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LEGAL UPDATE
Watch Out! Recent Government Settlements Implicate Referring Physicians and Laboratories

$48.5 million settlement with Health Diagnostics Laboratory, Inc. and Singulex, Inc.

On April 9, 2015, the U.S. Department of Justice ("DOJ") announced a $48.5 million settlement with two cardiovascular diagnostic testing laboratories, Health Diagnostics Laboratory Inc. of Richmond, VA and Singulex Inc., of Alameda, CA, to resolve allegations that they violated the False Claims Act by paying physicians in exchange for patient referrals and billing federal health care programs for unnecessary testing. The settlement arises out of a qui tam complaint originally filed in 2013 by a billing service provider and a nursing supervisor who were familiar with the operations of one of the physicians involved in this arrangement.

As alleged in the lawsuits, the laboratories induced physicians to refer patients to them for blood tests by paying them processing and handling fees of between $10 and $17 per referral and by routinely waiving patient co-pays and deductibles. As a result, physicians allegedly referred patients to these laboratories for medically unnecessary tests, which were then billed to federal health care programs, including Medicare.

The qui tam complaint alleged that the laboratories attempted to justify the processing fees by assigning various responsibilities to the physicians. However, it was alleged that the physicians only did minimal processing tasks with the remaining tasks being performed by lab technicians from an independent laboratory. The complaint referenced the Medicare Claims Processing Manual in noting that Medicare does not pay for routine handling charges where a specimen is referred from one laboratory to another.

With respect to medical necessity, the complaint alleged that certain physicians gave all patients referred to these laboratories a diagnosis of high cholesterol even though there was no clinical indication to support the diagnosis. It further alleged that these physicians referred patients for follow-up testing even when the patients' results indicated no need for additional tests.

In addition to the monetary settlement, HDL and Singulex were also required to enter into separate corporate integrity agreements ("CIAs") with the Department of Health and Human Services Office of Inspector General ("OIG"). Many aspects of the CIAs are relatively standard, including management certification obligations, mandatory compliance training and independent review organization oversight.

However, the CIAs also contain a new provision entitled "Focus Arrangement Procedures" which scrutinizes all payments between the labs and (1) any actual source of health care business or referrals to the labs that involves, directly or indirectly, the offer, payment or provision of anything of value or (2) any physician (or immediate family members) who makes a referral to the lab for designated health services.

Within a defined period after entering into the CIAs, the labs must create procedures reasonably designed to ensure that each "focus arrangement" does not violate the Anti-Kickback Statute and/or Stark. These procedures must include:

- Creating and maintaining a "centralized tracking system" for all existing and new focus arrangements;
- Tracking remuneration to and from all parties to focus arrangements
- Tracking service and activity logs to ensure that parties to the focus arrangement are performing the services required under the applicable focus arrangement;
- Monitoring the use of lease space, medical supplies, medical devices, equipment or other patient care items to ensure that such use is consistent with the terms of the applicable focus arrangement;
- Establishing and implementing a written review and approval process for all focus arrangements, the purpose of which is to ensure that all new and existing focus arrangements do not violate the Anti-Kickback Statute and Stark, and that includes at least: (i) a legal review of all focus arrangements by counsel with expertise in the Anti-Kickback Statute and Stark, (ii) a process for specifying the business need/rationale for all focus arrangements, and (iii) a process for determining and documenting the fair market value of the remuneration specified in the focus arrangement;
- Requiring the compliance officer to review the focus arrangements tracking system, internal review and approval process, and other focus arrangements procedures on at least an annual basis and to provide a report on the results of such review to the executive compliance committee; and
- Implementing effective responses when suspected violations of the Anti-Kickback Statute and Stark are discovered.

In addition, the CIA also requires the labs to ensure that the focus arrangement is in writing and signed by the labs and all other parties to the focus arrangement. Also, compliance training is required for the labs' owners and full-time staff. Finally, any agreement for a focus arrangement must include a certification that the parties will not violate the Anti-Kickback Statute or Stark with respect to performance of the arrangement.

$3.2 Million Settlement with Family Dermatology, P.C.

In another recent DOJ action, Family Dermatology, P.C., which owns and operates a dermatopathology laboratory and several dermatology practices throughout the eastern United States, agreed to pay more than $3.2 million to settle allegations that it violated the False Claims Act and the federal Stark Law by

engaging in improper financial relationships with a number of its employed physicians. The allegations arose out of qui tam lawsuits filed by three whistleblowers who collectively will receive more than $584,000 from the recovery.

The settlement resolved allegations that financial relationships that Family Dermatology and its affiliates had with a number of their employed physicians violated Stark and the False Claims Act. Specifically, Family Dermatology employs a number of dermatologists as independent contractors and it has routinely required them to use Family Dermatology's in-house pathology lab, which operates under the name Nelson Dermatopathology, for their pathology services. The government alleged that Family Dermatology's financial relationships with a number of these physicians did not comply with the requirements of Stark, and that Family Dermatology improperly billed Medicare for dermatopathology services performed by Nelson Dermatopathology on specimens that were sent to the laboratory by these physicians.

As with the HDL/Singulex settlement, the OIG entered into a CIA with Family Dermatology as part of the settlement. The Family Dermatology CIA includes the same "focus arrangement" provisions as included in the HDL/Singulex CIAs. Given that the OIG often sets forth new policies and expectations in its CIAs, the inclusion of the focus arrangement procedures in each of the new CIAs would seem to indicate new points of emphasis from the OIG for laboratories to consider in structuring their referral arrangements with physicians.

In sum, the government's actions in these cases illustrate its continued scrutiny into laboratory referral arrangements with physicians. They also follow on the heels of a 2014 OIG Special Fraud Alert, which also deals with the federal government's longstanding concerns regarding lab payments to referring physicians. See http://www.chamblisslaw.com/Media-Center/Legal-Updates/87303/OIG-Sticks-It-to-Physician-Specimen-Collectors.

As such, physicians and laboratories who engage in referrals for federally funded health care services should be careful to make sure that any such referral arrangements are appropriately structured to avoid the issues triggering the claims here. In particular:

- Referring physicians should avoid receiving any sort of "processing" or "handling" fees for the routine transfer of specimens to a testing laboratory;
- Testing laboratories should not be routinely waiving patient co-pays or deductibles;
- Referring physicians should ensure that any tests being ordered are medically necessary;
- Any payments received by the referring physicians should be fair market value and not vary based on the volume or value of referrals, and should be related to legitimate services performed by the physicians; and
- As noted above, labs should take steps, where appropriate, to implement the various "procedures" outlined in the CIAs, including the requirement that all arrangements with referring physicians be documented in writing and the implementation of a tracking system for any related payments.

Taking into account these measures should help to protect physician-laboratory referral arrangements from government scrutiny of the sort imposed in the HDL/Singulex and Family Dermatology actions.

If you have any additional questions about either of these recent settlement actions, please do not hesitate to contact a member of Chambliss' health care section.