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FALSE CLAIMS BASED ON MEDICAL NECESSITY

In the earlier part of this two-part article, we addressed issues related to medical necessity of clinical laboratory services, including medical necessity criteria, documentation requirements, financial liability for tests determined not to be medically necessary, and certain protective actions available to a clinical laboratory. A clinical laboratory's liability under the False Claims Act (FCA), 31 U.S.C. § 3729, criminal statutes, and regulations providing for administrative sanctions is discussed below.

ROLE OF CLINICAL LABORATORY

As demonstrated in the first part of this article, Medicare regulations, as currently applied, generally result in a clinical laboratory bearing the financial loss from medically unnecessary tests. A clinical laboratory's liability under the FCA for submission of claims for tests that are not medically necessary is less clear and depends, in part, on the role of the clinical laboratory in determining the tests ordered and for which payment was claimed. At one time, clinical laboratories argued frequently that physicians were solely responsible for the selection of tests and that the laboratory had no responsibility for the medical necessity of tests for which it claimed payment. It is now recognized generally that laboratories may bear some responsibility for medically unnecessary tests. Laboratories are under an obligation not to mislead physicians or otherwise take any action that results in the physician's ordering of unnecessary tests for which the laboratory will claim payment. Compliance guidance published by the Office of Inspector General (OIG) in 2008 states that a laboratory "should take all reasonable steps to ensure that it is not submitting claims for services that are not covered, reasonable and necessary." [1] The OIG has also imposed an education requirement on clinical laboratories, stating that laboratories "are in a unique position to educate their physician clients." [2] According to the OIG, they should advise physicians that claims will be paid only if the service is "covered, reasonable, and necessary for the beneficiary, given his or her clinical condition." [3] Additionally, physician clients should be provided with annual written notices that include specified information regarding Medicare payment policies. [4] Physician clients who use "customized profiles"

should receive an additional notice warning that sanctions may be imposed for causing the submission of false claims. [5]

CASE LAW

There has been significant litigation regarding application of the FCA to claims for clinical laboratory tests that are not medically necessary. The mere fact that a claim submitted by a laboratory is for a test that is deemed not medically necessary should not result in FCA liability. According to one federal court, "a laboratory may rely on the ordering physician's determination of medical necessity in the laboratory's certification to HHS on the CMS-1500 form." [6] The court's finding, however, did not result in dismissal of the FCA claims against the laboratory. The court stated that the relator's allegation that the laboratory encouraged physicians to order medically unnecessary tests through a false marketing program and test panels on pre-printed requisition forms could violate the laboratory's duty to ensure that it was not submitting false or incorrect claims, a duty reflected in the OIG Compliance Guidance.

In *United States ex. rel. Reidel v. Boston Heart Diagnostics Corp.*, 2018 WL 4354944 at *12-13, 16, Medicare & Medicaid Guide (CCH) ¶ 306,368 (D. D.C. Sept. 12, 2018), the United States District Court for the District of Columbia recognized that submission of false claims had been adequately alleged based on a laboratory's use of a pre-selected panel of tests that resulted in claims for unnecessary services, but dismissed the claim against the laboratory because it had not been alleged that the laboratory knew that the tests resulting from use of the pre-selected test panels were not medically necessary. Another federal court indicated that while a physician's certification of medical necessity may generally provide protection against FCA liability for submitting claims for unnecessary services, that would not be the case where the provider "had a specific basis to second-guess" the physician's certification of the patient's medical needs, *i.e.*, the laboratory was on notice that there was a substantial risk that the physician's certification was false. [7]

Medical necessity issues can also impact providers of anatomic pathology services. Medicare permits pathologists to order special stains when they are medically necessary and other requirements are satisfied. [8] Although pathologists have argued that this should be a matter of medical judgment, a recent settlement indicates that the Department of Justice (DOJ) may disagree. DOJ required a North Carolina pathology group to pay approximately $600,000 to settle FCA allegations for billing allegedly unnecessary special stains. In its related press release, DOJ stated: "The government considers the use of special stains before the analysis of the routine…stained specimen to be medically unnecessary." [9]

Submission of claims for tests that are not medically necessary can also lead to criminal penalties if they are part of a scheme to knowingly and willfully defraud Medicare or another health care benefit program. A federal appellate court recently upheld the criminal conviction of the owner of an addiction medicine clinic and independent clinical laboratory and an individual who assisted her based on the laboratory's submission of claims for medically unnecessary tests. The Court found that referring physicians ordered tests but did not specify the type of test. The defendants decided which tests would be performed based on whether or not the patient was insured. This resulted in insurers being billed for sophisticated tests that the defendants knew were unnecessary. [10]

Similarly, in *U.S. v. Bertram,* 900 F.3d 743, 748-51 (6th Cir. 2018), a United States Court of Appeals upheld the conviction of owners of a toxicology laboratory that had filed claims for testing frozen urine samples seven to 10 months after their receipt and had not disclosed the testing delay on the related payment claims. In upholding the jury's determination that the laboratory's owners had violated the federal health care fraud statute, 18 U.S.C. § 1347, the appellate court stated that the laboratory's owners had reason to know that the tests were no longer medically necessary when they submitted the payment claims, and that the claims omitted the date on which the tests were ordered and samples collected.

