

Legal Compliance Issues For Diagnostic Testing Centers

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Diagnostic testing is the lifeblood of the medical profession. Doctors and hospitals constantly refer patients for various types of bodily fluid, imaging, genetic, and other tests. Tests are usually performed at diagnostic centers that are located separately from the physician's office. Most hospitals have their own diagnostic centers but hospitals may also refer some patients to separate facilities too.

Diagnostic tests are usually ordered for purposes of screening, to diagnose whether a patient has a disorder, to evaluate how severe a disorder is, and to monitor how well (or poorly) the patient is responding to treatment. Many disorders are treated after the diagnostic test but some, such as colonoscopies, are treated contemporaneously with the test.

Physicians and diagnostic centers should speak with an experienced healthcare lawyer before starting any practice and before developing any new business relationship. There are numerous federal and state laws that regulate medical practices and services.

What are the common types of diagnostic tests?

Diagnostic tests include:

- **Bodily fluid analysis.** These tests include blood tests, urine tests, tests for the fluid that surrounds the spinal cord and brain, and synovial fluid (joint) tests. Physicians may also order tests for saliva, sweat, and gastric tract liquids.
- **Imaging tests.** These tests take pictures of parts of the body. Common diagnostic imaging tests include:
 - X-rays.
 - CT scans (computed tomography)
 - MRIs (magnetic resonance imaging)
 - Other imaging tests such as *"ultrasonography, radioisotope (nuclear) scanning, positron emission tomography (PET), and angiography."*
- This test uses a viewing tube to observe body organs and cavities. The end of the endoscope has a camera and light so the physician can observe through a monitor. Tools can be passed through an endoscope channel. An endoscopy is used to examine, among other organs – the nose, mouth, respiratory tracts, colon, bladder, and uterus. Sometimes the physician needs to create incisions to use the endoscope.
- **Measuring bodily functions.** Common examples include examining the electrical activity of the heart – an

electrocardiography (ECG) and the brain – electroencephalography (EEG).

- This test examined tissues samples that are moved and then examined with a microscope. The physician or medical examiner is usually looking for abnormal cells that may show disorders such as cancer.
- **Genetic testing.** This type of testing generally involves examining cells (from a patient's blood, skin, or bone marrow) to check for chromosome abnormalities and gene (including DNA) abnormalities. Genetic testing involves testing a fetus for a genetic disorder and children/adults for whether they are at risk for a disorder, and adults.

There are some risks with every test. Test results are normally based on the average values within a healthy population.

Physician supervision of diagnostic tests

Medicare has different rules and regulations for different types of diagnostic tests. An experienced healthcare lawyer can explain how Medicare monitors and regulates various tests. One of the most common types of tests are imaging tests. The Centers for Medicare & Medicare Services (CMS) generally uses the standards set by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) for inpatient diagnostic imaging standards.

The CMS requires that physicians must supervise imaging tests for outpatient diagnostic services. According to AAPC, only *“a doctor of medicine or osteopathy legally authorized to practice medicine in his or her state of practice, as defined by §1861(r) of the Social Security Act,”* may act as a supervisory physician. Generally, the following people do not qualify as a “physician” and cannot act in a supervisory physician capacity – for purposes of diagnostic tests:

- Nurses
- Physician assistants
- Clinical nurse specialists
- Certified nurse midwives

There are also rules that your healthcare compliance lawyer can explain about – if and when a radiologist can order his/her own imaging tests.

CMS *“recognizes three primary levels of physician supervision”* for outpatient diagnostic services:

- General supervision. Here, the medical procedure should be under the doctor's control and direction. The doctor who orders the test is responsible for maintaining the testing equipment and training staff on how to perform the tests. The physician does not need to be in the room during the procedure.
- Direct supervision. The term *“direct supervision”* *“varies according to the precise location at which the service is provided:”*
 - In the doctor's office. Here, the supervising doctor must be physically in the office suite and readily available to provide aid and direction throughout the procedure.
 - Hospital outpatient diagnostic services at an independent diagnostic facility. *“The supervising physician must be present in the office suite and immediately available to furnish assistance and direction throughout the procedure's performance.”* The doctor cannot be performing another procedure that cannot be interrupted. He/she must be able to provide timely aid. There are additional rules for on-campus health providers.
 - Personal supervision. Here, the doctor must be in the room where the procedure is being performed.

The supervision requirements apply *“to the technical component (the actual test administration) of a diagnostic service.”* Doctors must always provide *“the professional component (reading/interpreting of results) for diagnostic services.”*

If the physician fails to provide the necessary level of supervision, then CMS may not find that the service is reasonable or necessary – and, thus, may not pay the claim. CMS also has diagnostic imaging requirements for determining who can order

medical imaging tests and who is qualified to administer the imaging tests.

In addition to the CMS physician supervision tests, doctors may be bound by state law and the laws and regulations for their types.

Diagnostic centers and Stark Law

Physicians and diagnostic centers need to be extra careful when doctors refer their patients to a diagnostic center. It is commonplace for general practitioners and specialists to regularly recommend diagnostic centers to their patients. If, however, the doctor has a financial interest in the diagnostic center, then all sorts of red flags are raised.

