ALSTON & BIRD

TO: American Clinical Laboratory Association

FROM: Joyce E. Gresko
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DATE: November 26, 2018

RE: **Sec. 8122 of the SUPPORT for Patients and Communities Act**

Section 8122 of the Support for Patients and Communities Act, Pub.L. 115-271, which added a new Section 220 to title 18 of the U.S. Code, imposes new criminal penalties on laboratories for actions that previously had not been considered to be criminal, or even prohibited, conduct. Criminal offenses include soliciting or receiving any remuneration "in return for referring a patient or patronage" to a laboratory or "in exchange for an individual using the services of" a laboratory. Each occurrence is punishable by up to $200,000 and 10 years of imprisonment.

On its face, Section 8122 is not limited to drug abuse-related testing but instead applies to all laboratories, and to all clinical laboratory tests, regardless of the type of laboratory testing performed, and thus has a sweeping impact that may not have been intended or appreciated by its drafters. The section also applies to services payable by both private payors and the Federal health care programs (*e.g.*, Medicare, Medicaid, TRICARE). Some aspects of the section are in direct conflict with the Federal Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b)) and its implementing regulations, and the scope of the section's text is unclear, creating confusion for laboratories and those who refer services to laboratories as to how the law applies to laboratories and which law applies.

A. 18 U.S.C. § 220 creates confusion where it overlaps with the Federal Anti-Kickback Statute.

Whereas the Federal Anti-Kickback Statute applies only to items and services payable under the Federal health care programs, 18 U.S.C. § 220 applies to "services covered by a health care benefit program." The definition of the term "health care benefit program" was added to the U.S. criminal code at 18 U.S.C. § 24(a) by the Health Insurance Portability and Accountability Act of 1996, Pub.L. 104-191 (HIPAA). The definition is: "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." The Department of Justice

interprets the term "health care benefits program" to include Medicare, Medicaid, and other government payors.[1]

Preemption language at 18 U.S.C. § 220(d) states that the "section shall not apply to conduct that is prohibited under [the Federal Anti-Kickback Statute]" – but it does not say whether the section applies to conduct that is *permissible* under the Federal Anti-Kickback Statute. (Rule of construction language in an earlier legislative draft read: "Nothing in subsection (a) should be interpreted to supersede or preempt other applicable Federal or State law, including but not limited to, [the Federal Anti-Kickback Statute].") This has left laboratories unsure which law applies in certain circumstances.

For example, a statutory exception in the Federal Anti-Kickback Statute states that the law 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."[2] This well-established exception also is reflected in a safe harbor regulation promulgated by the Department of Health and Human Services Office of Inspector General (OIG) that acknowledges that providers of health care items and services, including clinical laboratories, employ sales personnel whose job it is to recommend those items and services and who get paid for doing so. But 18 U.S.C. § 220(b)(2) includes a provision that can be read to exempt clinical laboratory employment arrangements from the reach of criminal prosecution only if the employee's payment does not vary with the number of tests or procedures performed, or the amount billed to or received from a health care benefit program for any type of diagnostic testing. These kinds of commission-based employment agreements are common for salespeople in all industries, including health care, and they have been permissible for clinical laboratory employees as well, until now. The employee exception in the Federal Anti-Kickback Statute applies to laboratories, and the employee exception in the new statute <u>also</u> applies to laboratories. This is one example of an overlap between the laws that has created confusion for laboratories, referring physicians, and health insurers alike.

B. Beneficial conduct by laboratories all of a sudden may have been criminalized.

While the language of 18 U.S.C. § 220 is modeled on the Federal Anti-Kickback Statute, the language is not identical, and it contains certain terms and phrases whose meaning and scope are unclear. The concept of "remuneration" is well understood to include anything of value, but other concepts are murkier. For example, what does it mean to "refer a patient or patronage" to a laboratory? What does it mean to provide remuneration "in exchange for an individual using the services of" a laboratory? These phrases could just as easily apply to innocuous interactions as to nefarious ones, leaving laboratories greatly concerned that their everyday course of business all of a sudden may have been criminalized. Furthermore, laboratories fear that clarification of these phrases may come only in the form of criminal indictments: although the Department of Justice

[1] *See*, e.g., Grand Jury Indictment in <u>U.S. v. Peresiper</u>, ¶ 2, E.D.N.Y. (Jun. 1, 2018); Grand Jury Indictment in <u>U.S. v. Do</u>, ¶ 2, S.D.Tex. (Jul. 6, 2017).

[2] 42 U.S.C. § 1320a-7b(b)(3)(B).

and Department of Health and Human Services are given discretion to engage in rulemaking, they are not required by the law to do so.