According to the court, fraud includes "half-truths" that omit material facts, in this case, the substantial testing delay. The court recognized that generally a laboratory can rely on the physician's certification that the tests were medically necessary at the time that the tests were ordered but stated that that did not protect the laboratory's owners when they knew that the laboratory's own acts—its extreme delay in testing the specimens—had made the tests medically unnecessary. That, combined with the laboratory's failure to disclose the testing delay to the insurer, was adequate grounds to violate the federal health care fraud statute. The decision demonstrates that tests can be medically unnecessary for many reasons, and when related payment claims are submitted, sanctions can be imposed, particularly when the tests were known by the laboratory to be not medically necessary.

ADMINISTRATIVE SANCTIONS FOR UNNECESSARY TESTS

A clinical laboratory's administrative liability for submission of claims for tests that are not medically necessary depends upon the specific regulation and particularly whether it includes an intent standard. As discussed in the first part of this article, any suspected overpayment can result in suspension of Medicare payments. [11] Similarly, Medicare billing privileges can be revoked for a pattern or practice of claiming payments for unnecessary services, apparently without regard to whether the laboratory had reason to believe that the tests were not medically necessary. [12] Civil money penalties may be assessed for submitting a claim for an unnecessary item or service, but only if it is an "item or service that a person knows, or should know is medically unnecessary, and which is part of a pattern of such claims." [13]

TOXICOLOGY TESTING

The opioid crisis is well recognized. The need for toxicology testing is likely to increase significantly as part of medical treatment of opioid-dependent individuals. Audits and investigations of laboratories performing these tests are currently common and may become even more frequent in the future, particularly given findings from previous audits and investigations of toxicology testing arrangements.

Toxicology testing related to drugs of abuse generally includes two types of tests: (1) "screening" tests, sometimes referred to as "presumptive" testing, and (2) "quantitative" or "definitive" testing that identifies the specific drug and quantity in the patient. Compliance issues related to toxicology are similar to those related to other types of clinical laboratory testing. The Centers for Medicare & Medicaid Services (CMS) has determined that significant amounts were improperly paid for urine drug screenings based on insufficient documentation, including documentation necessary to support the physician's intent to order the test or to support its medical necessity for the individual patient, and unsigned medical records documentation. [14]

Laboratories performing toxicology testing have also been pursued by governmental authorities and private third-party payers for unnecessary tests, including tests performed too frequently, tests that were based on standing orders without assessment of the individual patient's needs, unnecessary or excessive quantitative testing that did reflect the results of the screening tests, and claims reflecting validity testing. [15] These findings should assist other laboratories performing toxicology testing comply with applicable regulatory requirements. Toxicology testing can also raise issues related to coding (including the use of modifiers, such as in *USA v. Wagoner,* No. 2018 WL 4539819 (N.D. Ind. 2018) (modifier 91)) and financial arrangements with referring physicians, as discussed below.

FEDERAL ANTI-KICKBACK STATUTE

The OIG's view of the anti-kickback statute (AKS), as applicable to clinical laboratories, is reflected in Special Fraud Alert: Laboratory Payments to Referring Physicians, *reprinted at* 79 Fed. Reg. 40,115 (July 11, 2014) (Special Fraud Alert). The AKS makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce, or in return for, referrals of items or services reimbursable by a federal health care

program. According to the OIG, when remuneration is paid purposefully to induce or reward such referrals, the AKS is violated. [16] The OIG stated that "both sides of an impermissible kickback transaction" are liable. [17] , [18] Violation of the AKS can result in criminal penalties, and exclusion from federal health care programs. The AKS also permits the OIG to initiate administrative exclusion proceedings or to impose civil money penalties for AKS violations. [19] Moreover, claims for items or services resulting from an AKS violation are not payable by Medicare and may constitute false claims under the FCA, even if the items or services are medically necessary. [20] , [21]

The OIG indicated that the AKS was implicated when a clinical laboratory pays a physician for services. Whether an actual violation occurs, however, depends on the intent of the parties, as the AKS prohibits knowing and willful payments if one purpose of the payment is to induce or reward referrals of federal health care program business. [22] According to the OIG, this is true even when the payment is fair market value for services rendered. The OIG stated that the probability that a payment was for an illegitimate purpose, however, was increased if it exceeded fair market value or was for a service for which the physician was already paid by a third party, such as Medicare. [23] The OIG recognized that historically it has been concerned with arrangements in which the amounts paid to a referral source took into account the volume or value of business that the referral source generated. [24]

