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THE STARK STATUTE: PARSED, PROBED AND PANNED

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The single worst piece of legislation I have confronted in my entire career, its drafters were not unduly burdened by any knowledge of the way Medicare works. – Alice G. Gosfield[1]

Sponsored by Fortney "Pete" Stark in 1989, the original version of the Stark statute –the Ethics in Patient Referrals Act--addressed referrals only for Medicare clinical laboratory services.[2] When its scope was significantly expanded[3] to encompass more designated health services ("DHS"), it also represented then and remains today, one of the most intrusive government interjections into the private operations of medical groups -- ever. It imposes structural demands to qualify as a group practice; and it controls compensation within the definition of a group practice by establishing how profit sharing and productivity bonuses may be paid within a private practice. The language of the statute uses terms such as "personal supervision", "direct supervision" and "incident to" with no appreciation that these are not equivalent and have had a long-standing history in the Medicare program-- long before the anti-referral statute was adopted. It has fundamental internal inconsistencies which are described more fully below, but include such basics as how a referral is defined when it is made to the hit list of DHS.

Since 1993, when the law became a reality, I have authored or co-authored more than 16 separate published articles on the Stark statute.[4] This speaks to the complexity of the statute and the difficulties in complying with it, as it has evolved over the years.[5] The statute itself has changed very little since its inception. The regulations interpreting it are another story. That it is so complex is noteworthy, especially given its relatively narrow scope. It applies only to physicians and only to their referrals of Medicare patients for DHS. The anti-kickback statute (AKS) has a far broader sweep. Still further, the complexities of Stark are compounded by the fact that it is not an intent based statute like the AKS; it is a strict liability statute. The participants to a transaction may have hearts and intentions as pure as the driven snow, but if their arrangement does not fit into an exception, they have liability for violating the law. And the role of whistleblowers with respect to enforcement cannot be over-stated. When it was first promulgated, I couldn't imagine how the government would get access to internal documentation of private compensation formulas to determine compliance. The very first settlement regarding internal

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[1] At many presentations on the statute since 1992, and also, in Gosfield, "Stark And Medicare's Physician Reimbursement Rules: Unraveling The Knots", HEALTH LAW HANDBOOK (2015 Ed.), WestGroup, Thomson Reuters pp. 18-211

[2] For a more extensive consideration of the statute and regulations see Chapter 3, of Gosfield and Shay, MEDICARE AND MEDICAID FRAUD AND ABUSE, WestGroup, ThomsonReuters, 2023-2024 ed.

[3] 42 USC §1395nn

[4] See https://www.gosfield.com/read/publications

[5] In 2009, the American Health Lawyers Association convened a public interest session over two days to consider the significance and problems with the statute: "A Public Policy Discussion: Taking the Measure of the Stark Law" as viewed by a broad array of stakeholders. The white paper notes the pros and cons of the statute from various perspectives and makes some suggestions for simplification, but it is a contextual review at a high level and does not delve into the details for the statute or regulations. https://www.ebglaw.com/wp-content/uploads/2014/06/30455_DMatyas.pdf

compensation formulas was issued merely 22 years after the statute's enactment![6] Most of the settlements and cases brought regarding Stark violations are instigated by whistleblowers. Congress has further solidified the connection between Stark and false claims in the Fraud Enforcement Recovery Act[7] where it created liability if a provider or supplier retained monies otherwise due to the government more than sixty days after identifying the overpayment.[8] Those claims submitted to generate the inappropriate payment convert to false claims thereafter, available for enforcement or action by whistleblowers.

So, after 16 articles, some of considerable length, what more could there be to say about this mess of a statute? In all my writings, I have not explicitly identified the truly confounding aspects of the law and regulations. For the attorney audience for this book, to truly understand how to advise clients on this law, it is critical to have both broad and deep context, as well as finely honed analysis and a real understanding of how that information can be deployed in the service of client interests. The issues considered here are not a historical report on how the regulations have developed. I report on the Stark world as it exists today. It is not a survey of all things Stark.[9] It is an idiosyncratic dissection of confounding and troubling aspects of the law and regulations.

1.0 Does It Work?

The predicate for the statute was a series of studies in the late 1980s and early 1990s that purportedly found that physicians invested in health care entities referred to those facilities more often than physicians without such financial interests, particularly for imaging.[10] The fundamental import of the statute was to control utilization. It has not worked. In a study by the Government Accountability Office (GAO) in 2007, the rate of the use of advanced imaging services generally grew fourfold from 1995-2005.[11] They made additional recommendations in four separate studies of Medicare imaging issues from 2008 through 2014.[12] These studies were not focused on whether the rate of physicians who were

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[6] US DOJ Press Release, "New York Heart Center To Pay More Than $1.33 Million To Settle Allegations Of False Claims Act And Stark Law Violations" (August 14, 2014) https://www.justice.gov/usao-ndny/pr/new-york-heart-center-pay-more-133-million-settle-allegations-false-claims-act-and

[7] Public Law 111-21 (May 2009)

[8] 31 U.S.C. § 3729(a)(1)(G)(2010 and 31 U.S.C. § 3729(b)(3)(2010).

[9] For a broader understanding of the statute see Chapter 3, Gosfield and Shay, MEDICARE AND MEDICAID FRAUD AND ABUSE, WestGroup, Thomson Reuters (2023-24 ed)

[10] See n 1, supra and for a good review of the national efforts of the OIG in surveying self-referral practices which helped define the scope of services included as DHS, see, Sutton, "The Stark Law In Retrospect", Annals of Health Law (vol 20) Winter 2011, pp 15-48

[11] GAO, "GROWTH IN ADVANCED IMAGING PAID UNDER THE MEDICARE PHYSICIAN FEE SCHEDULE" (2007) https://oig.hhs.gov/oei/reports/oei-01-06-00260.pdf

[12] GAO, "Medicare Part B Imaging Services: Rapid Spending Growth and Shift to Physician Offices Indicate Need for CMS to Consider Additional Management Practices (GAO-08-452)," United States Government Accountability Office, June 2008, https://www.gao.gov/new.items/d08452.pdf; "Medicare: Trends in Fees, Utilization, and

invested in the referred to facilities exceeded others, but that the volume of imaging itself has rapidly expanded. So, the context for provision of imaging studies overall is relevant. However, focusing on the self-referral issue alone, in 2012, the GAO found increased use of advanced imaging by those who could self-refer by comparison with those who did not.[13] Later, Following the recommendations of policy commentators[14], Congress enacted a law to create a program requiring physicians to consult appropriateness criteria before prescribing advanced imaging[15], but the penalty phase of the program was abandoned indefinitely in 2023.[16] And this is only the story of imaging.

The GAO also took up studies of self-referral rates for anatomic pathology[17], radiation therapy for prostate cancer[18] and physical therapy, [19] all DHS under Stark. Between 2004 and 2010, self-referred anatomic pathology services more than doubled and the growth rate of expenditures for self-referred anatomic pathology services was higher than for non-self-referred services. From 2006-2010, self-referred intensity modulated radiation therapy (IMRT) services increased more than fourfold (from 80,000 to 366,000). By contrast, from 2004 to 2010, non-self-referred physical therapy (PT) services increased at a faster rate than self-referred PT services. There are no comparable GAO reports available for the other DHS. I have been unable to identify updated statistics, and yet the law remains essentially untouched at its core.

By the early 2000s, Stark himself questioned the value of his legislation. “Stark says that today he'd go back and strip down the original fuzzy language, so the law simply forbids kickbacks. "I think we would have stopped more of the shenanigans that way," he says. He concedes that he created a whole cottage

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Expenditures for Imaging Services before and after Implementation of the Deficit Reduction Act of 2005 (GAO-08-1102R),” United States Government Accountability Office, September 26, 2008, https://www.gao.gov/assets/100/95803.pdf;; “Medicare Imaging Accreditation: Establishing Minimum National Standards and an Oversight Framework Would Help Ensure Quality and Safety of Advanced Diagnostic Imaging Services (GAO-13-246),” United States Government Accountability Office, May 2013, https://www.gao.gov/assets/660/654971.pdf; “Medicare Imaging Accreditation: Effect on Access to Advanced Diagnostic Imaging is Unclear amid Other Policy Changes (GAO-14-378),” United States Government Accountability Office, April 2014, https://www.gao.gov/assets/670/662658.pdf. GAO also did studies in 1989, 1994, and 1995 focusing primarily on the consequences of self-referral for advanced imaging services.

[13] “Medicare: Higher Use of Advanced Imaging Services by Providers Who Self-Refer Costing Medicare Millions (GAO-12-966),” September 2012, https://www.gao.gov/assets/650/648988.pdf

[14] Seinwald, Ginsburg, Brandt and Lee, “Medicare Advanced Imaging Payment: Dysfunctional Policy Making”, USC-Brookings Schaeffer Initiative for Health Policy, (March 2021) https://www.brookings.edu/wp-content/uploads/2021/03/Imaging_Paper_Final.pdf

[15] 1834(e)(1)(B) of the Social Security Act; 42 U.S.C. 1395m(e)(1)(B); 42 CFR 414.94(c)

[16] https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/appropriate-use-criteria-program

[17] https://www.gao.gov/products/gao-13-445

[18] https://www.gao.gov/products/gao-13-525

[19] https://www.gao.gov/products/gao-14-270

industry of entrepreneurs and Stark law firms that create and sign off on convoluted legal arrangements between doctors and their vendors. 'I get little thanks for it,' he says."[20] It is true that the work that health lawyers put into advice regarding Stark is significant, but the law's sponsor not only didn't understand what he had done, in describing what he would have preferred he apparently was unaware of the AKS which has been on the books since at least 1977 in its earliest forms!! His principal adviser on his staff was, Stephen H Bandeian, MD JD, a doctor-lawyer with both degrees from Harvard, who worked as staff on the House Ways and Means Committee which Stark chaired. Bandeian apparently thought the anti-kickback statute with its requirement of bad intent, was insufficient to thwart the burgeoning conflict of physician self-referral.[21]

