Pre-Publication Draft

NAVIGATING SPAGHETTI JUNCTION: THE INTERSECTION OF MEDICARE'S DIAGNOSTIC TESTING RULES

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Accepted for publication in the Health Law Handbook, 2020 Edition.
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I. Introduction

Diagnostic testing is a core component of healthcare treatment. Diagnostic testing is necessary in determining appropriate therapeutic steps to take with patients and in developing plans of care. The use of diagnostic testing in the Medicare system has changed over time, leading to various regulatory responses. From 1999 to approximately 2009, diagnostic testing increased significantly across a variety of disciplines, but especially with respect to imaging and cardiovascular studies. Since 2009, there has been some decrease in the volume of diagnostic testing performed, although expenditures on diagnostic testing still remain high, depending on the type of testing performed.

These changes have been driven by factors including the development of newer technologies as well as shifts within the health care industry itself. For example, when they were first introduced, cardiac event monitors were not portable and could only be used within a hospital. Over time, however, the devices became smaller and more portable, eventually being capable of use in a patient's home. Whereas portable devices might have weighed over 10 pounds initially, modern cardiac event monitors only weigh a fraction of a pound, allowing remote studies to be conducted and monitored in the outpatient setting.

A recent study, examining trends in cardiovascular diagnostic testing in fee-for-service Medicare, found that from 1999 to 2008 overall rates of testing increased, then steadily declined through 2016.[1] Other studies, such as those produced by the Medicare Payment Advisory Commission (MedPAC), have found similar results. In reports from June, 2010 and June, 2011,

[1] Kini, Vinay, M.D.; Timea Viragh, M.A.; David Magid, M.D., M.P.H.; Frederick A. Masoudi, M.D., M.S.P.H.; Ali Moghtaderi, Ph.D; Bernard Black, J.D., M.A., "Trends in High- and Low-Value Cardiovascular Diagnostic Testing in Fee-For-Service Medicare, 2000-2016," Jama Network Open, October 11, 2019, p. 7.

MedPAC addressed the rise in the use of diagnostic testing, especially with respect to advanced imaging services. For example, the 2010 study found that in 2006, 27% of physicians reported expanding their use of in-office testing and 20% reported they had increased their use of in-office imaging.[2] Physician offices accounted for 64% of spending on imaging under the Medicare Physician Fee Schedule (MPFS) in 2006, compared to 58% in 2000.[3] The 2011 report noted that from 2000 to 2009, cumulative volume growth of imaging per fee-for-service beneficiary surpassed all other categories of physician service except tests (including electrocardiograms, cardiovascular stress tests, and nerve conduction studies), with imaging rising by 85% as compared to 47% growth in all physician services.[4] The report also noted that imaging services at the time were migrating from inpatient to ambulatory settings, with inpatient settings dropping from 32% of all imaging studies in 2004 to 28% in 2009, while physician offices and IDTFs increased from 27% in 2004 to 28% in 2009, and hospital outpatient departments growing from 38% in 2004 to 40% in 2009.[5] The report speculated that the trend could be partially due to hospitals purchasing physician practices and converting them to outpatient hospital settings, but that such a hypothesis could not be confirmed with available data.[6]

Later reports produced by MedPAC in 2015 and 2016 noted a downward trend in the volume of imaging services beginning in 2009, decreasing between 2009 and 2015 by

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[2] MedPAC Report to Congress: Aligning Incentives in Medicare, p. 217, June, 2010.

[3] MedPAC Report to Congress: Aligning Incentives in Medicare, p. 218, June, 2010.

[4] MedPAC Report to Congress: Aligning Incentives in Medicare, p. 35, June, 2011.

[5] MedPAC Report to Congress: Aligning Incentives in Medicare, p. 36, June, 2011.

