The Stark Law and Its Impact on the Medical Practice

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Introduction

The intent of the Stark Law was to prohibit physicians from referring Medicare patients to facilities where the physician or an immediate family member of the physician had a financial relationship. Congress wanted to ensure the way patients were being treated was not affected by a physician’s potential financial gain. The original law was aimed at laboratory services.

In 1993 and 1994 the Center for Medicare and Medicaid Services, (CMS) published a rule that expanded to include 10 additional designated health services, (DHS). Congress also began applying some of the law to include Medicaid services. As the law has expanded to three phases, it has grown to encompass additional rules and regulations that physician must follow in order to stay compliant with the law. The Stark Law only applies to physicians who refer Medicare or Medicaid patients for designated health services to an entity where they or an immediate family member has a financial interest.

The difference between laws and regulations can be confusing. Laws are created by Congress, while regulations can be written by federal executive departments and administrative agencies to implement the authority of laws. Pete Stark, a representative from California initially introduced the law and CMS is the agency responsible for writing the regulations that implement the authority of the law.

With a basic understanding of the history of the Stark Laws, the different phases of the Stark Law and the impact of the Stark Law in the medical practice, administrators
and physicians will be better prepared to manage a compliant and profitable medical practice.

The goal of this paper is to provide the history of the Stark Law and how it has affected medical practices. The paper is based on an extensive review of literature. Additionally, this paper will examine the different phases of the Stark Law and the impact that the changes have had on medical practices.

**History of the Stark Law**

Rep. Fortney (Pete) Stark from the state of California introduced this law in response to concerns that “physicians were putting their own financial interest” ahead of the patient’s when considering what type of treatment to provide. These concerns were based on reports that physicians were making huge profits by referring patients to facilities where they held a financial interest. “The Stark statute became effective on January 1, 1995, but it was not until January 1, 2001-six years later that the government released any final regulations interpreting the statute.”¹(Gosfield, 2003)

During the six year period between the law being passed and the regulations being released there was much debate. CMS received several comments from physicians, hospitals and medical associations that helped them realize further clarification was necessary in order to ensure understanding and compliance among the medical community. The complexity of the law created some unexpected consequences for those in the field of medicine. At a time where physicians and hospitals were already experiencing a drop in reimbursement, the Stark law seemed to put up additional roadblocks, which would ultimately affect the way patients would receive care. The law was intended to identify and stop physicians and hospitals from making huge profits at the
expense of the patient’s care; however, in the beginning the regulations seem to have had the opposite effect. Many medical practices have taken a big hit to their bottom lines. Another unexpected result is that physicians are tired of trying to interpret what the law means and are beginning to choose not to participate in the Medicare and Medicaid programs.

The Stark Law is located in Section 1877 of the Social Security Act. The original intent was to prohibit physicians from referring Medicare patients to facilities where they had a financial interest. In the beginning, the law was specific to clinical laboratory services. The law was later expanded to include 10 additional DHS. Some felt the expansion of the law would ensure patient care would remain the physician’s primary focus, with profitability not being a consideration. Some physicians expressed concern that the law was prohibiting them from practicing medicine.

When the original law was passed in 1989, the bill also allowed for civil penalties to be assessed to any physician found in violation of the law. The penalties include:

1. denial of payment
2. refunds of amounts collected in violation of the law, up to $15,000 in civil monetary penalties for each claim submitted in violation of the law, up to $100,000 in civil monetary penalties for each arrangement or “scheme” that violates the law
3. civil monetary penalty of three times the amount claimed
4. exclusion from participation in the Medicare program or other governmental health programs.
Since the Stark Law is considered a “strict liability” statute, the government does not have to prove the violation was intentional. The only evidence they need to have is that a violation occurred. The US Department of Justice said if a physician is found to violate the Stark Law; then it is likely the violation would constitute a “false claim” which is punishable under the False Claim Act. ²

**Phase 1 of the Stark Law**

Phase 1 of the Stark Law was presented in its final form on January 4, 2001; however, most of the provisions for the law did not become effective until January 4, 2002. In Phase 1, the government attempted to clarify what the original law meant. The Stark Law in its original form was extremely confusing and left many unanswered questions even in the legal world. Phase 1 addressed prohibitions of self referrals, the general exceptions to the self referral rule and further defined key definitions in the law.

