# Regulatory Issues that Affect Funding of Physician-Backed Medical Enterprises: A Primer

by

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***Abstract***

This paper provides a summary of key federal regulatory issues that affect funding of physician-based medical enterprises. Margins in medical practices continue to face pressure from all sides. As physician compensation from core medical practices declines, physicians seek new avenues to profit. Many physicians start or sponsor spin-off businesses related to their practice or their medical background. As angel investors, venture capitalists and private equity firms consider investing in such medical businesses, the regulatory constraints on such enterprises becomes an important concern. Beginning with a hypothetical scenario suggested by recent regulatory enforcement cases, this paper examines key federal laws that govern physician-backed medical enterprises that could affect funding of such enterprises - the Stark law, the antikickback law and the False Claims Act.

## *Introduction*

As a long time oncologist sits down with a friend after a round of golf, he begins to describe a new venture that he is starting with a cardiologist and a neurologist. The trio is starting a new positron emission tomography scanning (otherwise known as a "PET scanning") facility. The basic idea is that all three physicians have stable practices that could bring a

significant volume of patients to the new venture, including Medicare and Medicaid patients. The new venture has already negotiated favorable pricing for acquisition of the PET scanning system and has acquired office space in a building owned by one of the physicians. The oncologist tells the friend that the group is looking for a few financial partners to help with some of the initial capital expenses. The oncologist tells the friend that they have a radiologist ready to come on board to run the facility and for "only $100,000, you could get a 5% stake in the business and have a lifetime of returns!" The friend says that he will think about it and promptly calls his business lawyer to ask about investing in such a physician-backed medical venture.

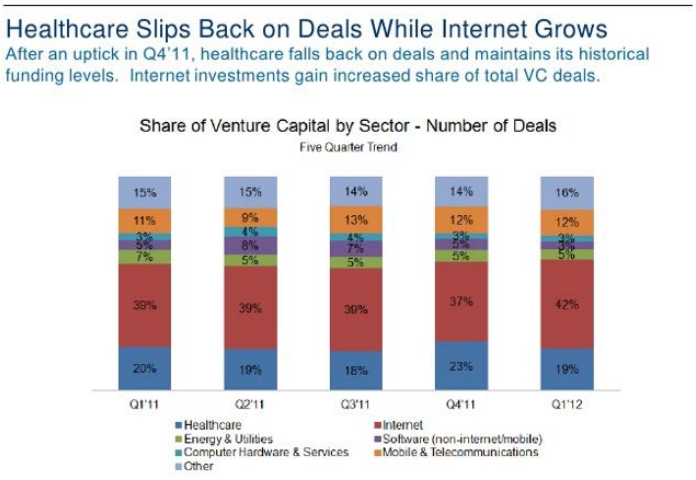
With this scenario as the backdrop, an initial question that the friend and his lawyer might discuss is: what factors are driving the physicians to start this venture? Physicians today face increasing pressure on compensation from their core medical discipline.[1] Margins in physician practices are getting smaller, which is attributable to many factors, including increasing regulatory costs,[2] general increases in business expenses[3] and reduction in payor reimbursement from government-sponsored programs such as Medicare and Medicaid.[4] In order to cope with

[1] R. Fields, *5 Trends Affecting the Future of Physician Compensation*, http://www.beckershospitalreview.com/compensation-issues/5-trends-affecting-the-future-of-physician-compensation.html; M. Mintz, M.D., *Primary Care Physicians Are Set to Lose Half Their Salary*, http://www.kevinmd.com/blog/2011/12/primary-care-doctors-set-lose-salary.html.
[2] T. Cheplick, Obamacare Expected to Increase the Loss of Doctor-Owned Practices, http://news.heartland.org/newspaper-article/obamacare-expected-increase-loss-doctor-owned-practices.
[3] J. Sarasohn-Kahn, *The New Cost-Conscious Doctor*, The Health Care Blog, http://thehealthcareblog.com/blog/2011/04/22/physicians-in-u-s-are-increasingly-cost-conscious/, April 22, 2011.
[4] J. Commins, Health Leaders Media, http://www.healthleadersmedia.com/page-1/FIN-269857/AMGA-Physician-Practices-Falter-on-Thinning-Margins, August 17, 2011.

such decreasing compensation, many physicians today turn to entrepreneurship to pursue medical opportunities outside of their core practice.[5]

Physician entrepreneurship is not without perils of its own even without a difficult regulatory climate. Physicians are often unprepared for the business and operational requirements of a start-up enterprise. While medical training provides technical subject matter competence, it does not provide significant business skills or a deep understanding of how to operate a multi-faceted business operation.[6] Despite significant hurdles, many physicians plow ahead to develop new medical businesses.