APPLICATION OF AKS TO CLINICAL LABORATORIES

The OIG or DOJ has stated or strongly suggested that the following arrangements may violate the AKS, depending upon the parties' intent:

- Payment by clinical laboratories to physicians to collect, process, and package patients' blood specimens or to collect and package patients' buccal swabs or urine specimens. [25]
- Provision of free or below-market point of care urine testing cups to perform billable in-office testing. [26] The OIG has taken a similar position with respect to arrangements where physicians agreed not to bill any payer for tests using the free cups and to return the cup to the laboratory for testing of the patient's urine sample. The OIG is currently pursuing physicians who accepted free cups from laboratories. The government has also pursued laboratories that have provided referring physicians with free buprenorphine test strips.
- Payments by laboratories to physicians under service or consulting agreements under which physicians provided little, if any, services to the laboratory, [27] or for soliciting participants for an unlawful business arrangement with the laboratory. [28] In fact, any arrangements for payments to physicians for services are potentially problematic unless the services are necessary for the laboratory's legitimate business purposes, payments are fair market value and not directly or indirectly related to the physician's referrals, and the services are actually provided. It is preferable the arrangement satisfy an AKS safe harbor —which should provide complete protection under the AKS—and the arrangement *must* satisfy an exception to the Stark law (discussed below).
- Lease payments by laboratories to physicians for substantially more space than that required by the laboratory. [29] The OIG has not addressed generally rental arrangements with physician groups for space that is used predominantly or exclusively to collect specimens from the group's patients. It may question whether such arrangements satisfy the safe harbor requirement that the leased space not exceed what is "reasonably necessary to accomplish the commercially reasonable business purpose of the rental" because arguably the sole purpose of the lease is to obtain referrals from the physician group from which the space is leased, which may not be considered a "commercially reasonable business purpose." [30]
- Provision of items or services related to electronic health records. [31]

- Labeling test tubes and specimen collection containers for dialysis facilities, at no cost, by laboratory personnel in its own facility, as necessary to obtain or retain dialysis center business. [32]
- Laboratory's agreement with physician practices to waive fees for patients covered under insurance plans requiring use of another laboratory, permitting the practice to use the laboratory waiving fees for all of its patients. [33] The OIG relied on the convenience to physicians resulting from use of a single laboratory and possible savings of interface maintenance fees that would no longer be required if the physician used a single laboratory. It is uncertain whether the OIG would reach the same conclusion if there were no such savings, as would be the case if each laboratory paid maintenance costs related to the interface provided to the physician.
- Any arrangement in which the laboratory intends to induce future referrals or generate business that will be paid under a federal health program or to compensate the other party for previous referrals or generation of business, payable under a federal health program.

The OIG has stated that the following arrangements should be permissible under the AKS:

- Any arrangement that satisfies a safe harbor to the AKS, including safe harbors for space or equipment rental arrangements, personal service and management contracts, and payments to bona fide employees. [34]
- Placement of a phlebotomist in a physician's office to collect specimens from the physician's patients, where the phlebotomist does not perform any services that are generally performed by office staff, including testing in the physician's office lab or clerical or medical functions. [35] Laboratories placing phlebotomists in a physician's office should monitor compliance on an ongoing basis. They also should confirm that the arrangement is consistent with state law that may specifically prohibit such arrangements.
- Physician discounts on tests covered by private payers as part of client-billing arrangements, so long as the discount is not linked to the referral of federal health care program business, such as Medicare. [36] A discount should not be used to induce such referrals, or vary with the volume or value of such referrals. A medical practice that refers more tests covered by Medicare or Medicaid than another lab that purchases an equal amount of tests covered by private payers should not receive a greater discount reflecting the Medicare and Medicaid referrals. Additionally, the discount arrangement should make commercial sense on a standalone basis, *i.e.*, profitable even if the laboratory did not receive referrals of any tests covered under a federal health care program. According to the OIG, discounted charges that are below "fully loaded costs" are suspect. There is, however, significant support that prices that exceed marginal cost should be sufficient under the AKS. [37] , [38]
- Provision of an electronic interface that would allow physicians to transmit orders for laboratory and diagnostic services and receive test results, offered to all physicians requesting the interface. [39] As discussed below, CMS has reached a similar conclusion under the Stark law.

ELIMINATING KICKBACKS IN RECOVERY ACT OF 2018

On October 24, 2018, the President signed the Eliminating Kickbacks in Recovery Act of 2018 (EKRA), sections 8121-8122 of the "Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act" or the "SUPPORT for Patients and Communities Act." This law effectively extended federal kickback prohibitions to clinical laboratory services covered under a private insurance plan or contract. The statute also applies to clinical laboratory services covered under a public plan, including Medicare and Medicaid, except for conduct that is already prohibited under the AKS. Statutory violations are punishable by fines up to $200,000, or imprisonment for up to 10 years, or both, for each unlawful "occurrence."