**Prohibition of self referrals**

Phase 1 further clarified the meaning of referral. The law defines a referral as follows: “A referral includes a request by a physician for an item or service which payment may be made under Medicare Part B, including the request for a consultation with another physician and the request or establishment of a plan of care by a physician that includes a DHS. Excluded from the definition are DHS that a physician both orders and personally performs, as well as requests by pathologists, radiologist, and radiology oncologist for services furnished as the result of a consultation by another physician.”³

Phase I specifically addressed clinical laboratory services only. Phase II added an additional 10 DHS.
General Exceptions to the self referral rule

Phase 1 of the Stark Law has allowed for exceptions that address different types of referrals including ownership and compensation arrangements. The statute allows for an exception when the physician is referring within a group. This means that when referring physician services are performed personally by, or under the personal supervision of another physician in the same group practice as the referring physician it constitutes an exception under the self referral rule. “Physician owners, full and part-time physician employees, locum tenens physicians, and physicians on call are considered to be group members when it comes to providing DHS.” In some cases, independent contractor physicians can be considered a member of the group. “There has to be a formal contract that complies with Medicare rules, for example, and the contractors pay can not be based on value or volume of referrals.”

Billing for services rendered under prohibited referral

The law prohibits a physician or entity from billing Medicare or Medicaid for services rendered under a prohibited referral. Medicare or Medicaid shall not pay for any services rendered as a result of a prohibited referral. In the event that a claim was submitted and paid for a service rendered as a result of a prohibited referral, the entity or practice who received the payment is required to refund all collected amounts in a timely manner.

Phase I left physician offices enlisting the help of the healthcare attorneys to make sure they were following the laws. The clarification of what the government considered a referral, made it necessary for medical practices to review current referral processes and make changes if necessary to comply with the law. Phase I only addressed referrals for
clinical laboratory services and provided certain exceptions to the law. These general exceptions created an opportunity for some medical practices to continue doing business as usual, while it left other medical practices scrambling to try to make sure they were compliant with the law. Although the Stark Law only applies to Medicare and Medicaid services, many insurance companies have started implementing language into their contracts regarding this. Many states have implemented their own self referral laws that medical practices must comply with as well.

**Phase II**

Phase II of the Stark Law addressed the part of the law regarding exceptions. This phase was passed in 1993 and added 10 more DHS to the list. This brings the number of DHS that apply under the Stark Law to 11. They are as follows:

1. Clinical Laboratory Services
2. Physical Therapy, Occupational, Therapy and Speech Pathology Services
3. Radiology and other imaging services
4. Radiation Therapy
5. Durable Medical Equipment and Supplies Prosthetics
6. Orthotics and prosthetic devices
7. Home Health Services
8. Outpatient Prescription Drugs
9. Inpatient Hospital Services
10. Outpatient Hospital Services
11. Parenteral and enteral nutrients and PEN associated equipment and supplies.
CMS realized from the numerous comments they received regarding the law that, clarification was needed to ensure compliance. Phase II also addresses the ownership and investment exceptions, the compensation arrangement exceptions and the reporting requirements and sanctions.  

**Statutory exceptions relating to ownership and investment interest**

In Section 1877c, ownership in the following instances shall not be considered to be an ownership or investment interest if the ownership or investment securities (including shares or bonds, debentures, notes or other debt instruments) may be purchased on terms generally available to the public, and which are as follows: securities listed on the New York Stock Exchange, the American Stock Exchange, or any regional exchange in which quotations are published on a daily basis or traded under an automated interdealer quotation system operated by the National Association of Securities Dealers and the corporation that on an average over the past three years had stockholder equity that exceeding $75,000,000  

Additional exceptions to the ownership or investment interest include:

1. Ownership in hospitals in Puerto Rico as long as designated health services are performed in Puerto Rico
2. Rural providers as long as substantially all the designated health services performed are performed on residences of the rural area and effective for 18 months beginning on the date of the enactment of the Medicare Prescription Drug, Improvement and Modernization Act of 2003
3. The entity is not a specialty hospital
4. Ownership in a hospital where the referring physician is authorized to perform services at and effective for 18 months beginning on the date of the enactment of the Medicare Prescription Drug, Improvement and Modernization Act of 2003

5. The entity is not a specialty hospital and the ownership or investment interest is in the entire hospital and not just a subdivision.