As physicians take the leap to start such businesses, funding remains somewhat uneven. A recent survey reports the trends in venture capital funding for healthcare enterprises generally. As of the first quarter of 2012, funding for healthcare ventures fell as a total percentage of venture capital investments:[7]




[5] New York City Health 2.0, Physicians as Entrepreneurs, Making the Leap and Making it Work, http://www.health20nyc.com/events/46603372/?eventId=46603372&action=detail.

[6] PR Newswire, *Can Doctors Be Savvy Entrepreneurs and Caring Practitioners in the Age of Health Reform? New Book, The Medical Entrepreneur Teaches What Medical School Does Not*,http://www.prnewswire.com/news-releases/can-doctors-be-savvy-entrepreneurs-and-caring-practitioners-in-the-age-of-health-reform-112794819.html.

[7] CB Insights, Venture Capital Report, Q1 2012, located at cbinsights.com. The report notes that funding of healthcare ventures has "flu-like symptoms."

The survey indicates that as of the first quarter of 2012 investment sentiment in the healthcare sector was mixed. Given the enforcement climate and the regulatory hurdles discussed below, it is not surprising to see hesitation in investor sentiment for physician-backed medical enterprises.

In examining any physician-backed enterprise, one must examine the following factors:

- What is its essence? (Manufacturing, distribution/sales, services)
- What elements drive its viability?
- Regulated in what ways by whom?
- What is its "business flow?"
- What is its "flow of funds?"

In examining the joint venture proposed by the scenario, this paper examines one aspect of the five-factor healthcare business tests – the regulatory environment for physician-backed medical businesses – specifically, the key federal regulatory constraints on physician ventures.[8] There are a number of laws and regulations that govern physicians that may affect physician entrepreneurial ventures. For example, in the beginning hypothetical, there may be state licensure issues or zoning or real estate restrictions on a PET scanning facility. Importantly, though, federal and state laws mandate numerous restrictions on the manner of operations of the new facility given the participation of the physicians.

Whether assessing physician-backed enterprises from a potential investor's investment perspective or assessing the valuation of physician-backed medical enterprises, the core federal regulatory framework that governs these businesses is an important consideration. This paper

[8] This paper focuses on physician-backed *medical* enterprises, but does not consider the issues raised by non-medical enterprises.

examines those constraints that govern physician-backed enterprises and have the potential to affect the funding of such businesses. In particular, this paper discusses the anti-self referral law known as the Stark law, the antikickback law and the Federal False Claims Act.

***What are key federal regulatory issues that affect funding of physician-backed medical enterprises***?

As the oncologist's friend and his lawyer assess whether an investment in the physician-backed venture makes sense, an assessment of the legal risks will be a key criterion. Today more than ever before, the regulatory environment for physician-backed ventures presents significant risks. The next question the prospective investor and his lawyer may ask is: what does the enforcement climate for these types of ventures look like today?

A. *Enforcement*. Today's healthcare enforcement climate is unique. With declining budgets and austerity programs, the United States government and state governments are looking for efficient ways to recover funds into the public coffers. Given the financial incentives that the healthcare regulatory system has created, there have been more resources dedicated to healthcare enforcement activities than ever before.[9] The United States Department of Justice, the United States Attorneys, the Federal Bureau of Investigation, the Office of the Inspector General of the Department of the Health and Human Services, state attorneys general, whistleblowers and patients are all potential plaintiffs regarding missteps in compliance.[10] Verdicts or settlements in healthcare fraud cases can run into the hundreds of millions or billions of dollars - not to mention the fact that criminal penalties exist. On July 2, 2012, the United States Department of Justice