The statute includes seven specific exceptions, including an exception for discounts that reflects substantially the same language as the related statutory exception in the AKS and an exception for arrangements that satisfy the AKS safe harbor for personal services and management agreements, as that safe harbor is currently in

effect These exceptions do not include all of the arrangements protected by a safe harbor under the AKS, including space and equipment rental arrangements. Additionally, as discussed below, the statutory exception for payments to employees is more restrictive than the AKS statutory exception and related safe harbor.

The statute permits the U.S. Attorney General, in consultation with the Secretary of Health and Human Services, to publish regulations that clarify the statutory exceptions or create safe harbors specifying conduct or arrangements that will be considered permissible under the law. While any final regulations will likely take some time to develop, laboratories should closely monitor developments, including any statements from the OIG or DOJ, particularly regarding anticipated enforcement efforts and whether the agency intends to develop safe harbors for arrangements similar to those that apply to the AKS. Statutory amendments are also possible, including those that might limit the application of the EKRA to laboratory tests that are related to drug testing or for patients of a recovery home or a clinical treatment facility, other providers which are subject to the EKRA.

FEDERAL SELF-REFERRAL STATUTE

The federal self-referral statute (Stark law) generally prohibits a physician from making a referral of a designated health service (DHS) covered under Medicare to an entity with which the physician or an immediate family member has a financial relationship. [40] DHS includes clinical laboratory tests and anatomic pathology procedures. [41] A financial relationship may include a direct or indirect ownership or investment interest or compensation arrangement. [42] In addition to penalties provided for in the Stark law, including nonpayment for services resulting from an impermissible referral, Medicare payment claims that result from Stark law violations may violate the FCA. [43]

The Stark law's broad self-referral prohibition is limited by specific definitions and exceptions. The definition of "referral" excludes services personally performed by the referring physician and certain services requested by a pathologist. [44] , [45] As a result, these services would not be subject to the self-referral prohibition. Similarly, under the Stark law, items, devices, or supplies that are used only to collect, transport, process, or store specimens for the laboratory providing them or to order or communicate the results of tests or procedures for the laboratory are not considered "remuneration." [46]

CMS has issued several opinions related to this provision. CMS has determined that the carve-out from the definition of remuneration permits the provision of a custom software interface used to order or communicate the tests and procedures furnished by the entity providing the interface to the physician, so long as the interface could not be used or modified to perform an alternate function and could not be resold or otherwise transferred. [47] CMS has also concluded that it was permissible for a laboratory's electronic test results to include additional information regarding recommended follow-up laboratory tests and a mechanism for the physician to select one or more of these tests. [48]

CMS has stated that the provision permits a laboratory to provide physicians with single-use liquid-based pap smear collection kits. [49] A laboratory may not, however, provide disposable, single use specula to collect pap smear specimens because they are not used solely to collect, transport, process, or store specimens, or disposable biopsy brushes because such brushes are considered surgical items, devices, or supplies that are not protected under the related regulation. [50]

Unless a financial relationship with a physician complies with one of the stated exceptions to the Stark law, a clinical laboratory will be unable to claim payment for clinical laboratory tests or anatomic pathology procedures covered under Medicare that were referred by the physician with whom it has the financial relationship. Exceptions to the self-referral prohibition that are of particular interest to clinical laboratories include:

- Physician services meeting specified requirements (potentially applicable to certain anatomic pathology services);

- In-office ancillary services that permit physicians and certain group practices to operate in-office laboratories;
- Rental of office space or equipment;
- Payments under bona fide employment relationships and under personal services arrangements;
- Indirect compensation arrangements;
- Payments by physicians for clinical laboratory services; and
- Nonmonetary compensation.

Each exception has particular requirements that must be satisfied. The exceptions for rental, personal service, and indirect compensation arrangements generally require the arrangement to be set out in writing, signed by the parties, have a minimum term of one year, not involve items or services that exceed what is necessary for legitimate purposes, and provide for compensation that is set in advance, consistent with fair market value, and not based on volume or value of referrals or business generated between the parties. [51]

The exception for nonmonetary compensation permits a clinical laboratory to provide a physician with items or services with a value that does not exceed a specified amount, which amount is adjusted each year based on changes to the CPI. [52] The maximum amount for 2018 is $407. The exception does not apply to cash or cash equivalents such as an American Express gift card that can be used generally for payment or a card that can be converted into cash. Items that may be provided include dinner, tickets to a sporting event, or a gift card that may be used at a specific store or restaurant only. The value of the items or services provided cannot reflect the volume or value of referrals or other business generated by the referring physician, may not have been solicited by the physician or his or her practice, and the arrangement may not violate the AKS.