[6] MedPAC Report to Congress: Aligning Incentives in Medicare, p. 36, June, 2011.

approximately 7%, with a shift in billing for cardiovascular imaging from professional offices to hospitals, which MedPAC believed explained the drop in volume.[7] The 2016 report noted that from 2000 to 2014, payment updates for fee schedule services generally increased by 10%, but that spending per beneficiary for such services grew at a cumulative rate of 70%, due to significant increases in volume.[8]

These increases in the volume of diagnostic testing performed within the Medicare fee-for-service system coincided with various regulatory changes, including the evolution of the Stark regulations, the creation of the anti-markup rule, and other changes in Medicare. For example, in 2014, Congress passed the Protecting Access to Medicare Act of 2014.[9] This law instructed CMS to establish Appropriate Use Criteria (AUC) for advanced diagnostic imaging services, essentially imposing prior authorization requirements on such services.[10] This had been recommended by MedPAC as far back as their 2010 report, which specifically advised that Medicare adopt a targeted prior authorization program for such services.[11] The 2011 MedPAC report reiterated this advice, suggesting that MRIs, CTs, and nuclear medicine services be subject to prior authorizations when outlier physicians ordered such services.[12] MedPAC noted at the time that it was unclear whether CMS had the authority to implement such a program absent a

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[7] MedPAC Report to Congress: Medicare Payment Policy, March, 2015 pp. 93, 95.

[8] MedPAC Report to Congress: Medicare Payment Policy, March, 2016, p.110.

[9] P.L. 113-93, April 1, 2014.

[10] Social Security Act § 1834(q).

[11] MedPAC Report to Congress: Aligning Incentives in Medicare, p. 224, June, 2010. Interestingly, the report also confronted the In-Office Ancillary Services exception under Stark and suggested that, at some point, it might need to be limited, such as to covering only specific services or physician groups.

[12] MedPAC Report to Congress: Aligning Incentives in Medicare, pp. 44-54, June, 2011.

change in the statute.[13] This was finally remedied in the 2019 MPFS publication.[14] Under the new system, AUC are developed or endorsed by national professional medical specialty societies or other provider-led entities (PLEs), which may be referenced by professionals ordering and furnishing advanced diagnostic imaging, defined as diagnostic MRIs, CT, and nuclear medicine services (including PET).[15] Under the AUC program, CMS identifies certain priority clinical areas which are used to identify outlier ordering professionals.[16] Ordering professionals must consult AUCs through the use of clinical decision support mechanisms (CDSMs), which are electronic tools to communicate AUCs to ordering professionals.[17] This consultation must occur prior to ordering advanced diagnostic imaging services performed in physician offices, hospital outpatient and emergency departments, ambulatory surgical centers, independent diagnostic testing facilities, and other provider-led outpatient settings determined by CMS, unless certain exceptions apply.[18] As of January 1, 2020, ordering professionals must use qualified CDSMs and report AUC consultation information on both professional and facility claims for advanced diagnostic imaging services.[19]

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[13] MedPAC Report to Congress: Aligning Incentives in Medicare, p. 53, June, 2011.

[14] See, 83 Fed. Reg. 59688-59701 (November 23, 2018).

[15] Defined at Social Security Act § 1834(e)(1)(B). See also, 42 CFR § 414.94(b). For an overview of the AUC program, see "Appropriate Use Criteria for Advanced Diagnostic Imaging," Medlearn Network Fact Sheet ICN 909377, December, 2018.

[16] 42 CFR § 414.94(e). Current priority clinical areas include: coronary artery disease (suspected or diagnosed); suspected pulmonary embolism; headache (traumatic and non-traumatic); hip pain; low back pain; shoulder pain (including suspected rotator cuff injury); cancer of the lung (primary or metastatic, suspected or diagnosed); and, cervical or neck pain. 42 CFR § 414.94(e)(5).

[17] "Ordering professional" is defined at 42 CFR § 414.94(b), as are CDSMs. Qualifying CDSMs are described at 42 CFR § 414.94(g).

[18] The exceptions themselves are described in 42 CFR §§ 414.94(i) and (j)(2).

[19] 42 CFR § 414.94(k).

These new requirements demonstrate CMS' continuing efforts to control the costs and volume of advanced diagnostic imaging services. They are one part of a large, complex network of regulatory requirements for suppliers of diagnostic tests. This article examines these rules and their interactions with each other, including Medicare's requirements regarding the supervision of diagnostic testing, the Stark regulations, the anti-markup rule, and requirements applicable to independent diagnostic testing facilities, with a particular focus on the physician experience with these regulations. The article does not address all aspects of diagnostic testing (for example, it does not cover clinical laboratory services), but is meant to illustrate the interlocking, overlapping nature of the rules and regulations it does address, and how they affect physicians performing diagnostic tests.

