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Look Before You Leap: Diagnostic Equipment Leases

New federal regulations published on January 4, 2001 appear to pave the way for previously prohibited types of medical and diagnostic equipment leases. Look before you leap, though; many lease arrangements which appear to comply with the new federal regulations can violate other laws — including the federal antikickback law.

Stark Prohibitions

Almost all physicians are well-acquainted with the so-called “Stark” prohibitions against physician referrals. The law generally prohibits a physician from referring a patient to an entity for “designated health services” for which Medicare or Medicaid might otherwise pay, if the physician or the physician’s immediate family member has a financial relationship with the entity. “Financial relationship” is defined very broadly, and includes ownership relationships, and various types of compensation relationships. Included within the long list of “designated health

services” are various diagnostic and imaging services, such as clinical laboratory services, radiology services, and various types of imaging services.

Therefore, under the strict terms of the Stark law, if one physician group (a group of cardiologists, for example) leased imaging equipment to a second physician group (a group of family practice physicians, for example), that lease would create a Stark “financial relationship” between the two groups. Cardiac imaging is a “designated health service” for Stark purposes. Therefore, if the family practice physicians referred patients to the cardiology group (by asking them to “read” the results of the cardiac imaging procedures, for example) that referral would be prohibited by Stark unless some exception applied.

“Volume or Value”

The Stark law does include several exceptions. One exception is for equipment rental. According to the law, Stark won’t be

violated when patients are referred between a lessee and lessor of equipment as long as several strict criteria are met, including requirements that the lease be at fair market value, is for at least a one year term, and is not determined in a way that takes into account the “volume or value” of any referrals between the parties.

The medical community has been troubled by the “volume or value” restriction in the Stark equipment rental exception. This requirement appeared to prohibit “per use” or “per click” leases, where the medical group renting the equipment pays a set amount each time the equipment is used, rather than a set amount per year. In new final Stark regulations released on January 4, 2001 and effective beginning January 4, 2002, however, the feds now allow “per use” leases to fall within the protection of the Stark equipment rental exception.

Some physicians and durable medical equipment suppliers nationwide, reacting excitedly to this new final regulation, have begun to structure leases of diagnostic and imaging equipment which fit within the exact requirements of this Stark exception. Before you do, however, be aware that these types of leases may violate the federal anti-kickback law. And, remember that violations of the federal antikickback law can result in substantial fines and prison time.

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Felhaber Larson Fenlon & Vogt

The Federal Antikickback Statute

Here's the problem. The federal antikickback statute makes it a felony to offer, pay, solicit or receive any remuneration in exchange for the referral of any patient or service, where the service may be paid, in whole or in part, by a federally funded health care program, including Medicare and Medicaid. Violation of the antikickback statute could subject an offender to a \$250,000 fine and 5 years in federal prison. In order to show that someone or something violated the antikickback statute, federal prosecutors must show that just one purpose of the offer, payment, solicitation or receipt of remuneration was to induce patient referrals.

The feds don't need to prove intent to establish a violation of the Stark referral law. They do need to prove intent to establish a violation of the antikickback law. Much of the conduct that violates Stark will also violate the antikickback statute if done intentionally.

While Stark has "exceptions", the antikickback law has "safe harbors". If your conduct would otherwise violate the antikickback statute but you can show that it falls squarely within the protective boundaries of a safe harbor regulation, your conduct will not be viewed as violating the antikickback statute.

Stark has an equipment rental exception, and there is also an equipment rental safe harbor. The two are very similar in their provisions. However, while the Stark exception was broadened this year to permit "per use" or "per click" leases, the antikickback safe harbor remained unchanged. Therefore, if our hypothetical cardiology group leases a cardiac scanner to a family practice group on a "per use" lease, and at least one of the cardiology group's purposes in leasing the equipment is to get the "read" referrals from the family practice group, then the lease, although technically proper for Stark purposes, violates the antikickback statute and potentially subjects both the cardiology group AND the family practice group to criminal sanctions.