**Statutory exceptions for certain compensation arrangements**

Phase II addresses several exceptions for certain types of compensation arrangements. Some of the most common questions are asked about the following exceptions:

1. Rental of office space
2. Rental of office equipment
3. Bona fide employment relationships
4. Personal service arrangements
5. Physician recruitment.

The rental of office space is considered an exception under the statute as long as certain requirements are met. The rental agreement must be in writing, it must be signed by both parties and it must specify the premises it covers. The agreement must be entered into for a minimum of one year. If the agreement is broken with or without cause before the first year is complete, the parties are not permitted to enter into a new agreement during the first year of the original agreement. The rented space must be reasonable and customary in size and the cost must be consistent with fair market value. The cost of the leased space must not take into consideration the value or volume of
referrals. The agreement must be commercially reasonable even if no referrals were made between the two parties.\textsuperscript{9}

The second exception that is commonly discussed is the rental of office equipment. The exception allows for this type of arrangement as long as the arrangement meets the following criteria: the lease is in writing and signed by both parties, the equipment rented or leased does not exceed what is reasonable and customary for business purposes, the lessee is the only party using the equipment while it is being leased, the term of the agreement is for a minimum of one year, if the lease is terminated, the parties are not permitted to enter into a similar agreement within the first year of the original agreement, the rental charges must be set in advance and are not determined by value or volume of referrals and the agreement would be commercially reasonable even if no referrals were made between the parties.\textsuperscript{10}

Both the rent of office space and the office equipment exception have preserved the medical practices’ ability to generate additional revenue as long as certain conditions are met. Medical practices had to incur additional cost for attorney fees to review existing contracts to ensure the contracts were in compliance with the law.

The bona fide employment relationship is another exception that is frequently discussed. This exception allows for remuneration from the employer to the physician or a member of the physician’s immediate family as long as the following conditions are met: the employment is for identifiable services, the amount of remuneration is consistent with the fair market value of the services provided, the remuneration is not tied to the value or volume of referrals by the physician, the arrangement would make sense even if no referral relationship existed. The exception also allows for productivity bonus
payments as long as the services are personally performed by the physician. The exceptions have forced medical practices to reevaluate physician compensation arrangements and in some instances dissolve the arrangements altogether.

The personal service arrangement exception provides physician with the opportunity to continue providing services to a referring entity as long as certain requirements are met. “The following requirements are necessary to meet this exception:

1. The arrangement must be in writing, signed by the parties specifying the services and covering all the service provided by the physician or immediate family member.
2. The service must not exceed those that are reasonable and necessary
3. The contract must have a term of at least one year
4. The compensation must not take into account the volume or value of referrals
5. The services must not involve counseling or promotion of a business arrangement or activity that violates state or federal law.”(Gosfield, 2004)

The physician recruitment exception is another one of the exceptions that has received a detailed review by many physician groups and hospitals. Recruiting a physician is exhausting and expensive and many small physician groups do not have the necessary funding to attract the desired candidates. The physician recruitment exception provides an opportunity for a physician to enter into a recruitment arrangement as long as certain requirements are met. “Under the Stark II physician recruitment exceptions, a physician has relocated his or her practice to the hospital’s geographical area if the
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physician has moved the site of the practice a minimum of 25 miles, or at least 75% of the physician’s revenues (including services provided to hospital inpatients) are from services provided to new patients whom the physician did not treat at the old location.

The regulation focuses on the following:

1. Relocation of the physicians practice, not the physician’s residence
2. Permits cross town recruitment of physicians (including resident physicians) who have practices less than one year without regard to any change in location of his or her practice.
3. Permits recruitment by federally qualified health centers in addition to hospitals. The recruitment exception does not extend to designated health service entities such as home health agencies or nursing homes.
4. Permits recruitment payments by hospitals to existing medical groups that employ recruited physicians under certain conditions.
5. Enables physicians to have staff privileges at other hospitals while having a recruitment contract with a hospital. "(Harris, 2004)

The physician recruitment exception allows hospitals to make recruitment payments to physicians when the following conditions are met:

1. Recruited physician relocates practice to hospital’s geographical area
2. The arrangement is in writing and signed by both parties
3. The arrangement is not conditioned on the physician’s referral of patients to the hospital.
4. When setting the recruitment payment volume or values of referrals are not taken into consideration.
5. The recruited physician is allowed to establish hospital privileges at any other hospital and is able to refer business to any other entities, unless it is prohibited under certain employment arrangements and services contracts.