[9] *See* J. Stuart Showalter, The Law of Healthcare Administration (5th ed. 2007), pps. 358-360 (discussing the difficult enforcement climate).
[10] *See* Office of the Inspector General, Department of Health and Human Services, http://oig.hhs.gov/fraud/enforcement/criminal/index.asp (describing enforcement activity).

announced that it entered into the largest ever settlement agreement with GlaxoSmithKline ("GSK") in which GSK agreed to pay $3 billion to resolve fraud allegations.[11] The GSK settlement included $1 billion in criminal fines and $2 billion in civil penalties. Many commentators believe the current regulatory climate is here to stay and medical ventures must re-double their compliance efforts in order to stay in business.[12]

As physician entrepreneurs and their investors consider medical entrepreneurial ventures, they must take account of regulatory compliance.[13] A savvy investor will want a detailed response regarding the new venture's compliance efforts. The days of being able to say that one did not know that they had to comply with such regulations or that the compliance effort was left to someone else are long over. The new venture must have a compliance plan in place from the moment of start-up.

With that cautionary tale as the backdrop, we now turn to three specific areas of federal regulation and enforcement for physician-backed medical ventures: the Stark law, the antikickback law and the False Claims Act.[14]

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[11] *See* United States Department of Justice, http://www.justice.gov/opa/pr/2012/July/12-civ-842.html (announcing the GSK settlement).

[12] C. Stamer, *Pharmas Face New Pressure To Put Patients Before Profits After GlaxoSmithKline Record $3 Billion Health Care Fraud, FDCA Conviction & Settlement*, http://slphealthcareupdate.wordpress.com/2012/07/11/pharmas-face-new-pressure-to-put-patients-before-profits-after-glaxosmithkline-record-3-billion-health-care-fraud-fdca-conviction-settlement/.

[13] *See* A. Gonzales, *Doctors fight hospital ownership rules under Affordable Care Act*, Phoenix Business Journal, July 13, 2012 (describing physician outrage over restrictions in PPACA restricting physician ownership of hospitals).

[14] The scenario presented at the beginning of this paper may also implicate other regulatory requirements, including the corporate practice of medicine doctrine from a state law perspective, among others. However, this paper focuses on the key regulatory constraints contained in the Stark law the antikickback law and the False Claims Act. In addition, the requirements of state anti-self referral or antikickback laws is outside the scope of this paper.

B. *The Stark Law*. One of the key questions that could affect the regulatory exposure for a physician-backed entity is: will the physician make referrals of Medicare or Medicaid patients to the business? If the physician will make referrals to the new venture, an entity in which the physician will be an owner, the Stark law is plainly implicated.

The Stark law is actually three sets of laws that were original enacted by Congress and signed by the President in the Omnibus Budget Reconciliation Act of 1989, which barred physician self-referrals of clinical laboratory services effective January 1, 1992.[15]The Omnibus Budget Reconciliation Act of 1993 expanded the restriction beyond clinical laboratory services to a range of additional health services and applied it to both Medicare and Medicaid (known as "Stark II"). The regulations that clarified the Stark law in 2007 are commonly referred to as "Stark III."

The basic prohibition set forth in the law is found at Title 42 of the United States Code Section 1395nn, which provides:

> (a) Prohibition of certain referrals
>
> (1) In general
> Except as provided in subsection (b) of this section, if a ***physician*** (or an ***immediate family member of such physician***) has a ***financial relationship*** with an entity specified in paragraph (2), then—
> (A) the physician ***may not make a referral*** to the entity for the furnishing of ***designated health services*** for which ***payment otherwise may be made under this subchapter***, and
> (B) the entity ***may not present*** or cause to be presented ***a claim*** under this subchapter or bill to any individual, third party payor, or other entity for designated health services furnished pursuant to a referral prohibited under subparagraph (A).
> (2) Financial relationship specified

[15]*See*http://starklaw.org/stark_law.htm (discussing the origins of the Stark laws).

> For purposes of this section, ***a financial relationship*** of a physician (or an immediate family member of such physician) with an entity specified in this paragraph is—
> (A) except as provided in subsections (c) and (d) of this section, an ***ownership or investment interest*** in the entity, or
> (B) except as provided in subsection (e) of this section, a ***compensation arrangement*** (as defined in subsection (h)(1) of this section) between the physician (or an immediate family member of such physician) and the entity.
> An ownership or investment interest described in subparagraph (A) may be through ***equity, debt, or other means*** and includes an interest in an entity that holds an ownership or investment interest in any entity providing the designated health service.