There has been, during all this time since its enactment, only one attempt to repeal the statute. As I wrote in 2015, "It is little remembered that the one attempt for at least partial repeal occurred during the budget stand off between Newt Gingrich and President Clinton. Clinton vetoed the Balanced Budget Act of 1995. The government shut down; and Mr. Clinton, with time on his hands, fell in with Ms. Lewinsky. At least that has always been how I interpreted what happened. The Balanced Budget Act of 1995 would have liberalized the Stark prohibitions on compensation arrangements, would have removed the references to compensation within group practices and would have expanded the types of facilities in which physicians could be invested and refer, subject to some conditions, among other things. There has been little attempt to repeal it since."[22]

While the modifications in the statute over the years have introduced, among other things, a self-disclosure protocol, further restrictions on physician ownership of hospitals, new exceptions as for physician wellness programs, and the above noted tightening of the relationship between Stark Act violations and False Claims, the law persists as a challenge for compliance, not to mention basic comprehension of its application in the real world. The regulatory history is its own checkered story. First, the regulations are published by the Centers for Medicare and Medicaid Services (CMS) and not the Office of the Inspector General (OIG) of the Department of Health and Human Services (DHHS). While final regulations had been published in 1995 under the limited clinical laboratory focused law enacted in 1989 – a glaring and confounding gap – there were no regulations whatsoever interpreting the 1993 broader statute until 2001, 8 years later![23] Even then, those regulations only addressed parts of the statute; and the next round of regulations completing at least the initial interpretation of the then version of the statute, were not published until three years later.[24] CMS now offers a website which includes all the Stark regulatory publications which have been included in updates to the Medicare

[20] Whelan, "Stark Regrets: I Shouldn't Have Written That Law", FORBES BLOG,(Nov. 30, 2007, 1:52 PM), http://blogs.forbes.com/sciencebiz/2007/11/30/stark-regrets-i-shouldnt-have-written-that-law/

[21] See, Sutton n 10 supra.

[22] See n 1 supra

[23] 66 Fed Reg 855 (January 4, 2001)

[24] 69 Fed Reg 16053 (March 26, 2004)

Physician Fee Schedule as well as the Hospital Outpatient Prospective Payment System regulations.[25] The regulators have faced their own challenges in trying to harmonize the terminology in the law with long-standing Medicare policy. I describe in more detail below.

2.0 Definition of Referral

Unlike the anti-kickback statute, which has no definition of referral even though it prohibits behavior which rewards referrals or induces referrals (a confounding problem as noted by commentators[26]), the Stark statute defines a referral – and since it is the essence of the prohibited behavior, not surprisingly this is where trouble starts.

> *Except as provided in subparagraph (C), in the case of an item or service for which payment may be made under part B, the request by a physician for the item or service, including the request by a physician for a consultation with another physician (and any test or procedure ordered by, or to be performed by (or under the supervision of) that other physician), constitutes a "referral" by a "referring physician"… Except as provided in subparagraph (C), the request or establishment of a plan of care by a physician which includes the provision of the designated health service constitutes a "referral" by a "referring physician".*[27]

The referred to sub paragraph (C) exempts from the definition of referral

> *A request by a pathologist for clinical diagnostic laboratory tests and pathological examination services, a request by a radiologist for diagnostic radiology services, and a request by a radiation oncologist for radiation therapy, if such services are furnished by (or under the supervision of) such pathologist, radiologist, or radiation oncologist pursuant to a consultation requested by another physician does not constitute a "referral" by a "referring physician".*[28]

So, for the statute to even apply, there must be a referral by a defined person, to a defined person for specified services.

The request must be made by a physician, which in common parlance would be understood to be a medical or osteopathic physician. But the Medicare statutory definition of a physician is far broader.[29] It includes physicians, dentists, podiatrists, optometrists and chiropractors the latter of whom Medicare recognizes solely for the performance of the single service of manipulation of the spine for a demonstrated subluxation. By contrast, even though non-physician practitioners such as nurse practitioners, physician assistants, certified registered nurse anesthetists and nurse midwives may substitute for and perform much of what physicians can do within their specified scope of practice, they

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[25] https://www.cms.gov/medicare/fraud-and-abuse/physicianselfreferral/significant-regulatory-history

[26] Joseph, "Defining 'Referral' in the Anti-Kickback Statute", ABA Health e-Source (April 22, 2022) https://www.americanbar.org/groups/health_law/publications/aba_health_esource/2021-2022/april-2022/def-ref/

[27] 42 USC §1395nn(h) (5)

[28] 42 USC §1395nn(h)(5)(C)

[29] 42 USC §1395x(r)

are not encompassed in the Stark statute, and, generally speaking, their referrals will not qualify for Stark law scrutiny.

The referral is a "request" by the referring physician, including a request for a consultation from a physician, and the services which flow from that request. A request would sound like an active seeking of a service from the person to whom the request is made. But, the statute includes the relatively passive act of developing a plan of care which includes services to be provided by another or others, even if no direct interaction occurs between the requestor and the recipient of the request, nor any mention whatsoever of who should perform the prescribed service.[30] This passive approach to referrals has been established in caselaw under the antikickback statute[31] but it creates a range of problems as applied under Stark. The regulatory definition[32] essentially recapitulates the definition of referral in the statute with the exceptions for those physicians whose requests for the technical component of their services whether laboratory for pathologists, imaging for radiologists or radiation therapy for radiation therapists (the "PRRT physicians"), do not qualify as referrals.

The statutory reference to a "consultation" is also problematic under Medicare. The Medicare statute defines "physician services" to include consultations.[33] In 2010, Medicare eliminated payment for consultations, even though they have CPT codes, stating they should be billed as visits in accordance with the rules for those codes.[34] The Manuals are replete with references to the performance of consultations, although they are not covered as such, but only as a qualifying visit in accordance with the separate rules for different levels of visits (evaluation and management services). The Medicare Claims Processing Manual offers detailed instructions on how to bill evaluation and management services.[35] When Medicare did pay for consultations, I represented an optometrist who had the pleasure of paying the government almost $300,000 (down from an alleged $1.4 million in the letter he initially received from the Department of Justice) because they claimed the request for his services in nursing homes was not clear. Nursing homes must make the services of dentists, podiatrists and optometrists available to their patients[36]. These clinicians are seeing the patients for a limited purpose. Typically, their notes are recorded, not as attending physicians, but as consultants, even when the attending physician did not specifically request their services. What then is a consultation request that triggers Stark's application to the services that flow from the consult or the exemption from Stark in the case of pathology, radiation therapy or radiology?

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[30] 42 USC§1395nn(h)(5)(C)

[31] See fn 23 supra.

[32] 42 CFR §411.351

[33] 42 USC §1395x(q)

[34] Medicare Benefit Policy Manual; Chptr 15 sec 30

[35] Medicare Claims Processing Manual; Chptr 12; §30.6

[36] 42 CFR §483.25 and .55

The regulators have stepped into the void:

> *Consultation means a professional service furnished to a patient by a physician if the following conditions are satisfied:*
>
> *(1) The physician's opinion or advice regarding evaluation or management or both of a specific medical problem is requested by another physician.*
>
> *(2) The request and need for the consultation are documented in the patient's medical record.*
>
> *(3) After the consultation is provided, the physician prepares a written report of his or her findings, which is provided to the physician who requested the consultation.*
>
> *(4) With respect to radiation therapy services provided by a radiation oncologist, a course of radiation treatments over a period of time will be considered to be pursuant to a consultation, provided that the radiation oncologist communicates with the referring physician on a regular basis about the patient's course of treatment and progress.*[37]

Note that the exemptions for the PRRT physicians are only available if the services are provided pursuant to a consultation request. As noted in (4) above, there are instances when a radiation therapist may have an ongoing relationship with a patient and initiate return services for follow up treatment or procedures. For interventional radiologists, though, they are not exempt from the effects of Stark on a broader basis since their exemption pertains only to *diagnostic* radiology services. When they engage in interventional radiology on the same basis today as cardiologists and vascular surgeons—a phenomenon I think of as the endovascular food fights—their services are not exempt from the impact of Stark. By the same token, the services they render that are not diagnostic likely won't qualify as DHS Their frequent investment in the facilities where they render their services are not protected under Stark even though their referrals may not meet the definition.

Another hallmark of a consultation is a report back from the consultant to the referring physician with his findings. The 'report' can be made by notating the findings in a common medical record used by the referring physician and the consultant, or by a formal report that is sent by the PRRT physician to the referring physician. But if no report is sent to a referring physician, and the findings are maintained only in the records of the PRRT physician, the protection of the exemption is nullified. I have no difficulty imagining my colleagues in the whistleblower plaintiffs' bar bringing false claims act cases on these bases, even though I've not seen one yet.

The potentially final flawed aspect of the definition of a referral lies in the scope of the services the statute encompasses. The statutory definition of referral states that it must be for "*an item or service for which payment may be made under part B.*" The regulations define DHS simply to be the list of services in the statute. But that definition does not cure the fundamental problem that some of the DHS services are NOT paid for under Part B. Home health and hospital services are paid for under Part A. Some outpatient prescription drugs are paid under Part D. And if the services are provided in a Medicare Advantage plan, they are paid under Part C. So the referral under those parts of the Medicare program

[37] 42 CFR §411.351

do not meet the statutory requirements for Stark to apply. I have not seen this issue raised in defense of a Stark enforcement action, but have been waiting for years.