Increased Federal Concern Over Diagnostic Test Referrals

Could the feds take the position that conduct which they just said doesn't violate one set of federal laws (Stark) actually violates a different federal law (the antikickback statute)? You bet. Here are three reasons that should give anyone entertaining such a lease arrangement pause:

1. In the comment and response section to the newly released Stark regulations, the feds warned repeatedly that conduct that could pass muster under newly revised

Stark exceptions could still violate the federal antikickback law;

2. The Health Care Financing Administration appears to be deeply suspicious that providers, particularly in the medical diagnostic community, will find new ways to circumvent Medicare billing rules. In one section of a Medicare instruction manual, HCFA discussed problematic leasing arrangements involving cardiac scanning services and mobile ultrasound equipment, and stated that "[T]he bonafides of these arrangements are extremely suspect"; and
3. An OIG advisory opinion issued in 1998 determined that a lease of imaging equipment by an ophthalmologist to an optometrist would not violate the antikickback statute, even if the equipment was used for telemedicine consultations and patients were referred between the two. The OIG cited several factors supporting its favorable opinion, however:
 - A. The rent to be paid was a direct "pass through" of the ophthalmologist's financial obligation for the equipment;
 - B. There were no oral or written agreements or understandings of any kind regarding patient referrals;
 - C. Neither will bill any insurance carrier or any patient for telemedicine consultations;
 - D. The optometrist will not advertise access to the ophthalmologist or charge a fee in connection with the consultations; and
 - E. The optometrist's patients have the freedom to choose any ophthalmologist they want.

Many of these factors are likely not present in our hypothetical lease between the cardiologists and the family practice group. The cardiologists likely leased the cardiac scanner to the family practice group so it could capture the "read" business generated by the family practice group, both groups will likely bill Medicare and Medicaid for their parts of the tests, the family practice group will likely advertise its acquisition of a cardiac scanner in order to attract new patients, and there will likely be an explicit or implicit agreement that the family practice group will refer all of its reads to the cardiology group. It isn't too hard to figure out what the OIG's opinion of our hypothetical cardiology group lease would be.

The Moral To Our Story

Always remember that an arrangement that may pass muster under one law may violate others. Make sure you get competent legal counsel to review your business transactions before you sign on the dotted line. ■

When Doctors Play Cop

The U.S. Supreme Court released an opinion on March 21, 2001, holding that a state hospital's performance of a urine test to detect the presence of cocaine in a pregnant woman, violates the U.S. Constitution if the test was done without the woman's consent, and the test results were provided to law enforcement. The holding in Ferguson v. City of Charleston may not have much direct significance for Minnesota clinics and hospitals, but the analyses of the various justices give hints as to where the Court may be going in future cases involving maternal, reproductive and fetal rights.

The Facts

Staff members at the Medical University of South Carolina hospital, a publicly-run facility in Charleston, South Carolina, became concerned in 1988 about an apparent increase in the use of cocaine by women who came to the hospital for prenatal treatment. By April of 1989, the hospital began ordering drug screens performed on all maternity patients who were suspected of using cocaine. Those testing positive were referred to county substance abuse facilities for counseling and treatment.

Soon thereafter, Nurse Brown, a nurse in the MUSC obstetrics department, learned that police in another South Carolina city were arresting pregnant women who tested positive for cocaine use on the theory that cocaine use harmed the fetus and therefore constituted child abuse. Nurse Brown discussed what she learned with MUSC's hospital attorney. The hospital attorney then contacted the Charleston city attorney and offered

MUSC's help in prosecuting expectant moms in Charleston.

The Charleston city attorney put together a task force including representatives of the hospital, the police, and the substance abuse treatment community. Task force recommendations led to the development of a 12 page policy (the "M-7" policy) addressing how MUSC would handle expectant mothers suspected of abusing cocaine.

The policy first established a profile of a suspected cocaine abuser, and then directed MUSC to obtain a urine test for cocaine if the woman met one or more of the nine criteria of the profile. Initially, the policy required all positive test results to be reported immediately to the police. Later, the policy was changed to require police notification only if the woman tested positive for cocaine a second time or if she missed an appointment with a substance abuse counselor.

The policy provided for education and referral to a substance abuse clinic for patients who tested positive a first time, with the threat of law enforcement intervention if the patient did not participate in treatment or if they tested positive a second time.

The policy identified the specific criminal offenses with which a woman could be charged, depending on the stage of her pregnancy. If the pregnancy was 27 weeks or less, the woman was to be charged with possession of a controlled substance. If the pregnancy was 28 weeks or more, the woman was to be charged with possession and distribution of a controlled substance to a person under the age of 18 – the fetus. If the woman delivered while testing positive for cocaine, she was to be charged with unlawful neglect of a child, and arrested immediately following delivery.

Significantly, the policy made no mention of any change in the prenatal care of patients testing positive, nor did it prescribe any special treatment for the newborns.