(Emphasis added.) The basic prohibition of the Stark law has several key features. The prohibition applies to *physicians* –defined as a medical doctor, doctor of osteopathy, a dentist, podiatrist, optometrist or chiropractor.[16] Physicians are prohibited from referring Medicare or Medicaid patients for "designated health services" to entities in which the physician (or an immediate family member of the physician) has a compensation or ownership or investment interest, unless an exception applies. Moreover, the designated health services entity is prohibited from submitting claims for services resulting from a prohibited referral.

"Designated health services" has been defined to include: clinical laboratory services; physical therapy, occupational therapy, and outpatient speech-language pathology services; radiology and certain other imaging 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; and inpatient and outpatient hospital services.[17] A "financial relationship" is defined to include any arrangement that involves ownership, compensation or investment, either

[16] 42 Code of Federal Regulations Section 411.351.
[17] *Id.*

through debt or equity. As mentioned above, the law extends the prohibition to immediate family members of the physician.[18]

The Stark law is a strict liability statute – meaning, intent is not required to violate the law. If the terms of the law are violated, the *mens rea*, or intent of the actor, is not relevant. In other words, it does not matter that a physician did not intend to violate the law or did not know the physician that he or she should not be acting in a certain way.

Penalties for violations of the Stark law are significant. Penalties include denial of payment, refund of payment, imposition of a $15,000 per claim civil monetary penalty, civil monetary penalty of three times the amount claims and imposition of $100,000 civil monetary penalty for each arrangement considered a circumvention scheme.[19] There are currently no criminal penalties for violation of the Stark law.

The Stark provides 35 different exceptions that provide that certain relationships are acceptable. These exceptions include physician services, bona fide employment relationships, space and equipment leases, personal services arrangements and physician recruitment, among others.[20]

The Stark Law's twin sister is the antikickback law. Many people confuse the two sets of laws or believe that compliance with the Stark law automatically means compliance with the antikickback law. However, the antikickback law must be dealt with on its own terms.

C. *The Antikickback Law*. The antikickback law prohibits offering, paying, soliciting or receiving anything of value to induce or reward referrals or general federal healthcare program

[18]Immediate family member or member of a physician's immediate family means "husband or wife; birth or adoptive parent, child, or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent or grandchild; and spouse of a grandparent or grandchild." *Id*.
[19]42 U.S.C. § 1395nn(g).
[20] 42 U.S.C. § 1395nn(b).

business.[21] The statute covers payments by *any* federal healthcare program. A violation of the antikickback law is a felony that is punishable by criminal fines of $25,000 per violation or imprisonment of up to five years or both. In addition, the Office of the Inspector General has the authority to exclude from Medicare and Medicaid programs those individuals who have violated the law. In addition, the law provides for civil penalties of $50,000 per violation, plus three times the amount of the remuneration involved.[22]

The statute includes a limited batch of exceptions, including properly disclosed discounts that are reflected in cost reports, amounts paid by an employer to an employee to provide healthcare services, amounts paid to a vendor as a result of a group purchasing entity and remuneration paid through a risk-sharing arrangement.[23] More importantly, perhaps, the antikickback law includes certain "safe harbors" – certain activities that are described in regulations adopted by the United States Department of Health and Human Services as not providing a basis for criminal prosecution or a basis for exclusion from a federal healthcare program.[24] The safe harbors include investments in other practices and businesses, rental of space at fair market value (i.e., not greatly above or below the cost of comparable office space), rental of equipment at fair market value, personal services and management contracts, sale of practices, referral services, warranties of equipment, discounts, remuneration to employees, group purchasing organizations, waiver of beneficiary coinsurance and deductible amounts, increased coverage, reduced cost-sharing or reduced premium amounts offered by HMOs or

[21] 42 U.S.C. § 1320a-7b(b)(1)(A) and 2(A).
[22] 42 U.S.C. § 1320a-7(b)(7) and 1320a-7a(a)(7).
[23] 42 U.S.C. § 1320a-7b(b)(3).
[24] 42 C.F.R.§ 1001.952; Office of the Inspector General, *Federal Antikickback Law and Regulatory Safe Harbors*, http://oig.hhs.gov/fraud/docs/safeharborregulations/safefs.htm.

other prepaid health plans, practitioner recruitment, investment in group practices and price reductions offered to eligible managed care organizations.