3.0 Definition of a group practice structure; operations

Contrary to popular belief, there is no group practice exception in Stark. Rather there is the definition of a group practice, arguably the most salient aspect of the entire law. It is essential to meet that definition for physicians to avail themselves of critical exceptions including, most importantly, referrals within a group for in office ancillary services. The definition is also where the most intrusive aspects of the law's impact can be seen. When the expanded Stark statute was enacted, it also coincided with the heyday of discussions of "group practices without walls." These were touted as loose affiliations of physicians that would claim to be a group practice but would operate with significant autonomy within the purported structure.[38] The idea was that previously separate practices could come together in this way to facilitate and strengthen their position in confronting managed care contracts. Proponents of these structures emphasized the retained autonomy of the prior separate practices. It was precisely this configuration of physician practices the Stark statute attempted to limit with its requirement that combinations of physicians qualify as defined group practices to take advantage of many of the exceptions including referrals to a physician, in office ancillary services, and group practice arrangements with a hospital. Other exceptions are available to groups as well as individual physicians, including personal services arrangements and electronic prescribing. Interestingly, for physician recruitment and retention payments, the regulators explicitly state the entity receiving the support need not meet the definition of a group practice; and they use the term "physician practice" to reference the entity which is eligible for financial support.

3.1 Structure

To qualify as a group practice, the configuration of physicians must practice as a single, unified entity. Confronting the concurrent phenomenon of health systems acquiring physician practices and physician practice management companies trying to do the same, the regulators dismissed those configurations.

> *For purposes of this subpart, a single legal entity does not include informal affiliations of physicians formed substantially to share profits from referrals, or separate group practices under common ownership or control through a physician practice management company, hospital, health system, or other entity or organization. A group practice that is otherwise a single legal entity may itself own subsidiary entities.* [39]

The challenge of the first stated exclusion has been met by health systems forming affiliated practice entities which are owned by the system and employ the physicians there, creating an affiliated group practice where all the profits may flow up to the health system which may be the practice's sole shareholder or sole member. In states with the corporate practice of medicine at play, a friendly professional corporation (PC) may be used with a single physician shareholder who is employed by the health system. The same model is used in states where physician practice management companies

[38] Rakowski, "The Group Practice Without Walls: Physicians Managing Managed Care,", Am J of Mgd Care (Sept 1995), pp. 86-88

[39] 42 CFR §411.352(a)

cannot own physicians or employ them. Typically, there are conditions under which that shareholder must relinquish her ownership, as when her employment terminates for any reason. The latter permission, above, was critical to permit one of the qualifications for in office ancillary services (IOAS) to exist. The IOAS exception addresses who may provide the services, at what location, and then, critically, who may bill for the service. The in office ancillary services may be billed by the performing physician or by an entity wholly owned by the group practice – not by the same constellation of physicians as those who own the group but by the group practice itself. [40]

There must be at least two physicians who are 'members' of the group – partners, shareholders or W-2 employees.[41] Despite this very clear requirement for those exceptions relating to group practices, the regulators also took the position that a solo practitioner – within his own practice -- was subject to the law! In the 2001 regulatory preface,[42] there are 44 references to solo practitioners. It is the result of the regulators' determination that a referral to "an entity" includes a referral within the physician's own practice. While they acknowledged that there is nowhere for profits of a solo practitioner to go, other than in his own wallet, what possible evil could there be in physicians referring within their own solo practice? Because he is a solo, the only referral can be to his own ancillary personnel or personnel he leases for that purpose. The Medicare reimbursement rules control the requisite level of supervision and locations for billing purposes. I have no problem with the idea that the law ought to take effect when a solo physician enters into a financial relationship with an entity outside of his practice for a space or equipment lease arrangement or personal services agreement with a provider of DHS to which he refers; but the solo practitioner must also comply with the location and supervision requirements of the IOAS exception in his own practice, when the rules for supervision and incident to, for example, already pertain as reimbursement rules.

3.2 Operations

To further combat the creation of pseudo groups, the group practice definition specifies that "Each physician who is a member of the group, as defined at § 411.351, must furnish substantially the full range of patient care services that the physician routinely furnishes, including medical care, consultation, diagnosis, and treatment, through the joint use of shared office space, facilities, equipment, and personnel."[43] I am unaware of any enforcement of this condition, but it would prevent a group from employing a physician to perform solely one procedure of those he performs elsewhere. Because of the breadth of the language, the services at issue need not be DHS, but any service of the physician. If the physician, generally, has a limited practice, where, for example, he only does invasive procedures, he could do only those within the group; and the group would still comply with the law. The requirement of using joint space sometimes means that the group must lease the location where that physician is located in order to comply with the definition, but this requirement prevents the creation of

[40] 42 CFR §411.355(b)(3)

[41] 42 CFR §411.352(b)

[42] 66 Fed Reg 856 et seq (2001)

[43] 42 CFR §411.352(c)

practices that simply cobble together constellations of barely involved physicians from whose services the group profits.

Beyond the scope of services provided, "substantially all of the patient care services of the physicians who are members of the group (that is, at least 75 percent of the total patient care services of the group practice members) must be furnished through the group and billed under a billing number assigned to the group, and the amounts received must be treated as receipts of the group."[44] The determination of whether the members are providing substantially all (75%) of their patient care services through the group is measured, typically, on a time basis. So, if there is a physician who works for two groups, he could only be a member of one of them since he can't provide 75% of his time in patient care services to two groups. In other words, a physician who is a shareholder must perform clinically within the group. Since the requirement does not pertain to independent contractors, that is the solution to these multiple setting issues. If, however, there is a member who works for a pharmaceutical company four days a week, and spends one day a week doing patient care services in the group, that one day is 100% of his time on patient care services. To clarify what counts, the regulators defined "patient care services":

> *"Patient care services means any task performed by a physician in the group practice that address the medical needs of specific patients or patients in general, regardless of whether they involve direct patient encounters or generally benefit a particular practice. Patient care services can include, for example, the services of physicians who do not directly treat patients, such as time spent by a physician consulting with other physicians or reviewing laboratory tests, or time spent training staff members, arranging for equipment, or performing administrative or management tasks.*[45]

That is, actually, a reasonably flexible approach to what qualifies to let a group practice operate within the bounds of the law. But the regulators went further with the following requirement: "Members of the group must personally conduct no less than 75 percent of the physician-patient encounters of the group practice."[46] In both of these quotes, the term "patient encounters" is used. It is not defined in the Stark definitions section.[47] On its face it would seem to include visits as well as face to face contact including procedures. It would not include interpretation of an image or of other diagnostic data where the physician does not interact face-to-face with the patient. The term "encounter" is used in Medicare Advantage (MA) [48] where encounter data is reported and feeds the calculation of the rate Medicare pays to the MA plan. The term is used in calculating eligibility of physicians for electronic health record

[44] 42 CFR §411.352(d)(1)

[45] 42 CFR §411.351

[46] 42 CFR §411.352(h)

[47] 42 CFR §411.351

[48] https://www.cms.gov/files/document/mppghpmsmemosprmetrics20230209g.pdf

incentives.[49] But neither of these programs existed when the terminology was introduced in Stark-world.

There is, in fact, a general Medicare definition for a reimbursable physician service under Medicare Part B although Stark does not explicitly reference it, either in the statute or regulations, nor does the definition use the word "encounters," but appears to describe an encounter in the first sentence.[50]

> *A service may be considered to be a physician's service where the physician either examines the patient in person*[51]

The rest of the definition pertains to visualizing an aspect of the patient's condition …or is able to visualize some aspect of the patient's condition without the interposition of a third person's judgment. Direct visualization would be possible by means of x-rays, electrocardiogram and electroencephalogram tapes, tissue samples, etc. but those would not be encounters.

The term "encounter" is otherwise used in connection with the requirements for care plan oversight services.[52] There, the statement is made that "only evaluation and management services are acceptable prerequisite face to face encounters for care plan oversight. EKG, lab, and surgical services are not sufficient face to face services for CPO."[53] Similarly, face to face encounters are required to qualify services for claims submission by home health agencies as well as durable medical equipment suppliers.[54] The term "encounter" is also used in the description of shared visits[55] as well as in the description of billing where more than half of the service is counseling or coordination of care.[56]

Taken together, it is difficult to know whether this 75% rule pertains exclusively to visits or would also include surgical procedures and telehealth services. The rule was published in 2001. Then, the only clarification was that the calculation was to be made "per capita and not on time,"[57] distinguishing it from the other 75% rule which is based on time. There has been no further elucidation of its meaning. As an example of how this could play itself out in a way that could be detrimental to a physician practice,

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[49] https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/EP_MultipleLocationsTipsheet.pdf

[50] The analysis of the term "encounters" here was first published in Gosfield, "Stark And Medicare's Physician Reimbursement Rules: Unraveling The Knots", HEALTH LAW HANDBOOK. WestGroup, ThomsonReuters, (2015 Es.), pp.

[51] Medicare Benefit Policy Manual Ch. 15 §30A

[52] Medicare Benefit Policy Manual Ch. 15 §30G

[53] Medicare Benefit Policy Manual Ch. 15 §30.6

[54] 42 CFR §410.38(g); 42 CFR §424.22

[55] Medicare Claims Processing Manual Ch. 12 §30.6.1B

[56] Medicare Claims Processing Manual Ch. 12 §30.6.1C

[57] 66 Fed Reg 905 (Jan 4, 2001)

in a two physician practice which performs in office intravenous drug infusions, patients may come multiple times a week where no physician is involved in seeing them. The volume of services taken as a whole, where the patient is seen by ancillary personnel face to face in the office, could distort the calculation of what qualifies as an encounter. Until some enforcement, in the absence of a Stark Advisory Opinion (of which there have been only 12 since 1998),[58] there is no way to know.

The use of terminology with diverse meanings in the Medicare reimbursement system creates ambiguity. This problem is especially acute in the context of other fundamental reimbursement terms that have to be squeezed and reformed to work in the statute's muck and rubble.

4.0 More Terminology Quagmires: Personal Supervision, Direct Supervision, Incident To

With its fundamental focus on Medicare referrals, one would have expected that the drafters of the legislation would have sought guidance regarding the terminology they wrote into the statute itself. They did nothing of the kind even while they did use some terminology very specifically peculiar to Medicare alone (i.e., "Incident to"). Before there were any regulations interpreting the statute, I spoke on a program with one of the drafters and informed her that some of the language would turn the program on its head from concepts which had applied since its inception in the 1960s. She was dumbstruck.