The exception also allows hospitals to provide financial support for recruitment to medical groups through an existing medical group when the following conditions are met:

1. A written agreement must be signed between the parties, who are directly receiving the payments.
2. Remuneration must be passed directly through and remain with the recruited physician, except for actual costs incurred by the group practice in recruiting the new physician.
3. For income guarantee purposes, the costs allocated by the group practice to the recruited physician may not exceed the actual additional incremental costs attributed to the recruited physician.
4. The records of actual costs and passes-through amounts must be maintained for at least five years and made available to the Department of Health and Human Services upon request.
5. The remuneration can not take into account the volume or value of referrals made by the recruited physician, the group practice or any other physician in the group.
6. The arrangement can not violate the Anti-Kickback Statute.
7. The agreement can not violate any federal or state law or regulation governing billing or claims submission. (Harris, 2004)
The exceptions provided in Phase II did provide relief to some physicians who felt the initial phases of the law were too complicated and would prohibit them from generating additional revenue.

**Reporting requirements and sanctions**

The Stark Law requires that all entities providing designated health services in which payments are made by Medicare, report all financial relationships to the Secretary of Health and Human Services (HHS) regarding the entity’s ownership, investment and compensation arrangements. The following information must be reported:

1. The covered items and services provided by the entity
2. The names and unique physician identification numbers (UPIN) of all physicians with an ownership or investment interest or compensation arrangement in the entity.

In immediate family members ownership or investment interest must be disclosed as well. If the Secretary of HHS determines that a violation of the law has occurred the following sanctions may be enforced:

1. The denial of payment for services rendered
2. Refund for certain claims
3. Civil money penalties
4. Exclusion from all federally funded programs

If CMS determines the services were rendered in violation, the physician or entity will be denied payment for the services. If payments were paid and later determined to have been a violation of the law, then a refund will be required. The government has imposed civil money penalties for those who violate the Stark Law. The civil penalty
could be as high as $15,000 per service billed. The law provides a higher penalty if a physician or entity is found to be involved in a circumvention scheme. The penalty is $100,000 for each arrangement. If a physician or entity fails to report required information to the Secretary, he would be subjected to a $10,000 fine for each day the reporting is required to have been made.\textsuperscript{14}

Phase III

Phase III of the Stark Law was released on December 4, 2007 and has created some significant changes to an already very complicated law. The new rules become effective on October 1, 2009. This phase addresses several issues. A few of the most meaningful issues are physician recruitment and retention arrangements, non-monetary compensation exception, and the removal of the fair market value safe harbor provision.

Physician Recruitment and Retention Arrangement

Phase III further clarified the rule in regard to physician recruitment and retention agreements. The clarification seems to be a positive change. Stark allows hospitals and federally qualified health centers or rural health clinics to pay for the recruitment of physicians to the area as long as certain conditions are satisfied. The following conditions must be satisfied:

1. The agreement must be in writing
2. The agreement can not be conditional upon the physician referring patients to the hospital
3. Compensation must not be based on the value or volume of referrals to the hospital
4. The physician must be permitted to hold hospital privileges at other hospitals and refer patients to those entities. \textsuperscript{15} (Jones, 2007)