The key terms in the antikickback law are referral and remuneration. Unfortunately, neither the statute nor the regulations define "referral." "Remuneration" is also not defined, but case law interpreting the statute and regulations define "remuneration" as essentially anything having monetary value.

While the statute provides that a violation requires that the individual knowingly or willfully intended to induce a referral, case law has provided further clarity such that even if only one purpose of a payment is to induce referrals (in the face of other legitimate purposes), the payment can be held to violate the statute.[25]

With the tenets of the Stark law and the antikickback law set out, we now turn to the engine that drives enforcement of the Stark law and antikickback law – the False Claims Act.

D. *The False Claims Act*. In order to address the issue of overcharging the United States Army during the Civil War, the False Claims Act was enacted. Over time, the False Claims Act has been used for other purposes and is now a key part of the constraints on physician-backed medical ventures.

The False Claims Act provides that a person is liable for penalties if he or she knowingly presents or causes to be presented to an officer or employee of the United States, a false or fraudulent claim for payment or approval; knowingly makes, uses or causes to made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government; conspires to defraud the Government by getting a false or fraudulent claim allowed or paid; or knowingly makes, uses or causes to be made or used, a false record or statement to conceal,

[25] *United States v. Greber*, 760 F.2d 68 (3rd Cir. 1985).

avoid or decrease an obligation to pay or transmit money or property to the government.[26] The prevailing view has generally been that claims submitted to Medicare or Medicaid that violate the Stark law or antikickback law are fraudulent and therefore subject to penalty under the False Claims Act as well. In fact, the Patient Protection and Affordable Care Act amended the language of the antikickback law to provide that claims submitted in violation of the antikickback law are *per se* violations of the False Claims Act.[27]

Violations of the False Claims Act result in civil penalties ranging from $5,000 to $10,000 per claim plus three times the amount of damages sustained by the government. The costs of bringing the action will be charged against the defendant.[28] In addition, filing a false claim with the federal government is a criminal offense, which can subject an entity to criminal fines of $500,000 or twice the amount of the false claim, whichever is greater, and an individual can be subject to $250,000 or twice the amount of the false claim, whichever is greater and can be sentenced up to five years in prison.[29] It is also important to note that an amendment to the False Claims Act defined "knowingly" under the Act to mean actual knowledge of falsity, deliberate ignorance of truth or falsity or reckless disregard for truth or falsity.[30]

An important component of the False Claims Act is the fact that private individuals can sue on their own behalf and on behalf of the government to recover damages and penalties. These lawsuits are referred to as whistleblower or *qui tam* claims. The law provides that an individual plaintiff is entitled to share in the award with the government.[31]

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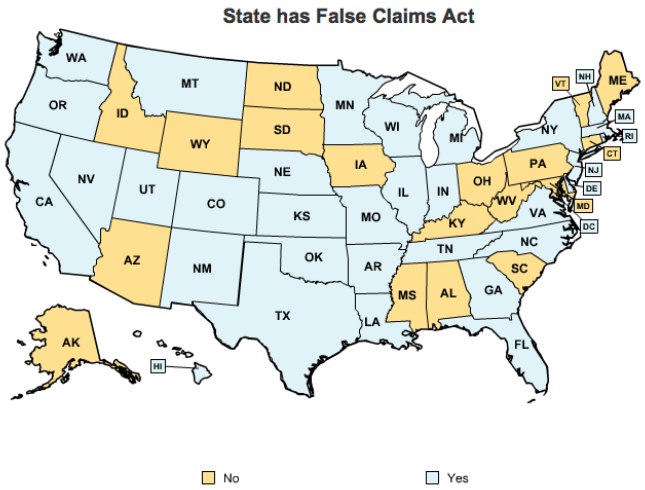
[26] 31 U.S.C. § 3729-3731.
[27] S. Oswald & D. Scher, *Healthcare Law Expands False Claims Act Liability under Anti-Kickback Statute*, 14 WESTLAW JOURNAL NURSING HOME 2 (2012).
[28] *Id.*
[29] 18 U.S.C. § 287.
[30] 31 U.S.C. § 3729(b).
[31] 31 U.S.C. § 3730.