A clinical laboratory should require that all such nonmonetary compensation be reported by the employee providing it to the physician and have a mechanism to make sure that the maximum permissible amount is not exceeded. The regulation does provide a cure mechanism for provision of excess nonmonetary compensation, but only if the excess value was not more than 50 percent of the limit and is repaid by the physician. Otherwise, the laboratory will violate the Stark law each time it claims Medicare payment for a laboratory test referred by the particular physician who received excessive nonmonetary compensation.

PRIVATE PAY ARRANGEMENTS

Federal Anti-Kickback Statute

Clinical laboratories increasingly enter into business arrangements that are limited to tests paid for by private payers. The intent frequently is to avoid the AKS and other federal laws that apply to Medicare, Medicaid, and other federal health care program business. Recent decisions demonstrate that this strategy may not be successful when the arrangement potentially affects the flow of business paid for under a federal health care program.

In *United States ex rel. Bruno v. Schaeffer*, 328 F. Supp. 3d 550 (M.D. La. 2018), a whistleblower alleged that physicians were offered investments in what were referred to as physician-owned labs. These laboratories, however, did not actually exist, and physician investors were paid based on their referrals to another laboratory, Quantum, for urine testing covered by private insurance. Participating physicians were also said to have been encouraged to refer tests covered under a federal health care program to a different laboratory, known as MedComp.

The court held that the facts alleged resulted in an impermissible indirect compensation arrangement between the physicians and MedComp in violation of the Stark law. [53] The court also determined that an AKS violation had been adequately asserted, rejecting the defendants' argument that it had been alleged only that physicians were paid based on referrals of *private insurance patients* to Quantum, and that it had not been alleged that physicians were provided a financial incentive to refer Medicare and Medicaid tests to MedComp. [54] According to the court, "[c]ompensation for private insurance referrals may constitute a payment to induce referrals of

federal health care program business if there is a nexus between the kickbacks for private insurance and Medicare or Medicaid business." [55] The court stated that it was plausible that physicians would send urine specimens covered by Medicare and Medicaid to MedComp because they received remuneration for referrals of private business to Quantum. [56]

Likewise, in *U.S. ex rel. Lutz v. Berkeley HeartLab, Inc.*, 247 F. Supp.3d 724, Medicare and Medicaid Guide (CCH) ¶ 305,901 (D. S.C. 2017), *appeal docketed sub nom. U.S. v. Johnson*, No. 18-01813 (4th Cir. July 18, 2018), another federal court determined that the waiver of copayments and deductibles related to private insurance policies could violate the AKS. According to the allegations—which were found sufficient to withstand a motion to dismiss—the company "leveraged the laboratories' no-balance billing practices to induce physician referrals by highlighting the practice in written pamphlets it gave to physicians." [57] The court stated that the induced referrals included all of the physicians' patients, including Medicare beneficiaries. [58] A similar determination was made by the United Stated District Court for the District of Columbia in *United States ex rel. Reidel v. Boston Heart Diagnostics Corp.,* 2018 WL 4354944 at *9-10, Medicare & Medicaid Guide (CCH) ¶ 306,638 (D. D.C. Sept. 12, 2018), in which the laboratory was alleged to have conditioned waiver of copayments and deductibles on the physician's continued referrals to the laboratory, including tests covered under Medicare.

These recent court decisions are consistent with the OIG's longstanding view. In OIG Advisory Op. No. 13-03 (June 30, 2013), the OIG declined to protect a proposed lab management arrangement with physicians that did not involve tests for federal health care program beneficiaries because it could increase the likelihood that the physicians would order services payable under a federal health care program from an independent lab that was related to the management company. [59]

These authorities demonstrate that the AKS requires careful consideration whenever one party to a business arrangement is in a position to refer tests covered under a federal health care program to another party to the arrangement (or otherwise generate business for the other party), or a related entity, irrespective of the basis for payments under the arrangement. Finally, state laws should not be disregarded. Many arrangements that would violate the AKS if payments under a federal health care program were involved violate state laws that frequently apply irrespective of the payer for the related services.

Eliminating Kickbacks in Recovery Act

As previously stated, the EKRA effectively extended federal kickback prohibitions to clinical laboratory services covered under private insurance arrangements. This statute may make arrangements which provide physicians with financial benefits from their referrals of clinical laboratory services paid by private payors an historic relic. Generally, arrangements limited to clinical laboratory tests paid by such payors will now be subject to the same kickback restrictions as arrangements that include tests covered under a federal health care program.

