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INSIDE *NIR*

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Appeals Court Upholds Broad Definition of "Referral" in Kickback Case

You can't avoid anti-kickback liability by splitting hairs—at least not when it comes to defining the word "referral." One physician alleged to have accepted payments for home health referrals tried to argue he never *actually* made any referrals so the payments couldn't be illegal kickbacks. That physician said referral should be defined as directing a patient to obtain services from a particular provider. He claimed that since he never told the patient where to get home health services, instead letting the patient choose, he wasn't paid for referrals. But the government said that interpretation defined the word "referral" too narrowly and the 7th Circuit Court of Appeals agreed. The court said referral also means to authorize services and to facilitate Medicare reimbursement.

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FTC Gets Ready to Flex Enforcement Muscle Regarding Healthcare Integration

With all the talk about using accountable care organizations (ACOs) and other ventures to integrate and coordinate health care services, reduce costs, increase efficiency, and move from volume to value, laboratories and other providers must be aware that one government enforcement entity is watching this shift with concern. The Federal Trade Commission (FTC) is charged with protecting competition and has been focusing on the potential anti-competitive effects of changes in the health care industry for many years. This month it is hosting a workshop titled "Examining Health Care Competition" to "study recent developments related to health care provider organization and payment models that may affect competition and consumer protection in the provision of health care services."

The agenda for the latest workshop focuses on five topic areas:

- Accountable Care Organizations,
- Alternatives to fee-for-service payment,
- Provider consolidations,
- Provider networks and insurance benefit packages, and
- Health insurance exchanges.

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Appeals Court Upholds Broad Definition of "Referral" in Kickback Case, *from page 1*

What happened

The physician claimed he never responded to offers from a home health company's owners for payments in exchange for referring Medicare patients for home health services. But the government claimed that after such offers were made, the home health company began providing services to a few of the physician's patients every month. The court noted that it was irrelevant whether the physician verbally or otherwise expressed his agreement with the referral scheme because his actions—accepting the payments—constituted conspiracy to violate the law.

The court said that whether or not the physician guided the selection of the health care provider was not the most important criteria for determining whether a referral occurred but rather whether the physician "facilitates or authorizes that choice."

— United States v. Patel, 7th Cir., No. 14-2607, 2/10/15.

The home health company was alleged to have paid the physician about $400 every time he certified a patient was eligible for and needed home health services and $300 every time he re-certified a patient for home health services. The physician made the certifications using required Form 485, which the home health agency prepared whenever the physician's patient chose that company for home health services.

The physician argued he never "referred" any patients because he never told patients to choose a specific home health provider and "the patients independently chose" their provider. In fact, he claimed to not have discussed home health providers at all but rather his medical assistant would provide brochures for several home health providers and the patients would select one. After the patient selected a provider, a Form 485 certification was completed and signed by the physician to authorize those services for reimbursement. The government asserted that the home health company paid the physician in cash each time he completed a Form 485 and that the physician had even indicated to the company via telephone on one occasion that he wasn't ready to sign the forms until the company was able to provide the cash payments. The physician was found guilty and sentenced to eight months jail time and 200 hours community service and had to forfeit the $31,900 of kickbacks he received.

Definition of referral

The physician argued that the general dictionary meaning of the word referral was "to personally recommend to a patient that he seek care from a particular entity." On the other hand, the government argued the term meant not just a recommendation about provider selection but "authorization of care by a particular provider."

The court agreed that common dictionary meaning of the term was to direct a patient to a provider for service but said that "is not the only common usage." The term is also commonly used in the health care industry to refer to a physician's authorization of care for health insurance purposes. In fact, the court noted, the physician in this case called patients receiving home health services for the first time "new referrals" when he submitted patient information to the home health care provider. The court said that whether or not the physician guided the selection of the health care provider was not the most important criteria for determining whether a referral occurred but rather whether the physician "facilitates or authorizes that choice." It is the physician's "gatekeeper" role that constitutes a referral, the court explained: "Without his permission, his patients' independent choices were meaningless."