Through the years, laboratories have developed certain practices and arrangements in reasonable reliance upon the Federal Anti-Kickback Statute that are beneficial to patients and the community alike. But given that 18 U.S.C. § 220 applies to all laboratories and all payors, some of these practices may now be considered criminal conduct. Potentially criminalized conduct includes:

- Donations to Federally Qualified Heath Centers (FQHCs): Laboratories frequently donate in-kind testing services and/or supplies to FQHCs, and this practice currently is protected under 42 USC 1320a-7b(b)(3)(I) and 42 CFR 1001.952(w). Oftentimes the donations are for routine testing that commonly is associated with the primary care services that FQHCs provide. FQHCs are supposed to establish collaborative relationships with other health care providers, which may include referrals to a lab for non-routine testing covered by a payor other than a Federal health care program, including a laboratory that donates services and supplies to the FQHC.[3] Under the new law, donations of free testing services and/or testing supplies could be considered paying or offering in-kind remuneration "in exchange for an individual using the services of" a laboratory, or "to induce the referral of an individual" to a laboratory. This would put the laboratory at risk with respect to privately-insured patients, and even for Federal health care program patient testing, the new law would create confusion at best.

- Group Purchasing Organizations (GPOs): A laboratory pays an administrative fee to a GPO of up to three percent for recommending or arranging for the provision of the laboratory's services to the GPO's members. This arrangement currently is protected by an exception in the Federal Anti-Kickback Statute at 42 U.S.C. § 1320a-7b(b)(3)(C) and a regulatory safe harbor at 42 C.F.R 1001.952(j) for the Federal health care programs. Under the new law as written, the fee could be interpreted as a GPO soliciting/receiving remuneration "in return for referring…patronage…to a laboratory," or interpreted as a laboratory paying remuneration "in exchange for an individual using the services of…a laboratory." The Federal Anti-Kickback Statute safe harbor does not protect arrangements with respect to commercial business also covered by GPO arrangements.

- Placement of phlebotomist in physician office: A laboratory provides a phlebotomist to a physician office to draw blood specimens being sent to that laboratory, when there is sufficient patient volume to warrant placement of a phlebotomist to service the practice's patients. The Department of Health and Human Services Office of Inspector General (OIG) has said placement of a laboratory employee would not necessarily be an inducement under the Federal Anti-Kickback Statute when the phlebotomist does not perform

[3] The most recent statistics from the National Association of Community Health Centers show that 18 percent of patients served by FQHCs are privately insured. *See* America's Health Centers (August 2018), *available at*: http://www.nachc.org/wp-content/uploads/2018/08/AmericasHealthCenters_FINAL.pdf.

additional tasks that are normally the responsibility of the physician's office staff.[4] Under the new law, providing a phlebotomist could be interpreted as the laboratory paying remuneration "in exchange for an individual using the services of…a laboratory." This practice all of a sudden may be impermissible for commercial business.

- Specimen collection: Laboratories may provide specimen collection devices to physician offices, which the OIG has said may not be deemed to be "remuneration" if used solely to transport/collect specimens (absent intent to induce referrals). There isn't an exception in the new law that would protect that practice (federal or private pay).

These practices do not pose a risk of harm to the Federal health care programs or to commercial health plans, and they provide benefits to patients and the larger community. They should continue to be permissible practices, even for commercial payors.

C. Recommendations

Congress can clarify the outer limits of 18 U.S.C. § 220 to ensure that laboratories are not subject to conflicting laws for the same action and to protect common beneficial laboratory business practices by amending the preemption language at 18 U.S.C. § 220(d) to read:

"(d) PREEMPTION.—

(1) FEDERAL LAW.—This section shall not apply to conduct that is prohibited under Sec. 1128B of the Social Security Act involving a Federal health care program (42 U.S.C. 1320a–7b(b)). Irrespective of the type of health care benefit program, conduct that complies with an exception under Sec. 1128B(b)(3) of the Social Security Act (42 U.S.C. 1320a-7b(b)(3)), a regulation under 42 C.F.R. 1001.952, or subregulatory guidance issued thereunder shall not be an offense under subsection (a).

(2) STATE LAW.—Nothing in this section shall be construed to occupy the field in which any provisions of this section operate to the exclusion of State laws on the same subject matter."

This language would leave intact the structures and legitimate business practices that have been deemed not to pose harm to the Federal health care programs when appropriate safeguards are in place.

Additionally, Congress can amend the exception for employee compensation at 18 U.S.C. § 220(b)(2) to read:

"(2) a payment made by an employer to an employee or independent contractor (who has a bona fide employment or contractual relationship

[4] *See* OIG Special Fraud Alert, Arrangements for the Provision of Clinical Lab Services (Dec. 19, 1994), *available at* https://oig.hhs.gov/fraud/docs/alertsandbulletins/121994.html.

> with such employer) for employment, if the employee's payment is not determined by or does not vary with the number of individuals referred to a particular recovery home, clinical treatment facility, or laboratory.

Such an amendment would ensure that so-called "body brokers" could not be compensated for steering individuals to particular recovery homes, clinical treatment facilities, and/or laboratories and benefit from unnecessary laboratory services furnished and billed by unscrupulous actors, but it would permit legitimate commission-based employment arrangements to stay in place for laboratory sales forces.