State of Arkansas
Bureau of
Legislative Research

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MEMORANDUM

TO: **Representative Mark Lowery**

FROM: **Jessica Beel, Legislative Attorney, Legal Research and Drafting**

DATE: **March 5, 2018**

SUBJECT: **Summary of Stark Law**

I am responding to your information request regarding the federal Stark Law and the applicability of the federal Stark Law to the testimony from the Joint Performance Review Committee on Thursday, January 25, 2018.

QUESTION

1. Based on the testimony in the Thursday, January 25, 2018, meeting of the Joint Performance Review Committee, has the University of Arkansas for Medical Sciences committed a Stark Law violation regarding its behavior with Baptist Health Systems?

SHORT ANSWER

As nonpartisan staff for the General Assembly, Bureau of Legislative Research staff cannot make speculative conclusions of fact pertaining to a situation of this type. A finding of whether the current situation constitutes a violation of the federal Stark Law would require an intensive factual review and determination by appropriate federal authorities and a court of law with proper jurisdiction.

Notwithstanding the inability of BLR staff to make factual conclusions, it is impossible to determine if the behavior discussed in the Thursday, January 25, 2018 meeting of the Joint Performance Review Committee would be a violation of the federal Stark Law. When applying the testimony to the three (3) critical questions of a Stark Law analysis, the answers to each question are uncertain.

DISCUSSION

I. Brief Summary of Stark Law

The federal Stark Law prohibits physician self-referrals of Medicare and Medicaid patients for

certain “designated health services” to entities with which the physician or an immediate family member of the physician has a “financial relationship”. Each of these terms have a special meaning under the Stark Law. However, several exceptions exist within federal law and regulations to this general prohibition.

II. Summary of Stark Law

The Stark Law[1] prohibits physician referrals of Medicare and Medicaid patients for "designated health services" to entities with which the physician or an immediate family member of the physician has a “financial relationship”. This type of referral is typically referred to as a physician self-referral.

A hospital may not submit payment for a Medicare or Medicaid claim for services rendered through a prohibited referral. *42 U.S.C. § 1395nn(a)(1)(B) and 42 C.F.R. § 411.353(b).* The United States may not make payments pursuant to a claim rendered through a prohibited referral, and hospitals must reimburse any payments that are mistakenly made by the United States. *42 U.S.C. § 1395nn(g)(1) and 42 C.F.R. § 411.353(c), (d).*

Please be aware that this law was recently amended to add an additional exception for indefinite holdover lease arrangements and personal service arrangements.[2]

A. Terms

In order to analyze an action of a physician under the federal Stark Law, an individual must understand what each of these terms mean under the federal Stark Law.

For purpose of the Stark Law, a “physician” means a doctor of medicine or osteopathy, dentist, podiatrist, optometrist, or chiropractor. *42 C.F.R. § 411.351.*

Under 42 C.F.R. § 411.351, a “referral” includes:

- Any physician request (in any form, whether written, oral, or electronic) for a service, item, or good that is reimbursed under Part B of the Medicare program;
- Any physician request for a consultation with another physician as well as all of the services ordered as a result of that consultation; and
- The establishment of a plan of care that includes the provision of designated health services or the certification or recertification of the need for designated health services.

[1] "Stark Law" is the popular name for Section 1877 of the Social Security Act which is codified at 42 U.S.C. § 1395nn (with 42 U.S.C. § 1396b(s) applying the law to state Medicaid programs) with federal regulations regarding this law at 42 C.F.R. § 411.350 - 411.389.
[2] This additional exception was added by § 50404 of Division F (also known as the Strengthening and Underpinning the Safety-net to Aid Individuals Needing Care Act of 2018 or the SUSTAIN Care Act of 2018) of the Bipartisan Budget Act of 2018, Public Law No. 115-119 .

Under 42 U.S.C. § 1395nn and 42 C.F.R. § 411.351, "designated health services" means any of the following items or services:

- Clinical laboratory services;
- Physical therapy services;
- Occupational therapy services;
- Radiology services, including magnetic resonance imaging, computerized axial tomography scans, and ultrasound services;
- Radiation therapy services and supplies;
- Durable medical equipment and supplies;
- Parenteral and enteral nutrients, equipment, and supplies;
- Prosthetics, orthotics, and prosthetic devices and supplies;
- Home health services;
- Outpatient prescription drugs;
- Inpatient and outpatient hospital services; and
- Outpatient speech-language pathology services.

Under 42 U.S.C. § 1395nn, a "financial relationship" means having either directly or indirectly:

- An ownership or investment interest in the entity (which may be through equity, debt, or other means, including an interest in an entity that holds an ownership or investment interest in any entity providing the DHS); or
- A compensation arrangement between the entity and the physician or an immediate family member of the physician.