II. Diagnostic Testing Basics

Medicare defines the term "diagnostic testing" to include X-rays, laboratory tests, and other diagnostic tests.[20] Physicians cannot simply order tests for patients, however; for a diagnostic test to be covered under Medicare, the physician ordering the test must have an existing relationship with the patient.[21] While this language might seem narrowly tailored, the term "physician" includes allopathic and osteopathic physicians, dentists and dental surgeons, doctors of podiatry, and optometrists.[22] Diagnostic tests can also be ordered by non-physician practitioners, such as nurse practitioners, physician assistants, certified nurse specialists, clinical psychologists, physical therapists, occupational therapists, speech language therapists,

[20] Social Security Act § 1861(s)(3). See also, 42 CFR § 410.10; Medicare Benefit Policy Manual, Chapter 15 § 80.6.1.

[21] 42 CFR § 410.32(a).

[22] Social Security Act § 1861(r); 42 CFR § 410.32(a).

audiologists, clinical social workers, certified nurse midwives, certified registered nurse anesthetists, and anesthesia assistants.[23] Suppliers[24] of this type – NPPs – are not considered "physicians" within the meaning of the Social Security Act, however. This can lead to its own implications, discussed below.

For Medicare coverage purposes, most services that are performed and which require an "order"[25] require that such order be in writing.[26] However, for *diagnostic testing specifically*, Medicare's rules differ somewhat. Within this context, an order may be (1) a written document signed by the treating physician or NPP that is delivered by hand, mail, or fax to the testing entity;[27] (2) a telephone call by the treating physician/practitioner or his or her office to the testing facility, provided that both the ordering entity and the entity receiving the order record the call in their respective medical records for the service[28]; or (3) an email.[29] The test order does not need to be signed, but CMS instructs that the test order should be indicated in the treating physician or practitioner's record for the patient.[30]

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[23] 42 CFR § 410.32(a)(2). See also, Medicare Benefit Policy Manual, Ch. 15 § 80.6.1.

[24] CMS uses the term "supplier" to refer to those health care practitioners and entities which render services under Medicare Part-B, whereas hospitals and other entities that bill under Medicare Part-A are referred to as "providers."

[25] For an excellent, in-depth examination of the requirements surrounding physician orders in the Medicare system, see, Blanchard, Timothy P. and Margaret M. Manning, "Evolving Medicare Policy on Physician Orders: Fundamental Concepts but Higher Stakes," Health Law Handbook, 2014 ed., pp. 482-529.

[26] Medicare Program Integrity Manual, Chapter 3 § 3.3.2.4.

[27] Medicare Benefit Policy Manual, Chapter 15 § 80.6.1.

[28] Medicare Benefit Policy Manual, Chapter 15 § 80.6.1.

[29] Medicare Benefit Policy Manual, Chapter 15, § 80.6.1.

[30] Medicare Benefit Policy Manual, Chapter 15, § 80.6.1; Medicare Claims Processing Manual, Chapter 12 §§ 30.2.9, 30.3.7.

Interestingly, CMS recently addressed the issue of orders sent by text message. In a 2017 memorandum, CMS stated unequivocally, "CMS does not permit the texting of orders by physicians or other health care providers. The practice of texting orders from a provider to a member of the care team is not in compliance with the Conditions of Participation (CoPs) or Conditions for Coverage)."[31] This guidance comes in spite of the fact that many physicians are increasingly relying upon text messages for communication both with other physicians and with their patients.[32] Nevertheless, until further notice, CMS does not permit orders to be sent by text, in spite of an otherwise liberal attitude towards diagnostic testing orders.

It is also worth noting that the term "diagnostic testing" now includes certain screening services. This was not always the case. For many years, screening services were not covered by Medicare at all. However, with the passage of the Patient Protection and Affordable Care Act of 2010[33], CMS was able to add coverage for twenty-six preventive care services.[34] These include diagnostic tests and screening services, such as for glaucoma, HIV, diabetes, colorectal cancer, prostate cancer, cervical cancer, lung cancer, hepatitis B and C, and depression.[35]

Under Medicare, testing itself consists of two separate components: the technical component (the "TC") and the interpretation of the test, referred to as the professional

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[31] S&C 10-10-ALL, December 28, 2017.