The agreement must also comply with the geographical rules. This rule was further defined in Phase III. “Under Stark II, a hospital’s geographic area was defined as the lowest number of contiguous zip codes from which the hospital draws at least 75% of its in-patients. CMS has adopted several changes in Phase III that expand that definition, particularly for rural hospitals.”(Frazier & Edquist, 2007) The changes in Phase III have made it easier for rural hospitals to recruit physicians. “In Phase III, rural hospitals can determine their geographical area by using an alternative test that encompasses the lowest number of contiguous zip codes (and in some cases, noncontiguous zip codes) from which the hospital draws 90% of its patients.”(Frazier & Edquist, 2007) The change has also made it possible for rural hospitals to recruit outside the geographical area if that area has demonstrated a need for recruiting a physician as determined by a CMS advisory opinion. Another clarification in Phase III is that contiguous zip codes are taken to mean contiguous to one another and not to the hospital. “CMS also clarified that a hospital may use any configuration that satisfies the “lowest number” test, which could mean that a hospital could use different geographic areas for different recruitment arrangements.” (Frazier & Edquist, 2007) \textsuperscript{16} These changes help both the rural hospitals as well as medical practices with recruitment efforts. Medical practices often have trouble recruiting physicians to rural areas and have limited funds to assist them in the efforts. The changes provide a legal way for hospitals and medical practices to work together to provide better patient care to the communities they serve.
Non-monetary compensation exception

Phase III further defined the non-monetary compensation exception to allow for physicians to receive items worth up to $300 within a calendar year. The exception also allows physicians to pay back any items that exceed the $300 limit without being in violation. The rule further states hospitals can have one medical staff appreciation function per year without regard to the $300 as long as the entire medical staff is included. This amount is adjusted for inflation. 17

Removal of the fair market value safe harbor

CMS removed the fair market value safe harbor after several comments regarding the feasibility of using national physician compensation surveys to determine physician compensation rates. Previously, physician compensation rates were to be determined by using national surveys. CMS realized computing fair market value in this manner didn’t take into consideration the geographical area. The removal of this safe harbor allows physicians to rely on surveys based on the region they practice in. MGMA surveys were cited as an acceptable resource to use.

Impact of Stark Law in the Medical Practice

October 1, 2009 is the deadline for medical practices and hospitals to be compliant with the new Stark rules. The changes in the law will make it necessary for physicians and hospitals to examine current contracts and agreements to ensure they meet the new standards. All agreements should be audited to ensure compliance. Any agreement found to be out of compliance must be restructured or terminated.

As expenses continue to rise and reimbursements continue to fall, medical practices have to reconsider how they will make up the difference. Phase III has forced
practices to analyze their additional revenue sources to make sure they comply with the law. One example that will impact the practice’s bottom line is the purchased service agreements. The rule states the practice can no longer mark up the professional fee when they bill the service to Medicare or Medicaid. A good example of this is a practice that performs x-rays and pays a radiologist to perform over reads. The practice is no longer able to mark up the charge for the professional component when it is billed to Medicare or Medicaid. The practice still must pay the radiologist for his or her services, but might not be reimbursed enough to cover the expense once the claim is processed by Medicare or Medicaid. Some physicians believe this is another example of how the Stark Law is impeding the ability to render safe and efficient patient care.

Some of the issues the new rules address are: in-office ancillary services, rental of office space, and office space for independent contractors.

**In-office ancillary services**

The expansion of the in-office ancillary service definition continues to protect the right of the physician to direct patient care. The following standards are addressed in the new rules:

1. The DHS must be performed by or supervised by the physician ordering the test or by another physician in the same group practice. This standard protects the physician’s role in caring for the patient, and allows the patient to receive services that are offered in a medical practice.

2. The services rendered must be billed by the group practice or the entity that performs the service. This standard assures the entity that provides the test is the same one who bills for the test.
3. The location of where the in-office ancillary test is performed is important. The standard is specific about the location. The in-office ancillary tests must be performed in the same building where the physician practices or in a centralized location that is used to perform the ancillary services. Further defining this standard assures the services being performed are a part of the medical practice.

4. The standard also addressed what is not considered an in-office ancillary service. Durable Medical Equipment (DME), (other than infusion pumps and services and enteral nutrients, equipment and supplies) is not considered in-office ancillary services. The logic behind this standard is the products are available for the patients to purchase. The standard further clarifies that physicians do not typically provide this service.¹⁸ (Kusserow & Yampolsky, 2005)

As long as the above standards are met, a solo or group practice may bill for DHS that are performed in the office.