The Majority Opinion – Justice Stevens

Justice Stevens authored the 6-3 majority opinion of the Court. The Court held that the initial and continuing focus of the M-7 policy was on the arrest and prosecution of drug-abusing mothers. As such, if the hospital didn't have the consent of the woman to obtain the urine sample, test it for cocaine, and provide the results of the test to law enforcement, then the testing and reporting procedure violated the 4th Amendment's guarantees against warrantless searches and seizures. The Supreme Court remanded the case back down to the Fourth Circuit Court of Appeals to determine what exactly the women consented to when they authorized one or more tests of their urine.

The Concurring Opinion – Justice Kennedy

Although Justice Kennedy joined five other justices in agreeing with the majority's result, he took issue with how the majority got there. Justice Kennedy believed that although the immediate goal of the M-7 policy was to obtain evidence for use by law enforcement, the policy also served the goal of protecting the health of mother and child when a pregnant mother uses cocaine. Justice Kennedy argued that other "special needs" cases (such as a case approving drug tests for railway employees involved in train accidents) allow constitutionally permissible warrantless searches of individuals' blood or urine. However, Justice Kennedy agreed that none of those prior "special needs" cases sanctioned the routine inclusion of law

enforcement personnel in the searching, testing and reporting process, as they were included here. Justice Kennedy believed that the routine inclusion of law enforcement in the M-7 policy made that policy unconstitutional.

Of interest to those who attempt to predict how a justice might vote on future reproductive rights cases is this quote from Justice Kennedy's concurring opinion: "There should be no doubt that South Carolina can impose punishment upon an expectant mother who has so little regard for her own unborn that she risks causing him or her lifelong damage and suffering".

The Dissent – Justice Scalia

Justice Scalia, joined by Chief Justice Rehnquist and Justice Thomas, issued the dissent in this case. First, the justices found that reporting positive drug test results to

the police simply did not constitute a "search". These justices, noting that South Carolina does not recognize a physician-patient privilege, found that once a woman voluntarily gives up her urine to a hospital, the hospital can do whatever it wants with it – including testing it and providing the test results to police. Responding to majority concerns that a woman who consents to tests on her urine for the purpose of medical treatment is essentially deceived by her physician if the physician intends to provide test results to law enforcement without her knowledge, these justices found that "information obtained through violation of a relationship of trust is obtained consensually, and is hence not a search".

Finally, the dissenters said that even if you believe that MUSC took and tested pregnant women's urine without their consent, the tests and reports to law enforcement were constitutionally

permissible because the goal was not to arrest patients, but to "facilitate their treatment and protect both the mother and unborn child".

Conclusion

Ferguson v. City of Charleston may not have much effect in Minnesota, since the Court's constitutional analysis applies only to state-run facilities, and because Minnesota, unlike South Carolina, recognizes a physician-patient privilege. Additionally, once the final HIPAA privacy regulations become effective on April 14, 2003, no hospital could disclose diagnostic test results to police under the circumstances set forth in Ferguson.

This case does give us an indication of how the individual justices on the Court may treat the next major case involving maternal and fetal rights. ■

NEWS: STAT!

The U.S. Supreme Court ruled on May 29, 2001

that supervisors are excluded from the protection of the National Labor Relations Act. Call us for more details about the Court's decision in NLRB v. Kentucky River Community Care, Inc.

Changes to OSHA's bloodborne pathogens standards intended to reduce needlesticks among healthcare workers and others who handle medical sharps went into effect on April 18, 2001.

Federal and state enforcers formed a new task force to enforce compliance in Minnesota with the Americans with Disabilities Act. Go to our website (www.felhaber.com) for further details.

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She investigates and litigates claims brought against health care providers and payers under the federal False Claims Act and its qui tam provisions, assists providers in responding to requests and demands of federal and state regulators and law enforcement, helps providers comply with Medicare and Medicaid self referral and fraud and abuse laws, and designs, implements and evaluates compliance plans for health care providers and payers.



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Donate a Round of Golf to a Rural Physician?

The U.S. Department of Health and Human Services Office of Inspector General (OIG) issued two advisory opinions of particular interest to the Minnesota health care community this spring. In the first, the OIG gave its stamp of approval to a proposed golfing fundraiser. In the second, the OIG OK'd a plan to recruit a new physician to a rural area.