[32] "Text Message Use Among Providers Raise HIPAA Concerns," Becker's Health IT & CIO Report, August 11, 2011, available at https://www.beckershospitalreview.com/healthcare-information-technology/text-message-use-among-providers-raise-hipaa-concerns.html.

[33] P.L. 111-148 & 111-152, March 23, 2010.

[34] P.L. 111-148 & 111-152, March 23, 2010, § 4104.

[35] For a full list of all 26 preventive care services, see https://www.medicare.gov/coverage/preventive-screening-services.

component (the "PC").[36] A diagnostic test under Medicare may be billed as a single service consisting of both components (billed "globally"), or it may be "split billed" with each component of the service being billed by a separate rendering provider. Test components may also be "purchased" from the performing entity and billed by the purchasing entity (usually along with one of the two components). This practice can lead to some confusion with respect to Medicare terminology for how the services are billed, specifically with respect to the concept of "global" services.

Under Medicare's billing rules for diagnostic testing, a "global" service is one where the billing entity performs both portions of the diagnostic test; in other words, where the billing entity performs both the TC and the PC of the test.[37] When this occurs, the billing entity submits a single claim for both portions of the service, and bills the test with an unmodified CPT code. Where this can become confusing for diagnostic testing providers is when one introduces the concept of purchased services. Under Medicare's billing rules, purchased diagnostic components cannot be billed "globally" and must instead be billed as two distinct services. In other words, when an entity purchases a diagnostic test and intends to bill both the TC and the PC, the billing entity must submit a claims form that includes both services with the appropriate CPT code modifiers: a -26 modifier for the PC, and a -TC modifier for the TC.[38]

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[36] Some services, such as Holter monitoring and other similar tests, have three components: the PC, the TC, and a "hook-up" component where the billing entity submits a claim for placing the device on the patient and/or instructing the patient in the use of the device.

[37] Medicare Claims Processing Manual, Chapter 1 § 30.2.9.

[38] Medicare Claims Processing Manual, Chapter 1 § 30.2.9. Specifically, the manual instructs, "If the billing physician or other supplier performs only the TC or the PC and wants to bill for both components of the diagnostic test, the TC and PC must be reported as separate line items if billing electronically (ASC X12 837 professional claim) or on separate claims if billing on paper forms (Form CMS-1500). Global billing is not allowed unless the billing physician or other supplier performs both components."

For the PC, interpretation may be performed by a qualified physician or NPP. The TC may be performed personally by a qualified physician or NPP, or by a technician supervised by a qualified physician. In practice, however, physicians and NPPs do not personally perform TCs; instead, a technician performs the test under physician supervision. Only a physician may supervise the performance of a TC of a diagnostic test. While NPPs are permitted to supervise other services, they may not supervise the performance of diagnostic tests. This issue turns on the regulatory requirements surrounding supervision, which state, "...all diagnostic x-ray and other diagnostic tests covered under section 1861(s)(3) of the [Social Security Act] and payable under the physician fee schedule must be furnished under the appropriate level of supervision by a physician as defined in section 1861(r) of the [Social Security Act]."[39] As noted above, the definition is limited to: allopaths and osteopaths; dentists and doctors of dental surgery; podiatrists; optometrists; and chiropractors.[40] Absent from that list are nurse practitioners, physician assistants, and other NPPs.[41]

Supervision may be performed at one of three levels:

1. General supervision. This means that the physician is providing overall direction of the service, and is responsible for training the non-physician personnel who perform the test,

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[39] 42 CFR § 410.32(b)(1).

[40] Social Security Act § 1861(r).