MARKETING ARRANGEMENTS

Compensation Arrangements

It has been generally acknowledged that payment of independent contractor sales representatives on a commission basis can be viewed as an AKS violation. [60] By contrast, while there have been occasional challenges to such arrangements, arrangements in which employed sales persons are paid on a commission basis have generally been viewed as permissible under the AKS, based on the statutory exception and related safe harbor for *bona fide* employment relationships. [61] , [62]

The statutory exception for payments to employees under EKRA prohibits payments that reflect the number of individuals referred to the laboratory, the number of tests performed, or related amounts billed or received for laboratory services. Therefore, longstanding commission-based payment arrangements that are permissible under the AKS may now be unlawful.

Marketing Activities

Compliance with requirements related to a laboratory's payment of sales representatives does not exempt the participants in the arrangements from other legal and regulatory requirements. As discussed above, the Stark law includes specific limitations on nonmonetary compensation that may be provided by sales representatives to referring physicians. Other financial benefits provided to referring physicians by employed sales representatives would violate that statute and potentially the AKS. The OIG has stated that laboratory marketing should be "clear," "correct," "honest," "straightforward," "fully informative", and "non-deceptive," such that physicians and other individuals authorized to order tests fully understand the services offered by the laboratory, the services that will be provided when tests are ordered, and the financial consequences for Medicare and other payers. [63] A recent federal district court decision affirms that the provision of false information that could induce physicians to order unnecessary tests, such as an untrue statement regarding a Medicare recommendation related to frequency of testing, can result in FCA liability. [64]

Moreover, even if the individuals directly involved in marketing did not provide any unlawful benefits to referring physicians or provide them with false or misleading information, they could be held liable for marketing an unlawful arrangement or an arrangement that would result in the laboratory's receipt of improper payments. The United States District Court for the District of South Carolina determined that when marketing consultants had knowledge that the arrangements which they marketed violated or presented a substantial risk of violating the AKS, or evidence that the arrangement's purpose was to induce referrals, a reasonable jury could conclude that they had the intent necessary to violate the AKS, on which several FCA claims were based. Similarly, the court found evidence that the tests were not medically necessary was sufficient to permit the government to continue its claim that the marketing consultants induced physicians to order medically unnecessary tests. [65]

PASS-THROUGH AND OTHER SIMILAR ARRANGEMENTS

Hospitals have marketed clinical laboratory tests to community physicians for their nonhospital patients for decades. These types of arrangements are frequently referred to as laboratory "outreach" programs. While many such arrangements continue to exist, new types of arrangements have been developed to take advantage of the hospital's in-network status with private insurers and, in some cases, its favorable payment rates.

These arrangements—often referred to as "pass-through billing"—are frequently joint ventures between hospitals and outside entities, such as reference labs or lab management or marketing companies. There are numerous variations of these arrangements.

In one such variation, tests are collected in areas outside the hospital's usual catchment area and referred to the hospital, which performs and bills for the tests. When the hospital is located in a rural area, it may receive payments based on higher rates than a nonrural facility, even though the tests are performed for individuals residing in a nonrural area. In another variation, a hospital may pay another laboratory to perform tests ordered from the hospital and then file the claim as if it had performed the test itself. These types of arrangements have resulted in a series of lawsuits from private insurers to which claims have been submitted which have asserted that its participation contract with hospitals was not intended to apply to these types of arrangements.

While these arrangements are often discussed without distinction, the details of the arrangement are important, including the terms of the hospital's participation agreement with the private insurer. In evaluating such arrangements, it is important to determine whether the hospital's claims for payment comply with the hospital's participation agreement and any related billing and payment rules. Payment claims must accurately reflect the arrangement, particularly, the laboratory performing the test. In the event that the hospital did not perform the tests for which it seeks payment, there must be a factual and legal basis for submitting the payment claim. While many payment arrangements recognize the need for laboratories to refer tests to a reference laboratory and permit the referring laboratory to bill for such tests, it may be difficult to assert that a hospital may claim payment

for a test performed by another laboratory on that basis when the test specimen was transported directly to the testing laboratory and the hospital's only involvement was submitting the payment claim.

Marketing services are frequently part of these types of arrangements. The hospital's joint venture partner may arrange for physician referrals to the hospital for laboratory testing. Even if the arrangement between the hospital and joint venture partner is limited to tests paid for by private third-party payers, compensation arrangements related to marketing services may raise issues under the EKRA, as well as state anti-kickback laws. Likewise, the hospital may want to address the joint venture partner's relationship with physician referral sources to avoid participation in an arrangement in which the partner unlawfully compensates physicians for referrals.

Finally, the hospital should consider financial issues related to these arrangements. Under these arrangements, third-party payers will pay the hospital for tests. If such payments are subsequently determined to have been improper, the payer may attempt to recoup the entire amount from the hospital, even though a substantial part of the payments received were paid by the hospital to its joint venture partner. [66]

CONCLUSION

Application of legal and regulatory requirements to clinical laboratory services can be complicated, and answers are not always clear cut. Careful attention to compliance is required, nevertheless, to minimize related legal, regulatory, and financial risks, and to operate on a profitable basis in an increasingly difficult and competitive environment.