B. Exceptions

Various exceptions exist regarding the general prohibition on self-referrals. The exceptions listed below are specifically mentioned within 42 U.S.C. § 1395nn; however, the majority of the exceptions to the Stark Law are within the federal regulations, which are voluminous. For example, among the exceptions within 42 C.F.R. § 411.355, services provided by an academic medical center and implants furnished by an ambulatory surgery center are both excepted from the general self-referral prohibition if certain conditions are met.

The exceptions to the Stark Law can be placed into three (3) categories:

1. General exceptions to both ownership and compensation arrangement prohibitions such as:
    a. Physicians' services provided personally by another physician in the same group practice;
    b. In-office ancillary services;
    c. Electronic prescribing;
    d. Prepaid plans such as HMOs (also known as health maintenance

organizations); and
   e. Other permissible exceptions as determined by the Secretary of DHHS;
2. Exceptions related only to ownership or investment prohibitions such as:
   a. Hospitals in Puerto Rico;
   b. Rural providers; and
   c. Hospital ownership; and
3. Exceptions relating to other compensation arrangements such as:
   a. Rental of office space or equipment;
   b. Bona fide employment relationships;
   c. Personal service arrangements;
   d. Remuneration unrelated to the provision of designated health services;
   e. Physician recruitment;
   f. Isolated transactions;
   g. Certain group practice arrangements with a hospital; and
   h. Payments by a physician for items and services.

Due to the complexity and multitude of these exceptions, this memorandum does not go into detail about any particular exception. If you would like more information about any of these exceptions, please let me know.

C. Applicability/Analysis

To determine whether the Stark statute applies to a particular arrangement, three (3) critical questions must be answered:

1. Does this arrangement involve a referral of a Medicare or Medicaid patient by a physician or an immediate family member of a physician?
2. Is the referral for a "designated health service"?
3. Is there a financial relationship of any kind between the referring physician or a family member and the entity to which the referral is being made?

If the answer to any question is "no," Stark Law does not apply. If the answers to all three questions are "yes," the list of exceptions will need to be examined to see if the arrangement falls within an exception.

D. Enforcement

The Centers for Medicare & Medicaid Services (CMS) is primarily responsible for enforcing the Stark Law. CMS is responsible for issuing advisory opinions and guidance on whether a physician's referral for certain designated health services to an entity are prohibited. CMS also has a call center for inquiries related to the Stark Law, the CMS Voluntary Self-Referral Disclosure Protocol, and the procedure for submitting requests for advisory opinions.

In addition to CMS, the Office of Inspector General (OIG) is authorized to seek civil monetary penalties and exclusion of providers for Stark Law violations. The United States Department

of Justice (DOJ) has authority to investigate and prosecute violations of the Stark Law if the violations are in conjunction with violations of the Anti-Kickback Statute or the False Claims Act.

The following sanctions can be imposed for claims submitted for designated health services in violation of Stark Law:

1. Denial of payment;
2. Requiring refund of funds received;
3. Civil monetary penalties of not more than $15,000 per designated health service where a violation is done knowingly; and
4. Civil monetary penalties of not more than $100,000 per arrangement and exclusion from the Medicare or Medicaid programs where a physician or entity knowingly enters into an improper cross-referral arrangement or scheme in order to avoid the self-referral prohibition.

In addition, a person or entity who fails to provide CMS or OIG with required reporting information on their financial relationships is subject to a civil monetary penalty of not more than $10,000 per day for which reporting is required under 42 U.S.C. § 1395nn(f).

A violation of Stark Law can also trigger federal False Claims Act violations because Medicare providers must certify that the providers are in compliance with federal law including Stark Law as a condition precedent to submitting a claim. Under the Fraud Claims Act, a claim is false if any person "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." A violation of the Fraud Claims Act carries a penalty of three (3) times the amount paid by the government and a civil monetary penalty of between $5,000 and $10,000 per claim.

III. Applicability to JPR testimony

It is a question of fact as to whether the actions of the University of Arkansas for Medical Sciences violated the federal Stark Law. As nonpartisan staff for the General Assembly, Bureau of Legislative Research staff cannot make speculative conclusions of fact pertaining to a situation of this type. A finding of whether the current situation constitutes a violation of the federal Stark Law would require an intensive factual review and determination by appropriate federal authorities and a court of law with proper jurisdiction.

Notwithstanding the inability of BLR staff to make factual conclusions, it is impossible to determine if the behavior discussed in the Thursday, January 25, 2018 meeting of the Joint Performance Review Committee would be a violation of the federal Stark Law. When applying the testimony to the three (3) critical questions listed above, the answers to each question are uncertain. It is unclear from the testimony if the arrangement involves the referral of Medicare or Medicaid patients. It is equally unclear whether the services referred are designated health services. In addition, it is possible that an exception could apply to this

situation. However, without additional information, it is difficult to list all possible exceptions that might apply and analyze whether the exception does apply in this situation.

In short, a party seeking to draw a factual conclusion on this matter would require additional information to analyze the situation consistent with the standards of review set forth in this memorandum.