4.1 Supervision: unspecified, personal and direct

The issue of supervising services recurs in the statute without much clarity. In the definition of referral discussed above, the breadth of the definition creates ambiguity:

> *the request by a physician for the item or service, including the request by a physician for a consultation with another physician (and any test or procedure ordered by, or to be performed by (or under the supervision of) that other physician)*[59]*,*

A similar approach is encoded in the exemptions for the PRRT physicians:

> *if such services are furnished by (or under the supervision of) such pathologist, radiologist, or radiation oncologist pursuant to a consultation requested by another physician does not constitute a "referral" by a "referring physician"*[60]*.*

The term "supervision" itself, is not defined either in the Stark statute or the regulations. Ignoring the cumbersome parentheticals within a parenthetical above, irrespective of the degree of supervision, a service performed under the aegis of the referred to physician is swept into the definition of a problematic referral or is excluded for the PRRT physicians. Presumably, without the modification of direct or personal supervision, the applicable definition would be the one that applies in Medicare Part B:

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[58] http://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/advisory_opinions.html

[59] (Emphasis added) 42 USC §1395nn(h)(5)(A)

[60] 42 USC §1395nn(h)(5)(C)

> *"General supervision" means the definition specified at 42 CFR 410.32(b)(3)(i), that is, the procedure or service is furnished under the physician's overall direction and control, but the physician's presence is not required during the performance of the procedure."*[61]

This refers to the essential definition which pertains under the diagnostic testing regulations.[62] But for Stark purposes, referrals which encompass supervision may be for other than diagnostic testing or hospital outpatient therapeutic services. Without a Medicare overarching, generally applicable, approach to levels of supervision, one can only impute the diagnostic testing regulations to the use of the term.

More problematic still, is the drafters' use of terminology in the exceptions to the prohibitions. The very first statutory exception is referral for physician services. Trouble arises immediately. A physician may refer to another physician for physician services which are

> *In the case of physicians' services (as defined in section 1395x(q) of this title) provided personally by (or under the personal supervision of) another physician in the same group practice (as defined in subsection (h)(4)) as the referring physician.*[63]

Why the use of the modifier "personal" for supervision by a referred to physician? The problem here is that the Medicare reimbursement rules define "personal supervision" as the highest level of physician involvement requiring the physician to be in the room with the patient receiving the services. "*Personal supervision* means a physician must be in attendance in the room during the performance of the procedure."[64] An example of the potentially disastrous effect of this language is referral to another physician for skeletal films or abdominal films without the use of contrast media. From time immemorial, these services have been subject to general supervision only. This was the primary provision I challenged the House staffer with whom I spoke on the law, many years ago. To have inserted the term "personal supervision", toward no particular end, also calls into question what kind of supervision was meant when the term is used without any modifier.

A parallel problem emerges with only the second exception under the statute: the one for in office ancillary services. By definition, these are services provided within a group practice, and not hospital outpatient or inpatient services or services in any other location except a physician office. Here, not content to have used "supervision" and "personal supervision" already, for no apparent reason this exception introduces the concept of "directly supervised" which has specific meaning in Medicare and has since its inception. In office ancillary services are those that are furnished—

[61] Medicare Benefit Policy Manual ("MBPM") Chptr 6, 20.5.3 dealing with hospital outpatient therapeutic services.

[62] 42 USC §410.32(b)(3)(i)

[63] 42 USC §1395nn(b)(1)

[64] 42 CFR §410.32(b)(3)(iii)

(i) personally by the referring physician, personally by a physician who is a member of the same group practice as the referring physician, or personally by individuals who are directly supervised by the physician or by another physician in the group practice, [65]

Direct supervision requires the physician to be in the office suite.

Direct supervision *in the office setting means the physician (or other supervising practitioner) must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician (or other supervising practitioner) must be present in the room when the procedure is performed.*[66]

Here, again, there have long been Medicare services, including DHS, that can be provided under the physician's general supervision (not on premises) which would not conform with this terminology. The conundrum of the misuses of these terms regarding levels of supervision, was confronted in a practical way by the regulators who simply chose to ignore the apparent intended distinctions. Early in the regulatory process in 2001[67], they clarified that they would apply the rules for supervision that otherwise apply under the reimbursement rules. They did this for referrals for physician services "provided that the supervision complies with all other applicable Medicare payment and coverage rules for the physician services,"[68] and the same for in office ancillary services "provided that the supervision complies with all other applicable Medicare payment and coverage rules for the services."[69] But the fact remains that different terms were used in the statute. The regulatory solution lowers the barriers to physician compliance, but what might a whistleblower do with the level of supervision actually provided given the statutory language? It is hard to imagine a court ignoring regulations published in compliance with the Administrative Procedures Act, but this issue has not been addressed by any court yet, as far as I know.

4.2 "Incident to"[70]

Related to the supervision issues, but offering different challenges, is the use of the term "incident to" in the statute. The terminology is relevant in the discussion of what may be allocated in productivity bonuses, but that application also raises another issue in the context of diagnostic services. Peculiar to the Medicare program from its inception, the concept of covering services "incident to" the physician's was an office-based recognition that other personnel in the office contributed to the delivery of the physician's service by providing services that were an "integral although incidental part of the physician's

[65] 42 USC §1395nn(b)(2)(A)

[66] 42 CFR §410.32(b)(3)(ii)

[67] See 66 Federal Register 856 et seq (January 4, 2001)

[68] 42 CFR §411.355(a)(ii)

[69] 42 CFR §411.355(b)(iii)

[70] For a longer, more detailed discussion of issues associated with incident to billing see Gosfield, n 50 supra.

personal professional service to the patient."[71] There must be an initial visit by the treating physician to establish the course of treatment that will be provided incident to. The services must be of a type commonly furnished in physician offices. A physician in the group must be on premises within the office suite and immediately available to assist at all times that incident to services are billed. Non-physician practitioners who may otherwise bill on their own numbers may be billed incident to a physician as well. Most astonishingly, one physician may be billed incident to another physician. In 2001 in a tussle over billing for physical therapy, citing their regulation at 42 CFR §410.26(a)(1), the regulators said "We deliberately used the term 'any individual' so that the physician (or other practitioner), under his or her discretion and license, may use the service of anyone ranging from another physician to a medical assistant."[72]

For purposes of allocating revenues to a physician in a group practice, the statute allows dollar for dollar allocation of revenues from services provided incident to. This has confounded respondents commenting on the various regulatory publications in which the regulators have repeatedly clarified that despite refusing to exempt incident to services from the definition of a referral, the allocation of dollars associated with those services is an exception to the rule otherwise prohibiting the allocation of dollars from DHS services referred by the physician. The clarity of this position has been evident since 2001, but commentators apparently didn't understand. In 2001, responding to other comments with respect to incident to, the regulators stated that group practice physicians can receive compensation directly related to the physician's personal productivity and to services incident to the physician's personally performed services, provided the "incident to" services comply with the requirements of §1861(s)(2)(A) of the Act and §2050, "Services and Supplies," of the Medicare Carrier's Manual (HCFA Pub. 14-3), Part 3-Claims Process and any subsequent or additional HHS rules or regulations affecting "incident to" billing.[73] In the 2004 comments, the regulators noted that "a number of commenters asked that we clarify that physicians in the group practice can be paid a productivity bonus or profit share based directly on services that are 'incident to' services personally performed by the physician."[74] Still not settled, based on comments from the public, in 2007 the regulators clarified once more that "incident to" services include both services and supplies (such as drugs) that meet the applicable requirements set forth in the Act.[75] It would seem that because the incident to rules permit allocation of dollars not generated by the physician himself, and that they rejected my argument that by definition, with incident to services an integral part of the physician's service, the rules explicitly permit physician productivity bonuses to take into account the revenue generated by the incident to services where the physician has referred to some other personnel to render the services.

The opposite problem was created in 2007-2008 when the regulators suddenly performed an about face on the way revenues from diagnostic services could be allocated. Although for the entire history of

[71] Medicare Benefit Policy Manual (MBPM) Chptr 15, sec 60.1

[72] 66 Fed Reg 55268 (Nov 1, 2001)

[73] 66 Fed Reg 909 (Jan 4, 2001)

[74] 69 Fed Reg 16080 (March 26, 2004)

[75] 72 Fed Reg 51016 (Sept. 5, 2007)

Medicare, until that point, all diagnostic services within physician practices were billed incident to the treating physician. Once the Stark allocation rules were published in 2001, this meant that diagnostic service revenues could be included in physician compensation based on productivity. In 2007, they took the position that only those services that do not have their own separate and independently listed benefit category may be billed as "incident to" a physician service, except as otherwise expressly permitted by statute (for example, physical therapy services to the extent authorized under §1862(a)(20) of the Act). There, they said "Consequently, diagnostic X-ray tests, diagnostic laboratory tests, and other diagnostic tests, all of which comprise a single benefit category under §1861(s)(3) of the Act may not be billed as 'incident to' services under §1861(s)(2)(A) of the Act."[76] It is noteworthy that the first settlement of a Stark case based on internal compensation rules was brought more than 22 years after the law's enactment and turned on this very issue.[77] But their explanation is fallacious because physical therapists (PTs) have their own benefit, their services are DHS, and those services can be billed either incident to a physician or on the PT's own number. Where diagnostic services or other services with their own benefit are billed in a physician practice, where they involve DHS, the profits from those services may only be allocated, if at all, in a profit sharing formula. It should be noted, that a significant volume of diagnostic testing is NOT DHS, such as electrocardiograms, Holter monitoring, electromyograms, nerve conduction studies and more. They cannot be billed incident to based on the above position, but allocation of those revenues is not subject to the Stark statute in any event because they are not DHS.[78] Those profits can be allocated in whatever manner the group chooses.