In addition, many states have adopted their own versions of false claims statutes. The table below shows the states that have adopted such statutes (as of 2009):[32]




In addition, Exhibit A contains a chart that compares the three key sets of laws in summary form that are examined in this paper: the Stark law, the antikickback law and the False Claims Act.

E. *How do these laws affect funding of physician-backed medical enterprises*? The regulatory burden that any physician-backed medical ventures must face is significant.[33] The first question that outsiders examining a physician-backed enterprise will ask is: what is the compliance effort? Said another way – does the venture have a plan as to how it will comply with the laws governing physician?

Without a compliance plan, both the new venture and the physician-owner subject themselves to undue risk. Moreover, third parties seeking to invest in such ventures, such as angel investors, venture capitalists and private equity firms will perform diligence on the

[32] The Henry J. Kaiser Family Foundation, Table dated 2009, http://www.statehealthfacts.org/comparemaptable.jsp?ind=790&cat=4.
[33] S. Mackie, *Liability of a Physician for Improper Referral of Patients to a Medical-Care Facility in Which the Physician Has a Financial Interest*, 61 AM. JUR. PROOF OF FACTS 3d 245 (2001 & Supp. 2012).

compliance plan and will not invest without assurance that the venture is prepared with a plan for compliance and resources dedicated to execution of the compliance strategy. The notion of having a compliance plan and executing in accordance with the plan is critically important – regulators will be more critical of those enterprises that have a compliance plan and fail to adhere to it than those that have failed to adopt a compliance plan in the first instance.

F. *What is the impact on the venture suggested by the PET scanning scenario?*

Returning to the initial hypothetical, the Stark law, the antikickback law and the False Claims Act each have potential implications to the PET scanning scenario.

From a Stark law perspective, PET scanning services are included in the definition of "designated health services" after a 2007 amendment to the Stark, which expanded the radiology services reference within the definition of "designated health services" to include PET scans. Given that the owners of the proposed venture are physicians, the intent is that they would be referring federal program patients to the joint venture and they would have a direct financial relationship with the joint venture, the Stark law will be violated, unless an exception applies.

There is no available exception directly available for this sort of joint venture. However, the joint venture could be restructured so that the "in-office ancillary services" exception[34] applies.[35] This exception allows physicians in a group practice to provide designated health services that are ancillary to the physician's core medical practice, as long as such services are provided in a location where the core medical services are routinely delivered, subject to several

[34] 42 U.S.C. 1395NN(b)(2).

[35] *See* D. Gottlieb, Imaging Likely to Feel Effects of MedPac Stark Law Plans, http://www.diagnosticimaging.com/healthcare_reform/content/article/113619/1574395 (discussing the impact of Stark on diagnostic imaging joint ventures); N. Travis, S. Chananie and J. Finnegan, *The Stark Reality About Shared Nuclear Medicine Imaging Equipment Leasing Arrangements After January 1, 2007*, 3 THE JOURNAL OF THE AMERICAN COLLEGE OF RADIOLOGY 12 (2006) (same).

requirements including supervision, location and billing requirements. In order to meet the definition of a "group practice," 75% of the patient care services of the practice must be provided by owners or employees of the group and each owner or employee referring Medicare patients to the group for designated health services must provide at least 75% of his/her patient care services through the group. The group practice definition also prohibits a group from compensating its members in any manner that directly takes into account the volume or value of their Medicare patient referrals.

If the proposed joint venture was restructured such that the core medical practices were joined together to become a group practice with a centralized location, the in-office ancillary services exception could have application. The group practice would then have to analyze whether the supervision, location and billing tests could be satisfied.

The supervision test[36] requires the designated health services to be furnished personally by: the referring physician, a physician who is a member of the same group practice as the referring physician, or an individual who is supervised by the referring physician or another physician in the group practice. In this instance, to the extent that the radiologist will be performing designated health services related to the read of the PET scans, the radiologist would have to become a member of the group practice.