OIG Advisory Opinion Addresses Payment After Program Exclusion

The OIG released an Advisory Opinion that confirms what happens after a provider is excluded from participation in federal programs with regard to reimbursement earned prior to exclusion. An excluded practitioner sold a practice to a buyer and as part of the sale required the buyer to remit to the excluded practitioner any payments received for services rendered prior to the exclusion date. The seller sought the Advisory Opinion to make sure this arrangement would not violate the law. If so, it would mean the provider could be subject to administrative sanctions.

Technically, the relevant law states that no payments from government programs such as Medicare and Medicaid can be made for any "item or service furnished by that [excluded] individual on or after the effective date of the exclusion." Payment can't even be made to another provider who provides services at the "medical direction" or pursuant to a prescription of an excluded physician if the provider had reason to know of the exclusion.

The OIG confirmed that this prohibition only applies when the service or item is provided "on or after the effective date of the exclusion." So it wouldn't apply to services provided before the exclusion date. Thus, in this case, the seller requesting the opinion could require the buyer to forward any payments received for services the selling practitioner rendered before the exclusion.

This advisory opinion, as with all OIG advisory opinions, is only applicable to the factual situation described in the request for the opinion. But this advisory still provides some comfort to providers involved in acquisitions when addressing how to deal with payments received for services rendered prior to an exclusion.

Source

Office of Inspector General, Advisory Opinion No. 15-02, Feb. 13, 2015.

Takeaway: The OIG confirms what may be an obvious expectation of providers—despite being excluded from Medicare participation, providers can keep payments for services rendered prior to that exclusion, regardless of when those payments are received. G2

The physician also tried to argue, to no avail, that the specific and very express definition of referral provided in the Stark law should be considered. That law and its regulations define a referral to be "the request by a physician for a consultation with another physician" or the "request or establishment of a plan of care" or request or order or certifying or recertifying the need for health care services. The physician argued that because the Anti-Kickback Statute didn't include similarly broad definitions, the ordinary dictionary meaning should apply. The court rejected this argument, however, and relied on the purpose behind the Anti-Kickback Statute to support its interpretation of referral to include certification and recertification of healthcare services for reimbursement purposes.

No harm, still foul

The court also said it was irrelevant that the government had conceded that all the patients did truly need the services provided and therefore, as the physician argued, there was no harm to the Medicare system. The court said there was still a danger of fraud because the physician could increase the cost of care by refusing to certify or recertify a patient unless he received the demanded kickback. And it would give the physician incentive to recertify services from a particular provider even if care wasn't really necessary or the provider wasn't providing quality care.

Legitimate payments are okay

The physician also argued that the government's definition of referral would mean a physician could violate the Anti-Kickback Statute for receiving *any* remuneration from an entity that happens to also treat the physician's patients. But the court clarified that "[p]ayments for legitimate services (such as giving a speech) cannot be construed as an illegal kickback." Instead, the physician has to "do *something* that either directs a patient to a particular provider or allows the patient to receive care from that provider."

This is relevant for labs because if a lab provides a physician payments based on patients who come to the lab for testing, it doesn't matter if the physician or a payer directs a patient to the lab or if the patient even randomly selects the lab. If the physician authorizes that test or otherwise facilitates reimbursement of that test, such payments could be a kickback.

(*United States v. Patel, 7th Cir.*, No. 14-2607, 2/10/15).

Takeaway: Another court has broadly interpreted the meaning of the word referral making it imperative that payments to physicians be carefully scrutinized for kickback liability. G2

CMS Seeks to Ease Meaningful Use Reporting Burdens

CMS announced it will be looking to ease the reporting burdens for participants in the meaningful use incentive programs beginning this year with a proposed rule change in the spring. CMS indicates the new rule would address issues raised by participants such as "software implementation, [and] information exchange readiness."