[41] There are exceptions to this general rule, however. These include the performance of diagnostic mammography tests regulated by the FDA; diagnostic tests personally performed by a qualified audiologists; diagnostic psychological and neuropsychological testing services when personally performed by a clinical psychologist or independently practicing psychologist, or when performed under the general supervision of a physician or clinical psychologist; diagnostic tests personally performed by a physical therapist certified by the American Board of Physical Therapy Specialists as a qualified electrophysiologic clinical specialist and permitted to provide the service under applicable state law; pathology and laboratory procedures listed in the CPT 80000 series; and diagnostic tests performed by a certified nurse-midwife, nurse practitioner, or clinical nurse specialists authorized to perform tests under applicable state law. 42 CFR §§ 410.32(b)(2)(i) – 410.32(b)(2)(vii).

as well as for maintaining the equipment. At this level of supervision, the physician need not be physically on site at all.[42]

2. Direct supervision. At this level, the physician is available within the "office suite" and is immediately available to provide assistance and direction throughout the procedure. However, the physician need not be in the same room as where the test is being performed.[43]
3. Personal supervision. At this level, the physician is physically present in the room where the test is being performed.[44]

Each diagnostic test reimbursable under Medicare's physician fee schedule is assigned an appropriate level of supervision, which may be determined by looking up the specific test on the Physician Fee Schedule Look-Up Tool, available online.[45] A "1" indicates "general supervision," a "2" indicates "direct supervision," and a "3" indicates "personal supervision" as being required (a "9" indicates that the supervision concept is not applicable to the service).[46]

Medicare's rules regarding diagnostic testing supervision have proven confusing on multiple bases, however. For example, one portion of cardiac stress testing (CPT 93016) is, itself, described as the "supervision" of a patient undergoing a cardiac stress test. In other words, the service itself is the supervision of the patient. The Medicare Physician Fee Schedule Look-

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[42] 42 CFR § 410.32(b)(3)(i).

[43] 42 CFR § 410.32(b)(3)(ii).

[44] 42 CFR § 410.32(b)(3)(iii).

[45] At https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PFSLookup/index.html?redirect=/PFSLookup.

[46] Medicare Benefit Policy Manual, Chapter 15 § 80.

Up tool indicates that the service must be performed under "direct supervision," even though the service itself cannot be split into TCs and PCs – it is a single, indivisible service. We represented an independent diagnostic testing facility (IDTF) client that wanted to use NPs to perform cardiac stress testing using the CPT 93016 code. In most instances, nurse practitioners are permitted to perform any medical service that a physician can perform.[47]

We contacted the client's Medicare Administrative Contractor (MAC) to ask the MAC to confirm that a nurse practitioner – if appropriately licensed under applicable state law – could personally perform the "supervision" of the cardiac stress testing. Initially, the MAC's medical director appeared confused by our inquiry, and cited to policy governing the performance of specific tests in IDTFs which stated that CPT 93016 had to be performed by a board certified internist or cardiologist with ACLS[48] certification. When we reiterated that the NP was personally performing the service, and not supervising a technician, and that the NP had ACLS certification, the medical director offered a confusing answer, which is quoted here:

> "It is correct in relation to 93016: 'an NP who is ACLS certified could personally perform the service, since the service is within the NP's scope of practice under applicable state licensure laws"[49] but this service may not be billed to Medicare for a service performed in an IDTF since the elements for both Supervising (of patient, the test itself and any participating technician) and Interpreting Physician are not met. This test requires a Board Certified Internist or Cardiologist who is also ACLS certified."

It should be noted that the medical director's attitude applies specifically to the IDTF context[50], however, and may rely on the tension between the language of the Social Security Act, the

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[47] Social Security Act § 1861(s)(K)(ii).

[48] Advanced Cardiovascular Life Support.

[49] Quoting our response to the initial statement that only an internist or cardiologist with ACLS certification could perform the service.

