regulation's prefatory language that it shall not be a criminal offense under the anti-kickback statute or under other laws that address the remuneration in exchange for referrals to engage in conduct described in an existing safe harbor, as long as all elements of the safe harbor are met. This would be an effective way to ensure that existing protected health care arrangements will not be disrupted needlessly and to delineate the reach of the new legislation.

Thank you for your consideration of ACLA's comments on this matter.

Sincerely,

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