Some of the potential changes under review include:

- moving hospitals to a calendar year reporting period, giving them more time to adjust to new software and "align with other CMS quality programs";
- changes to the incentive programs that will reduce reporting obligations and complexity;
- reduce the 2015 reporting period to 90 days in light of these potential changes.

Note that CMS emphasized these proposed changes are separate from the Stage 3 proposed rule that should be released in March and will address meaningful use requirements for 2017 and beyond.

Takeaway: Pathologists were among the physician specialties granted exemption from payment reductions in 2015 that will be imposed for failure to satisfy meaningful use requirements. This further easing of burdens in the meaningful use initiative is a positive sign regarding CMS's willingness to acknowledge the realities and difficulties of complying with these requirements. G2

CMS Delays Final Rule on Overpayments

The Affordable Care Act requires providers to report and return overpayments and provide a reason for the overpayment within 60 days after discovering the overpayment or the due date for a related cost report, whichever occurs last. Failure to do so risks false claims liability. CMS published a proposed rule implementing this requirement in February 2012 and has yet to finalize that rule. Citing "significant policy and operational issues that need to be resolved" and a need to coordinate with other government agencies, CMS is extending the deadline for finalizing that rule by one year until Feb. 16, 2016.

However, that doesn't alleviate laboratories' and other providers' obligations to report and return overpayments promptly. It merely means there isn't a specific framework developed for these reports. CMS indicates it must collaborate with the DOJ and OIG in developing these regulatory requirements.

"Further delay is extremely frustrating for clinical laboratories and other providers which are required to report and return an overpayment within 60 days of its identification, but have not been provided any real guidance as to when an overpayment is considered to have been identified," says health care attorney Robert E. Mazer, of Ober Kaler in Maryland. "On the other hand," he adds, "the government may be hampered in relying on grounds provided for under the proposed rule that may go beyond what the law requires. Many believe, for example, that the statute does not permit penalties to be imposed for failure to make a 'reasonable inquiry'—'with all deliberate speed'—after receipt of information about a possible overpayment, as the proposed rule requires."

Takeaway: It's encouraging that CMS is taking time to consider operational issues and hopefully provide specific regulation that can clearly indicate how the overpayment requirements will be enforced; however, the delay creates uncertainties for those trying to comply and avoid the risk of false claims liability.

LabMD Must Complete Administrative Process Before Taking the FTC to Court

LabMD's challenge to FTC authority over health care data privacy will have to wait. You may recall the FTC investigated LabMD's data security practices and filed an administrative complaint after it was discovered that patient files were made available on "a peer-to-peer file-sharing network." LabMD sought to have a court declare the FTC didn't have authority to regulate or enforce health care data privacy. LabMD also asserted that the FTC's complaint was filed in retaliation for LabMD's CEO publishing a book about government corruption.

The 11th Circuit Court of Appeals has upheld a district court dismissal of LabMD's claims, saying the FTC hasn't yet issued a final determination from which LabMD can appeal. The court explained that it cannot get involved until such final action is taken: "The FTC is best suited to develop the factual record, continue to evaluate its position on the issues, and apply its expertise to complete the proceeding. All of this will allow for more robust appellate review by this Court when the action concludes." The court also rejected LabMD's argument that because it claims the FTC actions are unconstitutional, the appeal should be heard before administrative proceedings are finalized. The facts supporting LabMD's constitutional claims "are indistinguishable" from those relating to the "procedures and merits" of the FTC proceeding, the 11th Circuit explained. So, LabMD will have to wait for its day in court.

(*LabMD, Inc. v. Federal Trade Commission, 11th Cir.*, No. 14-12144, 1/20/15).

Takeaway: The court isn't going weigh in on whether the FTC should be enforcing health care data security until the FTC takes final action on a case.

LabCorp seeks injunction to stop former director from competing

LabCorp sued a former director of its preimplantation genetic diagnosis (PGD) testing division for competing against LabCorp with a new entity. The director had sold his PGD business to LabCorp and entered into an employment agreement to serve as director at LabCorp. That agreement said he couldn't solicit LabCorp customers with whom he'd had contact during his employment or otherwise compete with LabCorp with regard to PGD testing during and for one year after his employment ended.