**Rental of office space**

Rental of office space has been further clarified in Phase III. In order to satisfy the requirement, the parties must enter into a written lease for a period of at least one year. The lessee must have exclusive use of the rented space during a specified period of time. The space can not be shared with other lessees. “CMS is apparently saying that the use must be for defined times periods that are set in advance according to a schedule.” (Phillips, 2007) This rule is meant to prevent a lessor from leasing the same space to more than one lessee at a time. One exception to this is the shared common areas. The common areas can not include exam rooms. The parties must agree to a price based on fair-market value and not take into account the volume or value of referrals. In
the event the parties terminate the agreement without cause, the law prohibits either party
from entering into a similar contract for a period of one year. “The parties are not
prohibited from entering into a personal service arrangement or a lease agreement for
completely different office space.” (Phillips, 2007)

Office Space for Independent Contractors

In order for agreements to meet the Stark requirements for office space leasing to
independent contractors, both parties must follow the guidelines set forth under the rental
of office space provision. Both parties must execute a written agreement that includes a
rate based on the fair market value. The rate can not reflect any compensation that is
based on volume or value of referral. The agreement must be for a minimum of one year.
If either party terminates the agreement without cause before the one year, he or she are
prohibited from entering into a similar agreement until the one year is over.

Joint Ventures between Medical Practices and Hospitals

In the 80s, reimbursement began to dwindle for physician services and that caused
physicians to look for others ways to create an income stream. Physician’s historically
sent their patients to the local hospitals when they needed to have a procedure or test
done. As physicians considered ways to generate an additional income stream, they
identified opportunities to partner with each other as well as hospitals to provide services
in locations other than the hospital setting. Joint ventures were a good way for physicians
and hospitals to collaborate and be profitable.

By the mid-90s most ventures between hospitals and physicians were thought to
be illegal according to Stark. When Stark II came along, it threatened the ventures
between physicians and hospital. The law placed restrictions on physicians stating they
could not refer any Medicare or Medicaid patient to an entity in which the physician or an immediate family member had ownership interest in. Phase III further defined a financial relationship to include ownership as well as some contractual agreements. The clarification of the law forced physicians and hospitals to review their business relationships with each other and in some cases restructure the arrangement. (Hetzel & Tomey)  

Phase III of the Stark Law gives additional clarification regarding what financial relationships need to be reviewed to ensure compliance. “Financial relationships that may trigger a Stark violation include the following:

1. Hospitals (e.g., leases, personal services, employment, medical directorships and recruitment agreements

2. Suppliers of service (e.g., mobile ultrasound suppliers, DME companies, home health agencies)

3. Group Practices (e.g., to evaluate compliance to perform ancillary services and to evaluate compensation arrangements with group practices)

4. Independent contractor physicians (e.g. to evaluate agreements for reading and interpreting services.)” (Wachler, 2009)  

The new rules address issues that could affect joint ventures between medical practices and hospitals, ambulatory surgical centers and other commercial enterprises. Medical practices should have all contracts reviewed to ensure they are in compliance with the new rules. In some cases, the relationships will need to be restructured or dissolved completely. The issues that will likely have the greatest impact on the medical
practice and these relationships are: services provided under arrangement, per click “leases,” percentage-based compensation, and the stand in shoes provision.

**Service under arrangements**

The new rule further defines what an entity is. Under the current rules, an entity is considered to be furnishing DHS, and therefore, is subject to the Stark Law only if the entity bills Medicare for the DHS. The current rule allows the entity to refer a patient to a physician who has ownership/investment interest without violating the law as long as the physician performing the service bills it to another provider who bills for the DHS. The revised definition states that CMS will consider a person or entity to be furnishing DHS’s if they perform or bill for the DHS. (Washlick, 2008)

**Per click “Leases”**

The new rule prohibits per click leases for office space or equipment when the payment is for space or equipment used to treat patients who are referred to the lessee by the lessor. “CMS makes clear that the prohibition on per click payments for space or equipment used in the treatment of a patient referred to the lessee by a physician applies regardless of whether the physician is the lessor or whether the lessor is an entity in which the referring physician has an ownership or investment interest. The prohibition applies only to situations where the lessor is a DHS entity that refers patients to a physician lessee or a physician organization lessee.” (Washlick, 2008)

**Percentage-based compensation**

Any lease for space or equipment that includes compensation based on a percentage of usage will no longer satisfy the space and equipment lease exceptions, the fair market value exception, or the indirect compensation arrangement exception. CMS
felt it necessary to make this change due to concern that payments based on a percentage of revenues earned by the lessee might provide an incentive for the lessor to increase referrals for DHS to the lessee.