5.0 Fair Market Value vs. Commercially Reasonable vs. Fair Market Value Exception

The three concepts in this heading are distinguishable and must be understood to effectively counsel clients. The first two are in the statute. The term "fair market value" appears in the statute 9 times including in one heading for the definition of fair market value which is also set forth. Commercially reasonable appears 4 times. "Fair market value exception" by contrast, is a regulatorily created concept. The statute incorporates the need for fair market value in the exceptions for office space rental[79], equipment rental[80], bona fide employment relationships,[81] personal services arrangements[82], group

[76] 72 Fed Reg 51016 (Sept. 5, 2007)

[77] Settlement Agreement between United States of America and Cardiovascular Specialists P.C., d/b/a New York Heart Center, Aug 14, 2014.

[78] Other confounding aspects of these rules include split/shared visits and what constitutes personally performed services. For a discussion of those issues see Gosfield at n 50 supra.

[79] 42 USC §1395nn (e)(1)(A)

[80] 42 USC §1395nn (e)(1)(B)

[81] 42 USC §1395nn(e)(2)

[82] 42 USC §1395nn(e)(3)

practice arrangements with a hospital,[83] and payments by a physician for items and services.[84] It also incorporates fair market value into the definition of "compensation arrangements and remuneration."[85] The definition of fair market value, then, becomes a critical element to the whole enforcement infrastructure. Many of the regulatory exceptions created using the Secretary's authority under section 1877(b)(4) of the Act also include requirements pertaining to fair market value compensation, including the exceptions for academic medical centers, fair market value compensation, indirect compensation arrangements, EHR items and services, and assistance to compensate a nonphysician practitioner.

5.1 Fair market value

The statute defines fair market value as

> *[T]he value in arms length transactions, consistent with the general market value, and, with respect to rentals or leases, the value of rental property for general commercial purposes (not taking into account its intended use) and, in the case of a lease of space, not adjusted to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor where the lessor is a potential source of patient referrals to the lessee.*[86]

It should be noted that the definition requires reference to external markers of value–general market value, value of rentals for commercial purposes. I have read many Stark implicated agreements in which other lawyers have inserted the concept that the parties have agreed that the compensation set forth reflects fair market value. At best, the statement is utterly meaningless, since what the parties agree to has nothing to do with what the law says fair market value requires. At worst, the statement impugns the legitimacy of the compensation because it explicitly states a standard which is not consistent with the statutory requirements.

In defining fair market value in the regulations, the provision combines the statutory language with additional explanations of its meaning.

> *''General market value' '(they say) "means the price that an asset would bring as the result of bona fide bargaining between well-informed buyers and sellers who are not otherwise in a position to generate business for the other party, or the compensation that would be included in a service agreement as the result of bona fide bargaining between well-informed parties to the agreement who are not otherwise in a position to generate business for the other party, on the date of acquisition of the asset or at the time of the service agreement. Usually, the fair market price is the price at which bona fide sales have been consummated for assets of like type, quality, and quantity in a particular market at the time of acquisition, or the compensation that has been included in bona fide service agreements with comparable terms at the time of the*

[83] 42 USC §1385nn (e) (7)

[84] 42 USC §1395nn (e)(8)

[85] 42 USC §1395nn(h)(1)(c)(iii)(III)

[86] 42 USC §1395nn(h)(3)

agreement, where the price or compensation has not been determined in any manner that takes into account the volume or value of anticipated or actual referrals. [87]

The requirement to look to external sources of value is solidified and reemphasized by that language. To comply requires some measure of what is happening in the external market, without reference to potential referrals. The exclusion of those who are in a position to make referrals as the touchstone for fair market value is also made clear in this further explanation. I believe it also additionally undermines any reference to agreement between the parties, since they are, by virtue of the fact that they have to pay attention to these regulations, in some referral relationship with respect to each other.

Regarding rentals and leases described in § 411.357(a), (b), and (l) (as to equipment leases only), the regulatory definition becomes even more granular:

'[F}air market value'' means the value of rental property for general commercial purposes (not taking into account its intended use). In the case of a lease of space, this value may not be adjusted to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor when the lessor is a potential source of patient referrals to the lessee. For purposes of this definition, a rental payment does not take into account intended use if it takes into account costs incurred by the lessor in developing or upgrading the property or maintaining the property or its improvements.[88]

The last phrase would appear to permit the landlord to convert general commercial space to medical office space, if that otherwise would be what landlords would do in an arms length relationship. But the first sentence above, does not permit the valuation to take into account the intended use of the space. That would not appear to reflect what general market value would entail in external, non-referral implicated, rental relationships.

The regulators have distinguished their approach to leases of space and equipment from their approach to compensation for services. "With respect to compensation for services, ''general market value'' means the compensation that would be paid at the time the parties enter into the service arrangement as the result of bona fide bargaining between well-informed parties that are not otherwise in a position to generate business for each other."[89] Against this background, many analysts believed that obtaining the services of a third party valuator would be both a reasonable and bolstering approach to determining fair market value. In 2020, this concept was significantly undermined with an extended discussion of the use of salary surveys.[90] "[E]xtenuating circumstances may dictate that parties to an arm's length transaction veer from values identified in salary surveys and other valuation data compilations that are not specific to the actual parties to the subject transaction."[91] They offer examples

[87] 42 CFR §411.351

[88] Id.

[89] 85 Fed Reg 77554 (Dec 2, 2020)

[90] Id et seq

[91] Id and 77556-8 (Dec 2, 2020)

where salary surveys would produce compensation that is too high as well as too low. The point is that the parties may not rely on surveys alone to justify their compensation rates. They must analyze the context for the transaction and then consider the factors taken into account in salary surveys. The regulators expect them to adjust their numbers as a result. They explicitly declined to limit the types of valuation methodologies they would consider acceptable and referred readers back to the Phase I regulations where they discussed valuation methods in some detail, allowing for any method that is reasonable.[92] This brings us to the second concept of "commercially reasonable".

5.2 Commercially reasonable

Until the 2020 publication, the regulators had never codified a definition of commercial reasonableness, by their own admission having merely touched on the concept in their publication of proposed regulations in 1998. They finally rectified that gap 22 years later:

> *Commercially reasonable means that the particular arrangement furthers a legitimate business purpose of the parties to the arrangement and is sensible, considering the characteristics of the parties, including their size, type, scope, and specialty. An arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties.*[93]

Contrary to the definition of fair market value, commercial reasonableness is specific to the internal needs of the parties to the transaction: "[T]he key question to ask when determining whether an arrangement is commercially reasonable is simply whether the arrangement makes sense as a means to accomplish the parties' goals. The determination of commercial reasonableness is not one of valuation."[94] Further, counter to arguments I have seen and heard other lawyers make, the fact that a transaction not only is not profitable but may affirmatively lose money for one of the parties, does not automatically render it not commercially reasonable. Interestingly, the regulators speculate that there could be circumstances in which it would not only be preferable but "necessary" for the parties to enter a money losing arrangement:

> *We acknowledge that, even knowing in advance that an arrangement may result in losses to one or more parties, it may be reasonable, if not necessary, to nevertheless enter into the arrangement. Examples of reasons why parties would enter into such transactions include community need, timely access to health care services, fulfillment of licensure or regulatory obligations, including those under the Emergency Medical Treatment and Labor Act (EMTALA), the provision of charity care, and the improvement of quality and health outcomes.*[95]

In addition, responding to comments they emphasized that commercial reasonableness does not look at the quantity of compensation at issue. Harkening back to their proposed publication 20 years earlier they reiterated that "The test is not whether the compensation terms alone make sense as a means to

[92] 66 Fed Reg 856 (January 4, 2001)

[93] 42 CFR §411.351

[94] 85 Fed Reg 77531 (Dec 2, 2020)

[95] Id.

accomplish the parties' goals; however, the compensation terms of an arrangement are an integral part of the arrangement and impact its ability to accomplish the parties' goals (84 FR 55790)."[96] Continuing the yin and yang of how the regulators have confronted the challenges of the statute's often ambiguous or vague language, they introduced by regulation an exception for fair market value compensation.

5.3 Fair market value exception

Even though there was no definition of commercially reasonable in 2001, when the fair market value exception[97] was published, the term was incorporated into this exception which can be used when other exceptions cannot be complied with in full. "This fair market value exception only covers items or services provided by a physician or any immediate family member to an entity."[98] It can also be used for compensation by a physician to an entity, when other exceptions cannot be met. But it is available also when other exceptions might otherwise apply. The exception can be used by groups of physicians who do not otherwise meet the definition of a group practice under Stark.

To use the exception, the arrangement must be in writing and specify the items, services or goods provided, the compensation and the term for which the arrangement will last. It can last for any period of time and may include a termination clause, but only one such arrangement for the same services, items or equipment may be entered into during a year. Because this section of the article is addressing amounts of compensation, the essential terms here are that the compensation must be set in advance, consistent with fair market value, and not determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician. Additional conditions prohibit, for lease of space and equipment, rental terms based on a percentage of amounts billed or collected or based on per use compensation. The arrangement must be commercially reasonable, may not involve counseling or promotion of an activity that would violate Federal or state law and may not violate the anti-kickback statute. Having been written 22 years ago, the language of the regulation has not been revised, but now incorporates the modern notions of fair market value and commercially reasonable that have been updated as of 2020.

6.0 Indirect Compensation Arrangements vs. Under Arrangements vs. Stand in The Shoes

All three of these concepts entail one party standing in for another in one way or another. The indirect compensation arrangement exception, by its name, involves one or more intermediate entities in the financial relationship. Under arrangements in the Stark context, as opposed to the traditional hospital reimbursement principle, involves one party under contract with another where the second party bills for what the first party does. Stand in the shoes is the most obvious of the three and entails an analysis of the relationships that exist between the physicians who own or work for their groups and the DHS entity with which their group has a relationship and to which they refer. I deconstruct and contrast them all here.

6.1 Indirect Compensation Arrangements

[96] Id at 77532.