With regard to the location test,[37] the PET scanning device would have to be located in a "centralized location" or in the "same building" in which the group practice maintains an office. This "location" requirement has a number of tests. The test that would appear to be most applicable here is met so long as the medical group maintains an office in the same building as the PET scanner that is normally open at least 8 hours a week and a member of the group

[36] 42 U.S.C. 1395NN(b)(2)(A)(i).
[37] 42 U.S.C. 1395NN(b)(2)(A)(ii).

practice regularly practices medicine and furnishes services to patients in the office at least 6 hours a week.

Finally, the billing test[38] requires the designated health services to be billed by the group practice or the physician performing or supervising the service. In addition, the 2010 Patient Protection and Affordable Care Act modified the Stark law such that in connection with referrals for positron emission tomography and other advanced imaging services, the referring physician must inform a patient in writing at the time of the referral that the patient may obtain the service from a person other than the referring physician or someone in the physician's group practice, and the referring physician must provide the patient with a list of suppliers who furnish the service in the area in which the patient resides.[39] In addition, Centers for Medicare and Medicaid Services has promulgated rules under the modification to the Stark Law notice requirement that: (a) requires the referring physician to provide a written disclosure notice to the patient at the time of the referral; (b) the disclosure notice must include a list of 5 other suppliers that provide the same services and are located within a 25-mile radius of the referring physician's office and the supplier's name, address and telephone number; (c) If there are fewer than 5 suppliers within the 25-mile radius, the referring physician must list all of the suppliers (if there are no alternative suppliers within a 25-mile radius, a written list is not required); and (d) requires the disclosure notice to be written in a manner "sufficient to be reasonably understood" by all patients.[40]

If the physicians did not want to join together in a group practice format, another potential structure is to keep their individual practices and each lease a portion of the PET

[38] 42 U.S.C. 1395NN(b)(2)(B).
[39] 42 U.S.C. 1395NN(b)(2).
[40] 75 Fed. Reg. 40140-2.

scanning device. Even in a multi-practice lease arrangement, the requirements of the in-office ancillary services exception must be met.

As if having to scrap the original structure because of the Stark law is not enough, the revised venture must also face compliance with the antikickback law. The original arrangement plainly involves referrals of federal program patients by the owner-physicians to an entity that would provide them with remuneration (distributions of profits of the enterprise). In order to be antikickback law compliant, the venture must be restructured. In particular, the venture should seek one of the available safe harbors under the antikickback law for the greatest assurance that the venture's activities do not run afoul of the antikickback law. In a re-structured venture, several safe harbors could potentially apply including the equipment rental, space rental and personal services safe harbors. It is clear that the venture must be restructured in order to be complaint with federal fraud and abuse laws.

***Conclusion***

The regulatory burden facing physician-backed medical ventures is significant. Even with a cursory understanding of the Stark law, antikickback law and False Claims Act, investors may shy away from such enterprises given that the enforcement climate is strong and the penalties are so significant. As is depicted in the hypothetical scenario, the federal fraud and abuse laws can turn a physician-backed medical venture upside down in short order.

If society views healthcare with an eye toward the impact on the quality, autonomy, access and cost of healthcare,[41] as we consider funding of physician-back enterprises, each of these areas appears to be raised. While some may argue that regulation of physician-backed

[41] *See* M. Hall, *The History and Future of Health Care Law: An Essentialist View*, 41 WAKE FOREST LAW REVIEW 341, 353 (2006) (discussing quality, autonomy, access and cost as the key drivers of healthcare law and policy).

enterprises improves quality of healthcare, it appears difficult to grasp that conclusion in light of the overwhelming force of regulation here and its at least indirect connection to healthcare quality. Patient autonomy appears to be these regulations strong suit where it can be argued that patients will have greater autonomy to make decisions when self-referral or the remuneration/referral conundrum is removed. However, free market policy advocates would say that the free market could enhance patient autonomy by freeing up patient choice, including the choice toward entities where conflicts of interest may exist. The fraud and abuse regulations appear to reduce access to healthcare as the economic burden of such regulations dampens the possibilities of new enterprises that could see patients. Finally, there can be little doubt that the fraud and abuse regulations create enormous costs in the healthcare system.

In the end, regulation of physician-backed medical enterprises is significant. As investors consider funding such enterprises, the regulatory hurdle is a massive wall that can now only be overcome by adventurous entrepreneurs who are armed with significant resourced dedicated to compliance.