CMS has said this new change will not affect services personally performed by a physician whether the service is clinical or administrative. These arrangements may continue using the percentage based compensation as long as the formula is based on the revenue generated directly from a physician’s services.\(^22\) (Washlick, 2008)

**Stand in the Shoes Provision**

The Stand in the Shoes (SITS) provision was addressed by CMS in Phase III of the Stark Law and implemented on December 4, 2007. This provision applies to physician organizations. A physician organization is a physician, a wholly owned professional corporation, a group practice or other physician practice. “Under this rule, a financial relationship between an entity providing DHS and a physician organization is attributed to the physician owners, physician employees and physician contractors of the organization.”\(^23\) (Phillips, 2008)

**Conclusion**

The original intent of the Stark Law was to make sure physicians made medical decisions without considering how much profit would be made. The concept made sense and did not seem like it would be too complicated to write a law that governed this type of behavior. The writing of the law began to get complicated as Congress tried to balance the concept without stripping physicians of their rights to practice medicine.
The Stark law has positive and negative sides to it. On the positive side, the law preserves the physician’s right to direct patient care. The law also holds physicians accountable when considering the best way to care for patients. Many feel the negative side outweighs the positive side. One major negative is the complexity of the law. Thus, it has taken three phases to explain it so that physicians were able to be compliant. Another negative aspect of the law is that it prohibits physicians from entering into certain types of business arrangements. Some would argue the law and all its phases have driven the cost of providing medical care up. Every time a revision or clarification is released, physicians spend money to have their agreements reviewed to ensure they are in compliance with the law. The greatest negative of all is the way the law is intertwined with the federal “Anti-Kickback Law.” This further confuses physicians, administrators and CFO’s.

On August 19, 2008, CMS released a statement regarding how it intends to audit Stark for compliance. CMS audit plans begin with hospitals surveying around 400 nationwide. Survey participation will be mandatory for those selected participants. The survey tool that is being used is called “Disclosure of Financial Relationships Report” (DFRR). If selected facilities do not respond, a fine of up to $10,000 each day it is overdue may be imposed. CMS has stated that after an analysis of the survey is complete, they will determine if there is a need to further expand the mandatory survey to all hospitals who participate with the Medicare program.24 (Kutak Rock, 2008)

Phase III addressed many aspects of the law; however, it has also left many under answered questions. Issues that might be addressed in the future are:
1. Changes to the “in-office ancillary exception” Some fear loopholes still exist that will allow practices to abuse the exception.

2. No action was taken on the way physician-owned implant and device companies are analyzed under Stark. This may be addressed in a future update.

3. Congress will likely address a possible new exception for gain sharing. They solicited comments for 2009 and proposed some regulatory language changes. In the end they did not act on those proposed changes, they instead composed a list of additional questions and ask for public comment.²⁵ (Saner, 2008)

The Stark Law is a very complex law that will continue to dictate the way physicians conduct business while trying to practicing medicine. As the law continues to be debated and revised, medical practices need to stay alert and evaluate each change as it pertains to their practice. It is important to remember, unlike some of the laws and regulations that are intertwined with the Stark law, the Stark law can be violated without intent to do so.
End Notes

1 Alice G Gosfield, JD, “The STARK TRUTH About the STARK LAW: Part I” (AAFP Family Practice Management, 2003) 27.


5 42 C.F.R § 411.353(a)

6 42 C.F.R § 411.351(DHS 1-10)

7 42 U.S.C.1395nn (b,c)

8 42 U.S.C.1395nn (b,c)

9 42 C.F.R § 411.357(a,1-7)

10 42 C.F.R § 411.357(b,1-6)

11 42 C.F.R § 411.357(c,1-4)


13 Steven M. Harris, “Stark II exceptions for physician recruitment by hospitals” (American Medical News, 2004) 47.

14 42 U.S.C.1395nn (8,f-g)

15 John W Jones, Esq., “Physician Recruitment in the wake of Stark III” (Physician’s News Digest, 2007)


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