[50] The medical director made certain to highlight that this policy applied within an IDTF specifically in his response to us.

diagnostic testing regulations, and the IDTF regulations. Under the Social Security Act and diagnostic testing regulations, NPs may personally perform diagnostic tests that can otherwise be performed by a physician. Under the IDTF regulations, however, supervising physicians must demonstrate proficiency in the performance and interpretation of tests performed by the IDTF.[51] Thus, the MAC would be justified in developing policy that specifically describes what it considers to be evidence of proficiency. This would only work within the context of an IDTF, however, and still runs counter to the text of the Social Security Act. Within a physician office, an NP should be able to personally perform CPT 93016.[52]

With the passage of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA),[53] Medicare tightened controls on who may be considered "qualified" to perform certain advanced diagnostic imaging (ADI) services. These services include MRIs, CT scans, nuclear medicine imaging procedures such as PET scans, but they do not include X-ray services, ultrasound, fluoroscopy procedures, or diagnostic/screening mammographies. However, national policy on what constitutes "qualified" providers has not solidified in all cases. As a result, diagnostic testing providers must consider applicable local coverage determinations (LCDs) to see whether their MAC(s) have issued an LCD on point.[54]

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[51] 42 CFR § 410.33(b)(2).

[52] We have prior communications from individuals within what was then referred to as the Health Care Financing Administration (the entity that later became CMS) explicitly stating that NPs may perform and be paid for a related service – CPT 93015 – dating back to July, 2002. The guidance has not been overturned, except with respect to services provided by IDTFs.

[53] P.L. 110-275 § 135(a)

[54] These policies can be found at https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Accreditation-of-Advanced-Diagnostic-Imaging-Suppliers.html.

For example, three MACs – CGS Administrators, Inc. (CGS); National Government Services, Inc. (NGS); and Wisconsin Physician Service Insurance Corp. (WPS) have each published LCDs on various non-invasive vascular studies.[55] With respect to the credentials required for physicians in performing these studies, the LCDs each generally require that the physician be a Registered Physician in Vascular Interpretation (RPVI), or American Society of Neuroimaging (ASN) (among other credentials). Examples of appropriate credentials for technicians include Registered Vascular Technician (RVT), American Registry of Diagnostic Medical Sonographers (ARDMS), or Cardiovascular Credentialing International's Registered Vascular Specialist (RVS) (among others).[56] For example, the accreditation standards for the performance of CPT 93925 (duplex scan of lower extremity arteries or arterial bypass grafts; complete bilateral study) are described in three different ways by three different MACs:

- CGS' and NGS' credentialing criteria state more generally that "Examples of appropriate personnel certification include, but are not limited to, the Registered Physician in Vascular Interpretation (RPVI), Registered Vascular Technologist (RVT), the Registered Cardiovascular Technologist (RCVT), Registered Vascular Specialist (RVS), and the American Registry of Radiologic Technologists (ARRT) credentials in vascular technology."[57]
- WPS' policy states that a licensed qualified physician is defined as: (1) having trained and acquired expertise within the framework of an accredited residency or fellowship program in the applicable specialty/subspecialty in ultrasound or must reflecte equivalent

[55] LCDs L34045; L33627; L35761; L35753.

[56] LCDs L34045; L33627; L35761; L35753.

[57] LCDs L34045, L33627, respectively.

education, training, and expertise endorsed by an academic institution in ultrasound or by applicable specialty/subspecialty society in ultrasound; or "Has the Registered Vascular Technologist (RVT), Registered Physician Vascular Interpretation (RPVI), or American Society of Neuroimaging (ASN): Neuroimaging Subspecialty Certification; and is able to evince proficiency in the performance and interpretation of each type of diagnostic procedure performed.[58]

While CGS and NGS maintain identical certification standards for "personnel," only one of their criteria specifically applies to physicians. Meanwhile, none of the other four MACs have yet published similar guidance on these services, effectively leaving open the question of what qualifies as appropriate certification for physicians and technologists to perform these tests in those regions.

This lack of clear guidance from MACs can be problematic. If a diagnostic testing provider's MAC has not pronounced on the issue, what standard should one adopt for purposes of determining appropriate certification to perform and/or supervise the tests in question? The safer approach may be to take whichever MAC has the most detailed standards and adopt those standards, unless there is a split between MACs where one MAC explicitly states that it uses a lower standard. Our own clients have inquired on issues like these, and we have taken the approach of using the more stringent standard, since it was – at the time – the only clear guidance on the matter where all other MACs either had no policy at all, or took the position that

[58] LCD L35761. Evidently, the physician can meet credentialing requirements by demonstrating certification as a technologist.

physicians and technicians must "demonstrate proficiency" in the performance of the test, without specifying how to actually demonstrate such proficiency.