[97] 42 CFR §411.57(l)

[98] 66 Fed Reg 919 (January 4, 2001)

To qualify for this exception, first the arrangement has to meet the definition of indirect compensation. There are also indirect investment and ownership arrangements that can be at issue for this exception to be triggered. The regulators stated they had in 2001 developed a simple test. In practice it is not so simple. To qualify as an indirect compensation arrangement there are three elements to examine[99]:

(1) There must exist between the referring physician (or immediate family member) and the DHS entity an unbroken chain of persons or entities that have financial relationships between them (that is, each link in the chain has either an ownership or investment interest or compensation arrangement with the preceding link). Depending on how complex the relationships, I find that drawing the chain can be helpful to isolate non-qualifying aspects. But at this stage of the analysis, all financial relationships whether of ownership or compensation, must be included in the consideration.

(2) the aggregate compensation received by the referring physician (or immediate family member) from the person or entity in the chain with which the physician has a direct financial relationship varies with, or otherwise reflects, the volume or value of referrals or other business generated by the referring physician for the entity furnishing DHS. Here the focus is on the direct financial relationship which the physician or immediate family member maintains. If the compensation is generally conditioned on referrals it will meet this test as will any per use or per click compensation. To make things more complicated, if the financial relationship is an ownership or investment interest, the regulators will look to that owned entity and where on the food chain of its relationships there is an unowned entity with a direct financial relationship other than ownership. The principal issue is whether the aggregate compensation the owned entity receives varies with volume or value of referrals to the DHS entity. Finally to meet the definition

(3) the DHS entity must know or have reason to suspect that the aggregate compensation received by the referring physician (or immediate family member) from the entity with which the physician has a direct financial relationship varies with, or otherwise reflects, the volume or value of referrals or other business generated by the referring physician for the entity furnishing DHS, or act in reckless disregard or deliberate ignorance of the existence of such relationship. "Reason to suspect" triggers a duty of reasonable inquiry into the circumstances. Obtaining a good faith written assurance from the referring physician that the financial relationship at issue falls within the indirect compensation arrangement exception is permitted. "Should know" or "ought to have known" standards are always thorny because they turn on context as well was what other similarly situated individuals or entities would do. So far, having gone through this three-pronged analysis, we only know that an indirect compensation relationship exists.[100] We do not know if it meets the regulatorily created exception for indirect compensation arrangements.

To meet that standard which was amended slightly in 2021, three basic conditions and one special condition apply:[101] (1) the compensation received must be fair market value and not calculated in a manner which takes into account volume or value of business between the parties; (2) the compensation

[99] 66 Federal Register 865 -870 (January 4, 2001)

[100] 42 CFR § 411.354(a)(2)(ii); and (b)(5)

[101] 42 CFR § 411.357(p)

arrangement is set out in writing, unless the relationship is one of employment which does not require a writing, and the writing specifies the services or items to be provided and is otherwise commercially reasonable; and (3) if the compensation is conditioned on physician required referrals, it meets the directed referral requirements elsewhere in the regulations.[102] Where the arrangement involves rental of office space or equipment, the rental compensation may not reflect any portion of the business generated, and if per unit or per use fees are used, they may not include those services generated by the engaged physician's referrals.

The basic thrust of the indirect compensation arrangement exception is that chains of relationships will be taken into account for compliance, and interposing additional parties between the referring physician or family member and the DHS entity will not truncate liability from improper effects created by the arrangement, regardless of intent, which is the case with all Stark exceptions. "Under arrangements" issues dig deeper into the relationship between the referring physician and the DHS entity, where someone else bills for the service furnished by the physician-owned entity.

6.2 Under arrangements

When the Stark regulations were first published, they permitted a physician to refer a patient to a DHS entity where the physician may have had an ownership interest in an entity actually furnishing services for another entity. The primary example given in the initial regulations was if physicians owned a lithotripter. Lithotripsy itself is not a DHS, as determined in a court case.[103] Under Medicare, lithotripsy is only payable when provided by a hospital. If the physician owned lithotripter provided services "under arrangements" to the hospital, the owning physicians would not have liability under the statute, even if the lithotripter entity was paid by the hospital on a per click basis.[104] By 2008, the regulators had more concern over abuses in "under arrangements" transactions where a physician-owned entity renders services for a different entity which is the entity which actually bills the Medicare program.

In the same 2008 publication,[105] stating that they wanted to take a "symmetrical" approach to these interrelated issues (per click lease payments or use payments to physician owned entities and under arrangements transactions) the regulators eliminated the opportunity for physician owned entities to be paid per click by a DHS entity for services provided by them or their physician-owned entity, when the patient was referred by a physician owner. They further extended their analysis to direct that a physician entity furnishing services "under arrangements" to another entity which bills for the services qualifies as a referral for DHS, even though the physician entity submits no claim to Medicare. "An "under arrangements" contract between a hospital and an entity providing an owner's referred DHS "under arrangements" to the hospital creates a compensation arrangement for purposes of these regulations."[106] Where a physician-owned entity receives payment, which can no longer be on a per click

[102] 42 CFR § 411.354(d)(4). See section 8.1 infra.

[103] Am. Lithotripsy Soc'y v. Thompson, 215 F. Supp. 2d 23, 26 (D.D.C. 2002)

[104] See, discussion at 66 Fed Reg 876 (Jan 4, 2001), and associated regulations

[105] 73 Fed Reg 48713 (Aug 19, 2006)

[106] 42 CFR § 411.354(c)

basis, and then profits are distributed to the owning physicians, that constitutes an indirect compensation relationship. Where such an arrangement exists, for the services referred by the owning physicians, the compensation must be on a basis other than per click – such as time based – while business not referred by the owners may be compensated per click. Where one entity furnishes, provides or renders the service but another entity bills for it, they are both DHS entities under the statue according to CMS.[107] So, as in the initial lithotripsy example, even though it is not itself DHS, it becomes DHS when billed under arrangements by a hospital – both the hospital and the lithotripter arrangements must be analyzed under the Stark statute.

6.3 Stand in the shoes

The "stand in the shoes" doctrine was created initially out of a concern that attorneys early on were advising their clients that if their physician organization had a direct financial relationship with a DHS entity, but the individual physician did not, then the Stark statute would not apply to the physician's relationship through his practice entity. The doctrine relates to the indirect compensation issues that arise from investment/ownership relationships as well as indirect compensation arrangements, as we have seen, but is separate because of who it addresses. To make it abundantly clear that the government would look through the physician entity to its owners and/or physician participants, the "stand in the shoes" doctrine was strengthened.

Today's version of it sets forth that a physician will be deemed to stand in the shoes of his practice and have a direct financial relationship with a DHS entity to which he refers if "(A) The only intervening entity between the physician and the entity furnishing DHS is his or her physician organization; and (B) The physician has an ownership or investment interest in the physician organization."[108] If the physician is not an owner of his organization he is 'permitted' to stand in the shoes of the organization. This can be useful when the arrangement is compliant with an exception and he chooses to claim the protection of safety under the applicable exception.

Taken together, all of these regulatory concepts stand for the proposition that superficial analysis is insufficient to comply with the law. There must be a careful analysis of less obvious, indirect financial arrangements and relationships associated with referred to DHS entities. To dig in to the essential relationship a referring physician has through other entities.

7.0. Shared Facility vs Timeshare

Two additional confounding concepts involve sharing of space, equipment and maybe more, among referring physicians and DHS entities from which they may lease. They both, however, have different predicates for their exceptions to apply. Both sets of rules primarily arise with respect to in office ancillary services.

7.1 Shared facility

The sharing of space, equipment and personnel who provide DHS has been a long tradition in American medicine. With the advent of the Stark statute, the focus on DHS as an arena for potential abuse became

[107] See, 73 Fed Reg 48721 (Aug 19, 2008)

[108] 42 CFR § 411.354 (c)(1)(ii)

stronger, especially in the era of group practices without walls and other informal associations and affiliations among groups providing DHS and groups referring for DHS. The original version of the shared facility rule was deemed inadequate by the regulators to prevent, abuse, but where appropriate conditions could be met to share equipment and space for the delivery of in office ancillary services would be permitted.

The in office ancillary services exception[109], which focuses on the technical components of services (referrals to a physician for the professional component are a separate exception[110]), has three elements to be addressed: (1) who renders the services; (2) where the services are provided; and (3) who bills for the services. The locational requirement has changed over time and is where sharing is addressed. The initial standard had been that if the billing physicians did not have 24/7 control of the location, then they had to have offices where the DHS services were being provided at which location they also provided 'substantially' the full range of their services. When the revised version of this standard was published with the second round of Stark regulations, the government acknowledged that the term "substantially" was vague and non-specific. They have rectified that with a far clearer and therefore more prescriptive test[111]:

If the location is shared among physicians or groups, there are three options: the non-owning group must have offices in the same building as the shared equipment where they provide services either (a) at least 35 hours a week and the referring physician or other members of his group are on site seeing patients at least 30 hours a week, with some of the services being non-DHS. This test means this would be a bona fide office location on almost a full time basis; or (b) at least 8 hours a week and the referring physician is regularly there at least 6 hours a week doing some non DHS services. This standard would mean the referring physician has his offices at that location and has regular office hours about one day a week; or (c) at least 6 hours a week and the referring physician is there and orders the DHS during a visit there, or the other group physicians are present in that building during the furnishing of the Stark service.

The statute also offers the option of providing DHS in a centralized building[112]. But when the new version of shared facility rules above were published, the definition of a "centralized building" was restricted to a location that must be used exclusively by the group 24/7/365 for at least six months".[113] Contrary to other provisions in the regulations, for these purposes "a mobile vehicle, van, or trailer that is owned or leased on a full-time basis (that is, 24 hours per day, 7 days per week, for a term of not less than 6 months) by a group practice and that is used exclusively by the group practice"[114] can qualify as a centralized building. This is particularly noteworthy since in 2001 they had

[109] 42 UZSC § 1395nn(h)(2)

[110] 42 USC § 1395nn(h)(2)

[111] 42 CFR § 411.355 (b)(2)

[112] 42 USC §1395nn(h) (b)(2)(A)(bb)

[113] 42 CFR § 411.351

[114] Id

specifically stated “A mobile van or trailer is not a building or a part of a building.”[115] Still further, a group may have more than one centralized building. Despite the effort to eliminate ambiguous metrics such as “substantially”, these conditions use the terms “normally” to describe when the office is open; “usually” to describe the extent to which the patient interacts with the group, and “regularly” to describe how the group functions at the centralized location. These terms are just as vague as ‘substantially’ and given the hourly requirements for co-location, why are they even necessary?