**Exhibit A**

**Summary and Comparison of Stark Law, Antikickback Law and False Claims Act**

| ***Factor*** | ***Stark Law*** | ***Antikickback*** | ***False Claims*** |
|---|---|---|---|
| Core Provision | Physicians are prohibited from referring Medicare or Medicaid patients for "designated health services" to entities in which the physician (or the physician's immediate family members) has a compensation or ownership or investment interest, unless an exception applies.<br><br>Moreover, the designated health services entity is prohibited from submitting claims for services resulting from a prohibited referral. | Prohibits offering, paying, soliciting or receiving anything of value (remuneration) to induce or reward referrals or general federal healthcare program business.<br><br>Covers payment for any federal healthcare program.<br><br>Remuneration and referral are the key terms. | The False Claims Act provides that a person is liable for penalties if he or she knowingly presents or causes to be presented to an officer or employee of the United States, a false or fraudulent claim for payment or approval; knowingly makes, uses or causes to made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government; conspires to defraud the Government by getting a false or fraudulent claim allowed or paid; or knowingly makes, uses or causes to be made or used, a false record or statement to conceal, avoid or decrease an obligation to pay or transmit money or property to the government. |
| Intent Required | Strict liability for overpayment.<br><br>Intent required (knows or should know) for civil monetary penalties for circumvention scheme. | Intent must be proven – knowingly standard. | Intent must be proven – knowingly standard. |
| Applies to | Physicians | Anyone | Anyone |

| ***Factor*** | ***Stark Law*** | ***Antikickback*** | ***False Claims*** |
|---|---|---|---|
| | | | |
| Type of Service | "designated health services" | Any items or service | Any claims for payment presented to an employee or officer of the United States, false records, conspires to defraud. |
| Exceptions | The Stark provides 35 different exceptions that provide that certain financial relationships are acceptable. These exceptions include physician services, bona fide employment relationships, space and equipment lease exceptions, personal services arrangements and physician recruitment, among others. | Limited - properly disclosed discounts that are reflected in cost reports, amounts paid by an employer to an employee to provide healthcare services, amounts paid to a vendor as a result of a group purchasing entity and remuneration paid through a risk-sharing arrangement. | None |
| Safe Harbors | None | The safe harbors include investments in other practices and businesses, rental of space at fair market value (i.e., not greatly above or below the cost of comparable office space), rental of equipment at fair market value, personal services and management contracts, sale of practices, referral services, warranties of equipment, discounts, remuneration to employees, group purchasing organizations, waiver of beneficiary coinsurance and deductible amounts, increased coverage, reduced cost-sharing or reduced premium amounts offered by | None |

| ***Factor*** | ***Stark Law*** | ***Antikickback*** | ***False Claims*** |
|---|---|---|---|
| | | HMOs or other prepaid health plans, practitioner recruitment, investment in group practices and price reductions offered to eligible managed care organizations (MCOs). | |
| Penalties | Penalties for violations of the Stark law are significant. Penalties include denial of payment, refund of payment, imposition of a $15,000 per claim civil monetary penalty, civil monetary penalty of three times the amount claims and imposition of $100,000 civil monetary penalty for each arrangement considered a circumvention scheme. There are currently no criminal penalties for violation of the Stark law. | Violations of the antikickback law are felonies that are punishable by criminal fines of $25,000 per violation or imprisonment of up to five years or both. In addition, the Office of the Inspector General has the authority to exclude from Medicare and Medicaid programs those individuals who have violated the law. In addition, the law provides for civil penalties of $50,000 per violation, plus three times the amount of the remuneration involved | Violations of the False Claims Act result in penalties ranging from $5,000 to $10,000 per claim plus three times the amount of damages sustained by the government. The costs of bringing the action will be charged against the defendant. In addition, filing a false claim with the federal government is a criminal offense, which can subject an entity to criminal fines of $500,000 or twice the amount of the false claim, whichever is greater, and an entity can be subject to $250,000 or twice the amount of the false claim, whichever is greater and can be sentenced up to five years in prison.<br><br>In addition, government can excluded participation in Medicare and Medicaid for violations of the False Claims Act. |