The issue of diagnostic testing and supervision has also proven confusing with respect to the similarities between diagnostic testing and the concept of "incident-to" billing. However, in the Stark Phase III rulemaking, CMS explicitly stated, contrary to the prior entire history of the Medicare program, that diagnostic testing can never be performed on an incident-to basis. Specifically, CMS stated, "...Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests, all of which comprise a single benefit category under Section 1861(s)(3) of the [Social Security] Act may not be billed as 'incident to' service..."[59] This change overturned Medicare policy which had existed since the creation of the Medicare program itself. Prior to the rulemaking, diagnostic testing had been permitted under incident-to billing rules. However, CMS indicated that the change was intended to clarify confusion introduced in the 2002 Medicare Physician Fee Schedule final rule, where CMS explained that, when diagnostic tests were provided "incident-to," the supervision requirement for the test, rather than the "incident-to" rule would apply.[60] This position was further modified with the publication of the 2003 Medicare Physician Fee Schedule, which explained that:

> "only services that do not have their own benefit category are appropriately billed as incident to a physician's service. Examples of benefit categories are diagnostic x-ray tests...and influenza vaccine and its administration...However, since Section 4541(b) of the [Balanced Budget Act of 1997] allows certain services with their own benefit category (that is, outpatient physical therapy services...and outpatient occupational therapy) to also be provided as incident to services, we cannot prohibit physicians and practitioners from billing these services as incident to. However, when these services are

[59] 72 Fed. Reg. 51016, September 5, 2007.

[60] 66 Fed. Reg. 55268.

billed incident to, requirements in Medicare Carriers Manual Section 2050 must also be met."[61]

With the Stark Phase III final rule, CMS made it clear that diagnostic testing simply could not be billed incident-to; the concept did not apply to diagnostic testing at all, regardless of the similarities in supervision requirements between the two.[62] This position is illogical, given that NPs, PAs, and certified registered nurse anesthetists (CRNAs) each have their own benefit category[63], and can each be billed incident-to. Nevertheless, when analyzing arrangements involving diagnostic testing, Stark must still be considered.

III. Stark Implications

The Stark law generally prohibits a physician from submitting claims for "designated health services" (DHS) to entities with which the physician has a financial relationship.[64] "Designated health services" is defined to include: clinical laboratory services; physical therapy; occupational therapy; outpatient speech-language pathology services; radiology and certain other imaging services; radiation therapy services and supplies; parenteral and enteral nutrients, equipment, and supplies; prosthetics, orthotics, and prosthetic devices and supplies; home health services; outpatient prescription drugs; and inpatient and outpatient hospital services.[65] Under the Stark statute itself, the list of DHS which are diagnostic testing includes: clinical laboratory

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[61] 67 Fed. Reg. 79994.

[62] Since the publication of Phase III, CMS has moved away from "omnibus" Stark rule publications as "phases" and has tended to publish updates to Stark in the annual Medicare Physician Fee Schedule, usually published some time between November and December of the year before the fee schedule will take effect.

[63] Social Security Act §§ 1861(s)(2)(K)(ii), 1861(s)(2)(K)(i), and 1861(s)(11), respectively.

[64] See generally, 42 CFR § 411.351, et seq. The definition of "financial relationship" itself is complex, and appears at 42 CFR § 411.354. This article does not address these complexities.

[65] 42 CFR § 411.351.

services, and certain radiology services (e.g., MRIs, ultrasounds, CAT scans, nuclear imaging, PET scans) reimbursable under Medicare or Medicaid. Other diagnostic services, such as electrocardiograms, nerve conduction velocity studies, electroencephalograms, Holter studies, and cardiac telemetry monitoring are not DHS. Each year, CMS publishes a list of DHS in the Medicare Physician Fee Schedule.[66]

With respect to Medicaid, the statutory language reads:

> "Notwithstanding the preceding provisions of this section, 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 of this chapter 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, 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."[67]

However, regulations applying Stark to the Medicaid context have never been published; to date, only Medicare regulations exist. Courts have attempted to apply the Medicare regulations to Medicaid, although this approach has not yet caught on nationally. For example, in U.S. ex rel. Schubert v. All Children's Health System, Inc.[68], the court found that, "The Stark Amendment 'prohibits physicians from referring their Medicare and Medicaid patients to business entities in which the physicians or their immediate family members have a financial

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[66] https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/index.html. See also, 42 CFR § 411.351 for "List of CPT/HCPCS Codes" definition, which includes the link.