7.2 Timeshare Arrangements

With the proscriptive and prescriptive approach to shared facilities noted above, by 2015 the regulators had enough experience based on comments made to them through multiple rule-makings as well as the self-referral disclosure protocol to loosen a little the types of arrangements that might exist between a referring physician and another group which had equipment to provide DHS that the physician would want to share. They acknowledged that in rural areas, as an example, or for other legitimate reasons, a physician not part of a group might want to lease from the group a turnkey operation at that location for him to render his services and bill as his services. Still further, although the lease exception for space and equipment requires exclusive use by the lessee during the periods of use, the timeshare exception does not require this.

The timeshare exception[116] can be used by a physician to obtain the use of, but not a possessory interest in, “premises, equipment, personnel, supplies or other services”. By the language of the exception any combination including more than one of the enumerated components can qualify. But, as we will see, because of the other conditions imposed to use this exception, it is not a substitute for lease of equipment or space. First, the exception is only available for use by a physician or his group obtaining use of the noted items from a hospital or other physician organization. It must be documented in a writing signed by the parties specifying which of the components are being obtained by the lessee. The components obtained must be used “predominately” for the provision of evaluation and management (E&M) services and on the same schedule – so that the E&M services are provided during the same sessions that the other components are obtained. Equipment that is used must be located in the same building, but not necessarily the same suite, where the E&M services are provided. The DHS services provided by the lessor must be incidental to the E&M services. The exception cannot be used for high end imaging, radiation therapy equipment or clinical or pathology laboratory equipment. As an example of the restrictions theses conditions represent, a physician using the location where equipment is obtained could not use that equipment on another patient of his for whom it would be more convenient to obtain an imaging service at the timeshare location, unless that patient received an E&M visit on the same day and time. In the prefatory comments they actually say “on an identical schedule”.[117] And as is always the case, the E&M visit would have to be medically necessary to be covered.

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[115] 66 Fed Register 888 (January 4, 2001)

[116] 42 CFR § 411.357(y)

[117] 80 Fed R Register71327 (Nov 16, 2015)

The arrangement may not be conditioned on the referral of patients to the lessor. The compensation must be fair market value, not taking into account the volume or value of business (as is true with all the exceptions) and also must be commercially reasonable even if no referrals occur between the parties. But in addition, the compensation may not be based on any quantum of the dollars generated by the services rendered by the lessee at the timeshare location, nor on a per unit of service which is not time based. In other words, an hourly fee would be legitimate, but a per service based fee for the DHS would not be compliant where it involves patients referred by the lessor. Per unit of service rendered by the lessee to his own patients on which he uses the timeshare equipment would be permitted. The arrangement cannot violate the anti-kickback statute. Or any other law governing billing and claims submission. These types of conditions which link compliance with other laws, are essentially superfluous since those laws pertain whether these regulations identify them or not. To state that they apply explicitly certainly makes that clear in case some purportedly creative lawyer would argue that since the regulation doesn't address anti-kickback, that statute could be overcome by the regulation. Such an analysis would be absurd.

8.0 Permitted Directed Referrals vs Value-Based Arrangements

What these two exceptions share is that the behavior they describe would appear to be affirmatively illegal if not protected by the regulations. Most of the other exceptions provide opportunities for financial relationships in association with referrals. These exceptions are in large part about the referrals themselves and their permitted nature.

8.1 Permitted Directed Referrals

These have been permitted in limited circumstances since 2001.[118] For personal services arrangements, managed care contracts, and employment, the party compensating the physician was permitted to direct that he refer within the health system or otherwise. This remains the case. With the massive consolidation that has been taking place in health care for the last twenty years, hospitals now employ many physicians and can require them to direct their referrals to the hospital's chosen specialists. For years, I have had still independent physicians complain that they have lost business they used to get from now hospital employed physicians who are directed to refer their patients to other hospital employees. The clients are routinely stunned when I have told them this is permissible. The original conditions that pertained in the three instances where directed referrals were allowed, was that if the patient had a different choice, that would take precedence. They are not permitted if the patient's insurer determines the provider, practitioner, or supplier; or the referral is not in the patient's best medical interests in the physician's judgment.[119] Even more astonishingly, although the compensation may not be based on the volume of referrals, "The requirement to make referrals to a particular provider, practitioner, or supplier may require that the physician refer an established percentage or ratio of the physician's referrals to a particular provider, practitioner, or supplier"[120]. So

[118] See 56 Fed Register 878 (January 4, 2001)

[119] 42 CFR §411.354(d)(4)

[120] 42 CFR §411.354(d)(4)(vi)

not only may the entity paying compensation direct referrals to it, it can mandate a quantum of all the referrals associated with the compensation relationship.

In the 2021 publication, this permission to require directed referrals was extended to a host of other exceptions as well: recruitment agreements, group practice arrangements with hospitals, fair market value, indirect compensation arrangements, obstetrical malpractice insurance subsidies, academic medical centers, and the exception for limited compensation under $5,000. [121] To qualify to be permitted to direct referrals, the compensation to the physician must be set in advance and any changes made only prospectively. It must be fair market value and comply with the compensation exceptions otherwise available. The arrangement must be documented in a writing signed by both parties. The requirement to refer may only relate to services associated with the basis for the compensation arrangement and no other services the physician provides.

The net effect of the permitted directed referrals is to allow physicians in relationships other than employment to generate business for the entity compensating them. It flies in the face of the essence of the statute's purpose as well as the purpose of the anti-kickback statute. It integrates the physician more solidly into the health care system which is compensating him. The result has been to change referral patterns significantly and to truncate referrals to otherwise independent physicians. The net effect of these types of consolidation is to increase health care costs,[122] which has repeatedly been demonstrated in numerous studies. The permitted directed referrals has the same effect as required referral in an employment relationship where physician practices merge into health care systems. It follows the delusion that integrated health systems deliver better value, which is not what the data shows. The value-based arrangements exception has similar issues.

8.2 Value-based Arrangements

This exception was published in 34 pages with explanations. The OIG version was 100 pages long. Stark is limited to physician referrals so it is more manageable than the far broader OIG safe harbor. The idea behind this exception was to permit otherwise independent providers to work together to improve value and to benefit economically from their activities. It addresses three levels of financial risk ranging from value-based activities with no financial risk to meaningful downside risk, to full financial risk – although the regulations under Stark address these in the opposite order. Without the exception, the behavior it permits would be illegal. Because of that predicate, the regulations have a somewhat theoretical quality to them.

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[121] 42 CFR §§ 411.355(e) and 411.357(c), (d), (e), (h), (l), (p), (r), and (z)

[122] Vogel, "Patients 'steered' toward health systems, more costly treatment after vertical consolidation, study finds" HealthCareDive (Sept 5, 2023) https://www.healthcaredive.com/news/patients-steered-toward-health-systems-more-costly-treatment-after-verti/692695/#:~:text=from%20your%20inbox.-,Patients%20'steered'%20toward%20health%20systems%2C%20more%20costly%20treatment%20after,published%20in%20JAMA%20Health%20Forum; Levins, "Hospital Consolidation Continues to Boost Costs, Narrow Access, and Impact Care Quality" (January 19, 2023) Leonard Davis Institute of health Economics, UPenn. https://ldi.upenn.edu/our-work/research-updates/hospital-consolidation-continues-to-boost-costs-narrow-access-and-impact-care-quality/.

To understand the regulations one must start with definitions, added to the overall Stark regulatory definitions.[123] A value based activity only qualifies if it is reasonably designed to achieve at least one value-based purpose of the value-based enterprise (VBE) or the participants. These include providing an item or service, taking an action or refraining from taking an action. Referring patients does not qualify as an activity[124] but establishing care plans does qualify.[125] Examples offered by the regulators include shared savings distributed by a entity to downstream physicians; physician participation in post discharge planning. A value-based enterprise (VBE) involves two or more participants who must meet four conditions: (1) collaborating to achieve at least one value-based purpose; (2) each participant is a party to a VBA with the other or at least one other VBE participant in the VBE; (3) has an accountable body or person responsible for the financial and operational oversight of the VBE; and (4) has a governing document describing the VBE and how the participants will achieve the value-based purpose. Value-based purpose involves coordinating and managing care of a target patient population (TPP) which is itself an identified patient population selected by a VBE or its participants. The TPP can focus on medical or health characteristics, like undergoing knee surgery or having newly diagnosed diabetes, geographic characteristics, like all patients in a zip code or county, selected payor status or as defined by a payer. A value-based purpose can include improving quality of care for a TPP, reducing costs or growth in expenditures of payors without reducing quality for a TPP, transitioning from health care delivery and payment based on volume of items or services to mechanisms based on quality of care and control of costs for a TPP. The regulators explicitly expect the directed referral rules to be used within the permitted arrangements.[126]

Where the VBA involves full financial risk[127], payment may be prospective only. All the costs of items and services covered by the payer must be included, for each patient in the TPP for a specified period of time beginning no more than 12 months from the commencement date. This gives the participants an opportunity to ramp up their activities before the financial risk kicks in. Both capitation and global budgets are permitted as are gainsharing and shared savings distributions. The remuneration to the physicians must be for or result from value-based activities undertaken by them. Harkening back to permitted referrals, remuneration may not be conditioned on referrals outside the TPP.