During the term of the employment agreement, LabCorp decided to terminate its in-house PGD testing and contract those tests out to a third party but wanted the director to remain employed and help with the transition. When fertility clinics who were clients of LabCorp started reporting problems with the tests performed by the third party, including refusal of the third party to perform certain tests, the director started performing those tests for those clients at a new lab he had developed so he could continue his research and training students. When LabCorp found out, it claimed he was violating the provisions in his contract preventing solicitation of LabCorp clients and competition with LabCorp.

"[LabCorp had a business interest in protecting its] customer goodwill, confidential pricing information, and confidential pricing strategy."

— Laboratory Corporation of America Holdings v. Kearns, U.S. Dist. Ct. Middle Dist. NC, No. 1:14cv1029, 1/30/15.

The employment contract did have some exceptions to the noncompetition provisions that addressed a patent the director had been independently pursuing with regard to IVF and PGD. The agreement permitted the director to take action on that patent application so long as it didn't interfere with his duties under the agreement. The court explained that to interpret that carve out to allow him to run his own laboratory and provide tests similar to or the same as those provided by LabCorp would render the restrictive covenants meaningless. The court said LabCorp demonstrated it had a business interest in protecting its "customer goodwill, confidential pricing information, and confidential pricing strategy." So the court granted a preliminary injunction preventing the director from doing business with LabCorp customers and prospects he had contact with while at LabCorp.

The court did find, however, that restrictions in the contract that prohibited "indirect ownership and investment in both (1) businesses involved in PGD testing that directly compete with LabCorp, and (2) companies that supply, service, advise, or consult with businesses involved with PGD testing that directly compete with LabCorp" were too broad and unjustified because they would effectively prevent the director "from investing in a startup trying to develop new PGD technology for commercial exploitation" or even from investing "in a paper company that supplies paper to a PGD testing laboratory." So the court wouldn't enforce that restriction.

(*Laboratory Corporation of America Holdings v. Kearns*, U.S. Dist. Ct. Middle Dist. NC, No. 1:14cv1029, 1/30/15).

Takeaway: Courts will allow labs to protect their proprietary interests but not so broadly that investment in any company even tangentially linked to the lab's business would be prohibited. G2

FTC Enforcement Regarding Healthcare Integration, *Continued from bottom of p.1*

A Washington, D.C., antitrust lawyer, Jeff Miles of Ober Kaler, thinks this current activity may be an indication that the FTC wants "an opportunity to defend itself against those claiming there is tension between the ACA [Affordable Care Act] and antitrust law." Whatever the reason, he indicates the FTC's concern and focus on health care and competition is a good thing, "for the simple reason that market power generally results in increased healthcare cost."

Prior workshops and guidance

The FTC's last workshop was held in 2014 and focused on quality, price transparency, regulation of health care professionals, and innovation. Prior to the 2014 workshop, hearings and public comment in the early 2000s resulted in a joint FTC and Department of Justice (DOJ) 2004 report Miles credits as "very beneficial." That report emphasized: "Vigorous competition promotes the delivery of high quality, cost-effective health care, and vigorous antitrust enforcement helps protect competition."

More than 10 years ago, that report highlighted the same concerns and issues currently being discussed: cost, utilization, quality, accessibility of information, and price transparency. Some of the recommendations in that report are still being

pursued today as well: incentives to lower cost and improve quality, providing greater transparency of pricing for patients/consumers, and reducing barriers to telemedicine.