Footnotes

1 HHS, OIG, Publication of OIG Compliance Guidance for Clinical Laboratories, 63 Fed Reg. 45,076, 45,079 (Aug. 24, 1998) (OIG Compliance Guidance).

2 *Id.*

3 *Id.*

4 *Id.*

5 *Id.* at 45,079-80.

6 *United States ex rel. Groat v. Boston Heart Diagnostics Corp.*, 296 F. Supp. 3d 155, 158, Medicare & Medicaid Guide (CCH) ¶ 306,186 (D. D.C. 2017).

7 *U.S. ex rel. Allen v. Alere Home Monitoring, Inc.,* 2018 WL 4119667 at *13, Medicare & Medicaid Guide (CCH) ¶ 306,359 (D. Mass. Aug. 29, 2018).

8 *See* Medicare Benefit Policy Manual (MBPM), Ch. 15, § 80.6.5.

9 Hickory Pathology Lab Agrees To Pay The United States $601,000 To Settle False Claim Allegation.

10 *U.S. v. Palin,* 874 F.3d 418, 424-25, Medicare & Medicaid Guide (CCH) ¶ 306,153 (4th Cir. 2017) *cert. denied*, 138 S. Ct. 1451 (2018), and *cert. denied sub nom*. *Webb v. United States*, 138 S. Ct. 1605 (2018).

11 42 C.F.R. § 405.371 (2017).

12 *See* 42 C.F.R. § 424.535(a)(8)(ii) (2017).

13 42 C.F.R. § 1003.102(a)(6) (2017).

14 Medicare Learning Network (MLN), Provider Compliance Tips for Laboratory Tests—Other—Urine Drug Screening, ICN 909412 (September 2016).

15 CMS recently specified that providers performing validity testing on urine specimens used for drug testing may not separately bill for those tests. MLN Matters, Proper Coding for Specimen Validity Testing Billed in Combination With Drug Testing, SE18001 (March 29, 2018).

16 Special Fraud Alert, 79 Fed. Reg. at 40,115.

17 *Id.*

18 In the past, enforcement activities have been principally directed at entities that provided kickbacks, rather than physicians who received it. That is no longer the case. As of May 31, 2018, 38 physicians have been convicted in connection with unlawful financial arrangements with Biodiagnostic Laboratory Services, LLC of Parsippany, New Jersey.

19 Special Fraud Alert, 79 Fed. Reg. at 40,115–116.

20 *Id.* at 40,116.

21 *See* 42 U.S.C. § 1320a-7b(g) ; *see also U.S. ex rel. Reidel v. Boston Heart Diagnostics* 2018 WL 4354944 at *3 (violations of FCA and Stark statute can be pursued under FCA because they would influence Medicare's decision to pay claims).

22 Special Fraud Alert, 79 Fed. Reg. at 40,116–117.

23 *Id.*

24 *Id.*

25 Special Fraud Alert, 79 Fed. Reg. at 40,116 n.5; *U.S. ex rel. Reidel v. Boston Heart Diagnostics*, 2018 WL 4354944 at *19–20.

26 79 Fed. Reg. at 40,116 n.5.

27 Criminal Complaint, *USA v. Biodiagnostic Lab. Servs, LLC,* Magistrate No. 13-8106 (D. N.J. April 9, 2013).

28 *See U.S. ex rel. Reidel v. Boston Heart Diagnostics*, 2018 WL 4354944 at *11–12.

29 Criminal Complaint, *USA v. Biodiagnostic Lab. Servs.*

30 *See* 42 C.F.R. § 1001.952(b)(6).

31 42 C.F.R. § 1001.952(y)(1)(i) (clinical laboratories excluded from permissible donors of EHR).

32 OIG Advisory Op. No. 16-12 (Dec. 5, 2016).

33 OIG Advisory Op. 15-04 (March 25, 2015).

34 *See* 42 C.F.R. § 1001.952(b), (c), (d), (i).

35 Special Fraud Alert: Arrangements for the Provision of Clinical Laboratory Services (Oct. 1994), *reprinted at* 59 Fed. Reg. 65,372, 65,377 (Dec. 19, 1994).

36 OIG Advisory Op. No. 99-13 (Dec. 7, 1999) ; Letter from Kevin G. McAnaney, OIG Industry Guidance Branch (April 26, 2000) (addressee redacted) (available on OIG website, Special Fraud Alerts, Bulletins, and other Guidance, Other Guidance).

37 *U.S. ex rel. McDonough v. Symphony Diagnostic Servs, Inc.,* 36 F. Supp.3d 773, 779-781, Medicare and Medicaid Guide (CCH) ¶ 305,029 (S.D. Ohio 2014).