Advisory Opinion 01-2: The Golf Fundraiser

A not-for-profit health center consisting of a skilled nursing facility, vocational counseling center, childcare center, home health division, family practice residency program, substance abuse residential treatment centers, and medical, dental and mental health clinics existed primarily to serve a Hispanic community. Business leaders in the health center's community formed a Golf Committee to hold an annual golf tournament to raise funds to support the health center's mission. Golf Committee members were business and civic leaders drawn from the community, including state legislators, local officials, and members of the academic community from the local university. Some of the Golf Committee members were people who did business with the health center, but the majority were not.

The Golf Committee solicited sponsorships and donations for the annual tournament. The sponsorship levels ranged from \$2500 to \$15,000. Non-sponsors could compete in the golf tournament for \$1,000 per foursome. Some of the sponsors and tournament participants were vendors who did business with the health center, including vendors who provided items or services to the health center that are reimbursed in whole or in part by federal health care programs.

Net proceeds of the golf tournament, approximately \$50,000 per year, are used for scholarship awards, holiday gifts to low-income families, the health center's homeless programs, and the health center's senior programs.

The OIG noted that the solicitation of donations and sponsorships for the golf tournament could violate the antikickback statute, particularly if the health center had an intent to induce or reward patient referrals. The OIG decided that it would not impose sanctions against the health center, though, because (1) the tournament appeared to be a bona fide charitable event, (2) Golf Committee members, tournament sponsors and participants were drawn from a large pool of people, most of whom did not do business with the health center, and

(3) the health center doesn't use tournament sponsorship or participation as a factor in determining who it does business with. Fore!

Advisory Opinion 01-4: Rural Physician Recruitment

A hospital located in a rural area had a difficult time recruiting and retaining head and neck surgeons (otolaryngologists) in its area. The hospital found a first year otolaryngology resident who was potentially interested in moving to the hospital's area following his five year residency. The hospital, in order to entice the resident to its area, planned to loan the new physician an amount of money sufficient to allow the physician to repay his medical school loans plus an additional sum to be used for other education expenses. The loan would be paid in five equal installments during each year of the physician's five years of residency. Interest on the loan would accrue from the date of each annual disbursement.

The hospital proposed that this loan would be forgiven in whole or in part if the physician met certain criteria following the completion of his residency. First, the physician had to establish and maintain a full-time practice within a three mile radius of the city in which the hospital was located. Second, the physician had to acquire and maintain professional staff privileges at the hospital. Third, the physician must agree to serve on the hospital's emergency room call rotation. Fourth, the physician must agree to assist the hospital in its education programs. Fifth and sixth, the physician must agree to help the hospital with its fund-raising efforts and help with physician recruitment efforts. Finally, the physician must agree to serve federally insured patients in a nondiscriminatory matter.

If the physician met these criteria, the hospital would incrementally forgive the physician's loan debt by forgiving one-third of his payment obligations for each year that the physician met all of his obligations under the agreement.

The OIG first noted that it had a practitioner recruitment "safe harbor" and this proposed arrangement didn't meet it, because (1) the hospital was not located in a "HPSA" (Health Professional Shortage Area) and (2) the benefit was not limited to three years.

However, the OIG decided that it would not impose administrative sanctions on the hospital if it pursued this recruitment

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Donate a Round of Golf ■ Continued from page 5

arrangement because (1) the loan arrangement posed a minimal risk for fraud and abuse to any federal health care program, (2) the physician, being new to the practice of medicine, would not have a ready stream of patient referrals in the hospital's area, (3) although the duration of this proposed arrangement was eight years (5 years of residency plus 3 years of payback) the only period during which the physician could refer patients to the hospital was 3 years, (4) the amount of the loan was reasonable and documented by the physician's outstanding medical school loans, (5) the benefit would be provided only to the physician and not to any other referral source, (6) the proposed arrangement would not be renegotiated during its term, (7) there would be no requirement that the physician make referrals to or generate business for the hospital, (8) the physician

would not be prohibited from establishing staff privileges at any other hospital, (9) the amount of benefit to the physician would not vary in any way depending on the number of patients he referred to the hospital, and (10) even though the hospital wasn't in a HPSA, it was in a MUA (medically underserved area) and therefore the public would benefit by getting increased access to otolaryngology services in a historically underserved area.

A Word of Caution

Advisory opinions are very useful in divining the OIG's thoughts about arrangements that may or may not violate the federal antikickback statute. Be aware, though, that an OIG advisory opinion can only be relied upon by the person or entity who asked for it. ■

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The *Health Law Monitor* is a report on legal developments. It is not intended to be legal advice and should not be relied on without consulting counsel.

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