ACOs

The FTC says in its federal register notice regarding the Workshop that "[s]ome health policy experts and economists have raised concerns that ACOs might increase the ability of providers to obtain and exercise market power." This concern is increased if the ACO requires merger of some providers. In the workshop notice, the FTC refers back to its 2011 joint policy statement with the DOJ regarding antitrust enforcement and ACOs in the Medicare Shared Savings Program. That policy statement explained how the DOJ and FTC would review ACOs under antitrust analysis, including when a rule of reason analysis would be applied, the parameters of a "safety zone" for ACOs that are "highly unlikely to raise significant competitive concerns," and anticompetitive conduct to avoid such as sharing confidential and sensitive pricing information (that could lead to collusion), exclusive contracting and tying purchase of ACO services to services provided outside the ACO. Finally, the policy statement offered a 90-day expedited antitrust review to newly formed ACOs.

Some concerns expressed in the FTC's workshop notice include potential that Medicare ACOs will promote development of commercial market ACOs and cost-shifting from Medicare ACOs to commercial ACOs. Some of the questions to be addressed at the workshop include whether ACOs do achieve efficiencies and cost savings and what strategies are employed to achieve these successes. Are the changes in cost and quality achieved via competition among providers participating in ACOs?

There's been no antitrust activity thus far regarding ACOs, notes Miles, and "both agencies [FTC and DOJ] have been very welcoming and very lenient about these ACOs."

New Payment Models

With regard to new payment models, the FTC asks for public comment on the alternatives that should be considered and who bears the risk in these alternate payment models, how prices will be established, and whether competition will be "a significant factor in establishing prices." The FTC notice indicates a focus on the "competitive implications of this shift away from traditional fee-for-service reimbursement" and asks for evidence that alternative payment methods can increase competition, improve care and reduce costs.

Consolidations in response to ACA

The FTC notes some providers have raised a concern that the Affordable Care Act (ACA) requires consolidation to achieve the desired cost reduction and quality improvement. It highlights hospital physician practice consolidations and hospital mergers involving different geographic or service markets and finally, provider-payer consolidations. In all these, the FTC is concerned about the ability of consolidated entities to affect pricing.

"A merger is the optimal way to achieve benefits," notes Miles. However, the downside is the merged entity's potential ability to raise prices—which is the FTC's concern. "Increased integration and coordination is important but you don't have to do a merger to achieve those effects. If there is some less restrictive

method to achieve the integration and coordination" the FTC will be less concerned with pursuing those methods, Miles advises. "A merger might maximize the benefits from integration and coordination, but the concern is that the merger's anticompetitive effects from the increase in market power will likely outweigh the marginal benefit from a merger over an arrangement that can achieve most of the same benefits while less restrictive of competition," he explains.

Because many hospital markets are so concentrated, he notes it may be difficult for any hospital to make horizontal acquisitions without running into antitrust issues. And niche programs likewise may have problems collaborating with local specialists but less problem merging with physicians and specialists they recruit from outside the geographic service area, he adds.

Payer's participation networks and benefit plans

At the workshop, the FTC also will be seeking feedback about the competitive effects of limiting the number of providers in a network, whether concentrated health insurance markets enhance competition, and whether "regulatory or legislative interventions may enhance or undermine innovative network and benefit design strategies" (such as any willing provider legislation and price transparency requirements).

Health Insurance Exchanges

Finally, the last item on the FTC's agenda is the health insurance exchanges. The FTC is considering the types of plans available, who is buying them and how state and federal exchanges differ, and the impact on health care insurance competition and pricing of insurance.

Comments regarding competition and changes in the health care industry may be filed online or in person until April 30, 2015. See the FTC and DOJ Notice in the Feb. 2, 2015 Federal Register for more detailed instructions for submitting comments. Note that comments will be made public.

Sources

Federal Trade Commission, Announcement for Public Workshop, "Examining Health Care Competition," Federal Register, Vol. 80 No. 21, Feb. 2, 2015, pp. 5533-5537.

Federal Trade Commission & Department of Justice, Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program; Notice, Federal Register, Vol. 76, No. 209, Oct. 28, 2011.

Improving Health Care: A Dose of Competition: A Report by the Federal Trade Commission and the Department of Justice (July 2004)

Takeaway: As the industry focuses on ways to shift away from fee-for-service, decrease costs and increase efficiencies, the effect on competition can't be overlooked. G2

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