38 The OIG's Mr. McAnaney also addressed the prohibition against charging Medicare substantially more than the provider's usual charge (42 U.S.C. § 1320a-7(b)(6)(A)) and stated that the prohibition is not implicated unless the overall volume of test charges made to payers other than Medicare or Medicaid that are below the Medicare/Medicaid fee schedule exceed one-half of the non-Medicare/non-Medicaid test volume. To our knowledge, the OIG has never pursued sanctions under this statutory provision.

39 OIG Advisory Opinion No. 12-20 (Dec. 19, 2012).

40 42 U.S.C. § 1395nn(a).

41 42 C.F.R. § 411.351 (definition of "clinical laboratory services").

42 42 C.F.R. § 411.354.

43 *U.S. ex rel. Drakeford v. Tuomey Healthcare Sys.,* 792 F.3d 364, 374, n.4, Medicare & Medicaid Guide (CCH) ¶ 305,342 (4th Cir. 2015). *See* also, n. 21.

44 42 C.F.R. § 411.351.

45 Each of the exceptions and definitions included in agency regulations reflects a provision of the Stark law. *See* 42 U.S.C. § 1395nn. For convenience, we will refer to the corresponding regulation.

46 42 C.F.R. § 411.351.

47 CMS-AO-2008-01.

48 CMS-AO-2017-1.

49 CMS-AO-2013-1.

50 CMS-AO-2010-01, 2013-02.

51 42 C.F.R. § 411.357(a), (b), (d), (p).

52 42 C.F.R. § 411.357(k).

53 *Schaeffer*, 328 F. Supp. 3d at 558–59.

54 *Id*. at 559–61.

55 *Id*. at 560.

56 *Id*. at 561.

57 *Berkeley HeartLab,* 247 F. Supp. 3d at 731.

58 *Id*.

59 *See also,* Special Fraud Alert at 40,117 ("Arrangements that 'carve out' Federal health care program beneficiaries or business from otherwise questionable arrangements implicate the anti-kickback statute and may violate it by disguising remuneration for Federal health care program business through the payment of amounts purportedly related to non-Federal health care program business").

60 *Joint Tech, Inc. v. Weaver*, Medicare & Medicaid Guide (CCH) ¶ 304, 295 (W.D. Okl. 2013).

61 *See generally*, *U.S. ex rel. Carrel v. AIDS Healthcare Found., Inc.,* 898 F.3d 1267, 1272-75, Medicare & Medicaid Guide (CCH) ¶ 306,346 (11th Cir. August 7, 2018).

62 On January 25, 2018, the DOJ announced settlement of an FCA action brought against a clinical laboratory, Primex Clinical Laboratories, LLC and DNA Stat, LLC, said to be a "laboratory management agreement that employed sales representatives…." Laboratory and Owner of Lab Management Services Company to Pay $3.77 Million to Resolve Kickback and Medical Necessity Claims (Jan. 25, 2018). The settlement resolves allegations against Primex including those related to an "improper sales and services agreement." According to the DOJ, the government contended that "DNA Stat's agreement with Primex as well as its agreements with its sales representatives took into account the volume and value of referrals physicians made to Primex for pharmacogenetic tests when calculating compensation." It does not appear that the arrangement involved a laboratory's employment relationship with commissioned sales representatives which would have been protected by the related statutory exception and safe harbor referred to above.

63 OIG Compliance Guidance, 63 Fed. Reg. at 45,081.

64 *U.S. ex rel. Allen v. Alere Home Monitoring,* 2018 WL 4119667, at *8, Medicare & Medicaid Guide (CCH) ¶ 306,359 (D. Mass. Aug. 29, 2018).

65 *U.S. ex rel. Lutz v. Berkeley HeartLab, Inc.,* 2017 WL 4803911, at *4-6, Medicare & Medicaid Guide (CCH) ¶ 306,140 (D. S.C. 2017), *appeal docketed sub nom. U.S. v. Johnson*, No. 18-01813 (4th Cir. July 18, 2018)

66 In a recent revision to the Medicare Program Integrity Manual, CMS instructed Medicare contractors involved with review, audit, or recovery activities to deny claims for clinical laboratory tests based on the lack of signed documentation reflecting the test order or where the contractor is unable to verify the test's medical necessity in the physician's medical record. Pub. 100-08, Medicare Program Integrity, Transmittal 836, CR10908 (Oct. 19, 2018). Private payers may take similar actions. Under many arrangements of the type discussed above, the hospital billing for the lab tests will have little if any contact with the referring physician, making it particularly difficult to secure his or her cooperation in obtaining patient medical records that may be required

to demonstrate to a third-party payer that lab tests requested by the physician were medically necessary and otherwise covered services.