Stark Law is a civil law that regulates referrals of patients who use Medicare to any designated health service (DHS) where the physician (or an immediate family member) has interest in that DHS. A diagnostic center is a designated health service. CMS prohibits the DHS from presenting claims to *“Medicare (or billing another individual, entity, or third-party payer) for those referred services.”*

Designated health services include:

- Clinical laboratory services.
- Radiology and certain other imaging services.
- Radiation therapy services and supplies.
- Durable medical equipment and supplies
- Other services.

The core principle behind Stark Law is that doctors should refer patients to a DHS based on what is in the best health interests of the patient – and not what is financially beneficial to the doctor or the diagnostic center.

CMS has numerous rules about referrals to a DHS. CMS also regularly publishes an updated list of codes in the Physician Fee Schedule for a relevant DHS *“because our regulations define certain DHS by CPT and HCPCS codes.”*

An experienced diagnostic center lawyer can explain what services qualify as a designated health service. Some services may not be included. Stark law also provides many exceptions that have very precise definitions. Skilled healthcare lawyers help physicians, medical practices, and diagnostic centers understand when these exceptions may apply and what the requirements are. A general principle is that any financial arrangements between the physician and the DHS cannot be based on the volume, percentage, or amount of any referrals.

What Stark Law exceptions may apply to the relationship between a physician/medical practice and a diagnostic center?

Stark Law provides for different types of exceptions including ownership/investment arrangements, compensation arrangements, and exceptions involving both ownership/investment and compensation.

Several of the combination (both compensation and investment) exceptions include the following. consider for referring patients to a diagnostic center.

- Physician services
- In-office ancillary services
- Preventive screening tests, immunizations, and vaccines

- Eyeglasses and contact lenses following cataract surgery
- Intra-family rural referrals

Compensation exceptions (for Stark Law) include:

- Rental of office space
- Rental of equipment
- Bona-fide employment relationships
- Personal service arrangements
- Physician recruitment
- Non-monetary compensation
- Fair market value exception
- Medical staff incidental benefits
- Risk-sharing arrangements
- Compliance training
- Many other exceptions

The in-office ancillary services exception is often considered for heart doctors, orthopedists, and other professionals who conduct their imaging tests in their office.

Stark Law Exceptions that Might Apply to You

In today's video, we discuss some exceptions to Stark Law, which deals with improper referrals by physicians and healthcare practitioners.

The Anti-Kickback Statute and diagnostic centers

The AKS is a federal law that imposes criminal penalties for unauthorized referrals. Illegal referrals generally include any inducement – by an entity such as a diagnostic center that is made to a physician – to include the physician to refer patients to the center. Most doctors provide a list of centers the doctors work with to their patients and let the patient choose which one the patient likes best. When diagnostic centers provide the doctor/medical practice with a benefit, the referral is tainted – because the referral is based on the financial well-being of the doctor and not by what is healthy for the patient.

Illegal inducements include financial payments, expensive meals, vacations, positions on various medical boards or organizations, and virtually anything of any value. Violations of the AKS may result in a criminal conviction, imprisonment, fines, and other consequences.

Both violators of Stark Law and the AKS may be precluded from the ability to submit any future bills to Medicare or Medicaid.

The AKS has “safe harbors” which can be implemented to help show a medical practice or diagnostic center is not in violation of the AKS. These safe harbors include many transactions and arrangements that are similar to the Stark Law exceptions. Experienced California healthcare lawyers explain how safe harbors work and when safe harbors should be considered for your medical practice.

Additional legal compliance issues for diagnostic centers?

Physicians and doctors need to be careful that the center does not order or provide tests that suggest the center is providing any medical advice or treatment. Doctors, health providers, and staff members must understand what actions may result in an unauthorized practice of medicine complaint.

HIPAA (Health Insurance Portability and Accountability Act) is a federal law that generally regulates how electronic health records are handled. Physicians regularly submit electronic requests to diagnostic centers to perform blood tests, imaging tests, and other tests. In return, the diagnostic centers regularly send the results of these tests to the physicians that ordered them. An experienced healthcare lawyer can explain when HIPAA applies and what conditions (including obtaining consent from the patient) must be met – when exchanging patient health information.

A failure to follow the strict legal compliance issues governing diagnostic centers and physician practices can result in fines, bills that will not be approved by Medicare and other healthcare agencies/entities, possible imprisonment, loss of license, and other consequences. Skilled diagnostic center compliance lawyers advise both physicians and diagnostic centers about Stark Law, the Anti-Kickback Statute (AKS), state anti-referral laws, Medicare requirements, the unauthorized practice of medicine, the corporate practice of medicine, the (HIPAA), the Medicare Anti-Markup Rule (AMR), and other compliance issues.

Physicians and diagnostic centers should contact Cohen Healthcare Law Group, PC to discuss referral arrangement, supervision requirements, HIPAA and other testing and business relationship laws. Our experienced healthcare attorneys help a broad range of healthcare providers and services.

Contact our healthcare law and FDA attorneys for legal advice relevant to your healthcare venture.