Where the VBE entails meaningful downside risk[128] the physician is responsible to repay or forego not less than 10% of the value (in cash or in kind) of the remuneration he receives. The payment methodology and measurement must be set in advance of furnishing items or services for which remuneration is paid. The remuneration may not be provided to reduce or limit medically necessary items or services to any patient whether in the TPP or not. Remuneration must be for or reflect results

[123] 42 CFR §411.351

[124] 85 Fed Register 77479 (Dec 2, 2021)

[125] 85 Fed Register 77501 (Dec 2, 2021)

[126] 85 Fed Register 77507 (decd 2, 2021)

[127] 42 CFR § 411.357(aa)(1)

[128] 42 CFR § 411.357(aa)(2)_

from value-based activities, and not conditioned on referrals of patients not part of the TPP. As is true for full financial risk as well records of the methodology to determine payment and the actual amounts calculated have to be kept for at least six years and made available to the Secretary of HHS upon request.

No financial risk is required under the permitted value-based arrangements, which is an arrangement for the provision of at least one value-based activity for a TPP.[129] The parties, whether individuals or a VBE and an individual must include a physician or the Stark statute does not apply. The VBA does not require care coordination and management to qualify. This exception is about compensation between physicians and an entity or other participants and not payments from a payor to a physician. The arrangement must be documented in a writing that sets forth the value-based activities to be undertaken under the arrangement; how the value-based activities are expected to further the value-based purpose(s) of the value-based enterprise; the target patient population for the arrangement; the type or nature of the remuneration; the methodology used to determine the remuneration; and the outcome measures against which the recipient of the remuneration is assessed, if any. The outcome measures against which the recipient of the remuneration is assessed, if any, are objective, measurable, and selected based on clinical evidence or credible medical support.

Taken together, both the permitted directed referrals regulation and the regulations governing value-based enterprises and arrangements entail directed referrals associated with compensation to a physician. Interestingly, Stark only covers designated health services. Among those services are hospital services as well as clinical laboratory, a wide range of imaging, radiation therapy and more, but certainly not all health care services. So, in applying the value-based regulations, some DHS services have to be at issue or Stark is irrelevant. There is no caselaw yet addressing this issue.

8.0 The Medicaid Conundrum

To conclude the confounding aspects of the statute, I want to address another manifestation that the people who wrote this law had no idea what they are doing. The Stark statute itself is part of Title XVIII of the Social Security Act which title governs Medicare. The drafters included the following provision in Title XIX governing the Medicaid program:

> *no payment shall be made to a State under this section for expenditures for medical assistance under the State plan consisting of a designated health service (as defined in subsection (h)(6) of section 1395nn of this title) furnished to an individual on the basis of a referral that would result in the denial of payment for the service under subchapter XVIII if such subchapter provided for coverage of such service to the same extent and under the same terms and conditions as under the State plan,*[130]

The federal government pays to states which participate in Medicaid its portion (federal financial participation) of the cost of the Medicaid program which is jointly funded in each state with federal and state dollars. This federal law purports to prohibit federal aid for any designated health service provided to a patient in violation of what Title XVIII provides, which is what the rest of this article addresses. There has never been a word of regulation published by the federal government pertaining to the application

[129] 42 CFR § 411.357(aa)(3)

[130] 42 USC §1396b(s).

of the Stark regulations to Medicaid. In fact, the regulators explicitly disclaimed the applicability of the regulations they did publish to Medicaid services: "We do not believe these rules and sanctions apply to physicians and providers when the referral involves Medicaid services,"[131] As I explain further, the statutory provision quoted above cannot be implemented as a practical matter.

A succinct description of how the government pays states to support their Medicaid programs is this:

> *"Each state's Medicaid expenditures for healthcare services are matched by federal funds according to various formulas. The formula that governs the majority of government funding takes into account differences in per capita income among the states and is called the federal medical assistance percentages (FMAP). For 2023, the FMAP ranges from a minimum of 50 percent in wealthier states such as California to 77 percent in Mississippi. The matching structure provides states with resources that automatically adjust for demographic and economic shifts, healthcare costs, public health emergencies, and natural disasters."*[132]

The amounts paid in FMAP to each state are many millions of dollars. There is no mechanism of any kind to either deduct amounts otherwise to be paid to reflect DHS provided in violation of Stark or to recoup monies already paid. I am unaware of any actual application of this statutory provision.

The statute goes on to describe the penalties for violating transactions:

> *and subsections (f) and (g)(5) of such section shall apply to a provider of such a designated health service for which payment may be made under this subchapter in the same manner as such subsections apply to a provider of such a service for which payment may be made under such subchapter.*

Section (f) is a statutory reporting requirement by entities of their ownership by physicians, but in the regulations interpreting this provision, CMS has made the requirement apply only upon request by a government agency.[133] Section (g)(5) provides for sanctions for a failure to make a required report. Even though, since the statute is addressing Medicaid services, there is no federal regulation implementing the Medicaid reporting requirement. To whom is the report made – a federal agency or a state agency? I am unaware of any state which imposes this specific requirement under the federal law, although there are certainly many states which have adopted "mini-Stark" statutes which are often tied to a physician's licensure.[134]

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[131] 63 Fed Register 16659 (Jan 9, 1998)

[132] Peter G Peterson Foundation, "How Do States Pay for Medicaid?" (June 2, 2023) https://www.pgpf.org/budget-basics/budget-explainer-how-do-states-pay-for-medicaid#:~:text=The%20federal%20share%20dropped%20in,enrollees%2C%20depending%20on%20the%20state.

[133] 42 CFR §411.361

[134] American Health Law Association, "State Health Care Fraud Law Toolkit: 50-State Survey with Summaries and Links" (May 20, 2022) https://www.americanhealthlaw.org/content-library/publications/surveys/ea433e21-8af9-4754-b6c8-9351e519f268/State-Health-Care-Fraud-Law-An-AHLA-50-State-Survey

The absence of any federal direction under the statutory provision has not daunted either whistleblowers or judges in their application of the statutory provision in false claims cases. *U.S. ex rel. Schubert v. All Children's Health System, Inc*.[135] alleged false claims and Stark violations by a children's hospital which would have virtually no Medicare patients. The principal allegation was that physicians employed by the hospital were overcompensated, thereby causing the hospital to submit false claims to the Medicaid program as well as Stark violating claims. The court rejected the government's assertion that their regulations did not apply to Medicaid. The court noted that the regulators had gone on to say, "Section 1903(s) does not, for the most part, make the provisions in Section 1877 which govern the actions of Medicare physicians and providers ... apply directly to Medicaid physicians and providers. As such, these individuals and entities are not precluded from referring Medicaid patients or from billing for designated health services. The state may pay for these services, but cannot receive FFP for them."[136] In yet another Florida case, the court distinguished between the impacts of Stark on Medicaid claims versus those submitted to Medicare. In refusing to dismiss the Medicaid allegations, the court stated, ''However, the Medicaid statute does not impose limits on referrals and reimbursements along the same lines as those imposed in the Stark amendment.''[137] Focusing again on the prohibition on payments to states for claims submitted pursuant to a referral that would be denied under the Medicare provisions of Stark, the court said, "Thus, the Medicaid statute prohibits payments to a state for medical services resulting from improper referrals, as defined under the Stark amendment." Of course, how that prohibition could be implemented as a practical matter was completely unaddressed. Other contemporaneous cases merely swept the Medicaid claims in with the Medicare claims without noting the distinctions in the legal authority for either.[138] Despite the courts' barely confronting how the law could be implemented, there is clearly a connection between Stark and Medicaid federal payment to the states. Whether it will ever be enforced or anyone's guess, and the volume of caselaw addressing the issue at all is minimal.

9.0 Conclusion

In selecting only 17 confounding issues to confront in this article, I have sidestepped a litany of other problems that exist between the statue and regulations. That said, we have clearly seen here that the drafters of the statute used, apparently indiscriminately, terms which had long standing use and meaning in Medicare but as applied in Stark, make no sense (e.g., the multiple levels of supervision). In struggling to make sense of this hodge-podge, the regulators used related terminology with differing other meanings in Medicare redefining them for this context only (e.g., under arrangements). This ambiguity only adds to the complexity of advising with regard to this law. In confronting their evolving understandings of the relationships Stark addresses, the regulators have adopted metrics for compliance with no boundaries (predominately, usually, normally, regularly) even as they very precisely defined the

[135] 2013 WL 6054803 (M.D. Fla. 2013).

[137] U.S. v. Halifax Hosp. Medical Center, 2012 WL 921147 (M.D. Fla. 2012).

[138] U.S. ex rel. Osheroff v. Tenet Healthcare Corp., 2012 WL 2871264 (S.D. Fla. 2012). For a good exposition of the regulatory issues and the case law, see Laemmle-Weidenfeld, "Courts' Acceptance of FCA/Stark Law Theory in Medicaid Cases Expands Further" (November 2014) AHLA, Member Briefing. https://www.jonesday.com/en/insights/2014/11/courts-acceptance-of-fcastark-law-theory-in-medicaid-cases-expands-further-iahlai

number of hours physicians must be present at a location to qualify as a shared facility. Against the thicket of challenges, they have also adopted permission for activities that appear to directly conflict with the intent of the statute (permitted directed referrals) and value-based transactions rules which nowhere seem to recognize that Stark is only relevant to referrals for designated health services. Finally, the application of Stark to Medicaid is mystifying and essentially unaddressed in any meaningful regulatory manner.

In my experience, the burden, unwieldiness and complexity of this regulatory environment makes advising on Stark both complicated and dangerous. There is no way a lawyer, even a seasoned health lawyer, can take a book off the shelf and advise a client on these issues. They are challenging and complicated. Even in writing this article, of the many hundreds of times I have read all the provisions addressed here, as I confronted how to explicate my problems with what is there, I found still new layers of problems I had not even expected to discuss. How this law has escaped repeal is a mystery. I am inclined to acknowledge Mr. Stark's own observation about his having created a small industry of analysts, not to mention regulators, who have made this their work. I emerge ambivalent. The complexity of all of this makes more work for me, for which I am grateful. It does nothing meaningful to improve value or quality in health care and for that I regret it.