[67] 42 USCA § 1396b(s).

[68] 2013 WL 6054803 (M.D.F.L. 2013).

interest."[69] "Clinical laboratory services" is itself defined in the regulations, but only applies to those services specifically listed on the Stark list of CPT codes.[70]

A. Stark Group Practices and Diagnostic Testing

Many of the exceptions under Stark rely on meeting the definition of a "group practice," because "referrals" under Stark may be both referrals outside of the group and referrals within the group. Meeting the group practice exception can protect a variety of intra-group referrals and compensation structures related to the operation of the group.[71] A "group practice" for Stark purposes requires that the group be a single legal entity.[72] In other words, the group cannot be a "virtual group" made up of multiple, otherwise separate legal entities. The group must also have two (2) physician "members."[73] The term "member" is defined to include (a) direct and indirect physician owners of the group; (b) physician employees of the group; or (c) locum tenens or on-call physicians providing services in place of a physician member.[74] Of note is the fact that independent contractors are not included in the definition of "member" for Stark purposes. However, group employees may be part-time employees and still qualify as "members."[75] It is

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[69] All Children's, at *5, quoting Fresenius Med. Care Holdings, Inc. v. Tucker, 704 F.3d 935 (11th Cir. 2013), emphasis added.

[70] 42 CFR § 411.351.

[71] For an even more in-depth dive into Stark and its implications on Medicare reimbursement, see Gosfield, Alice, "Stark and Medicare's Physician Reimbursement Rules: Unraveling the Knots," Health Law Handbook, 2015 ed., pp. 179-211.

[72] 42 CFR § 411.352(a).

[73] 42 CFR § 411.352(a).

[74] 42 CFR § 411.351.

[75] 69 Fed. Reg. 16077, (March 26, 2004). Specifically, the regulators stated, "We agree with the commenters' interpretation [of the Stark rules] that the physician counted for the '2 or more physicians' test can be part-time employed physicians. The group practice would still need to satisfy the remaining conditions of § 411.352."

also worth noting that the concept of a "member" of the group differs from that of a "physician in the group," which can include independent contractors while they are providing services on the group's behalf and in the group's "facilities."[76] However, the term "facilities" has never been defined or explained in this context, which leaves open the question of what would qualify as a "facility." A "physician in the group" must also reassign their right to payment to the group, which reassignment must be accomplished by contract (in addition to completing the required Medicare enrollment forms, such as the CMS-855R or otherwise reassigning through the PECOS system).[77]

To qualify as a "group practice," physician members must render "substantially the full range of patient care services" that they normally provide.[78] In other words, a physician cannot join a group solely to perform one type of service, when that physician provides a wide range of other services he provides elsewhere. Members, in the aggregate, must also perform 75% of their services with the group. This 75% measurement may be measured based on time (e.g., total time per member spent providing patient care services for the group), but can also be based on any alternative measure that is determined in advance, in a reasonable, uniformly applied, verifiable, and documented manner.[79] So in a group of 8 physicians, 3 shareholders each spend 100% of their time with the group, two half-time employed physicians, and three independent

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[76] 42 CFR § 411.351.

[77] For more in-depth examinations of the Medicare enrollment process, see Shay, Daniel, "Enrollment in Medicare: Fraternity Hazing or Keeping Out Bad Actors?" Health Law Handbook, 2009 ed., pp. 1-34; Shay, Daniel, "'Halt! Who Goes There?': Coping with the Continuing Crackdown on Medicare Enrollment," Health Law Handbook, 2011 ed., pp. 71-102; Shay, Daniel, "The Medicare Part-B Enrollment Obstacle Course: It Hasn't Gotten Any Easier," Health Law Handbook, 2019 Ed., pp. 303-335.

[78] 42 CFR § 411.352(b).

[79] 42 CFR § 411.352(b).

contractor physicians could qualify; but if one of the shareholders was engaged at the VA once a week, paid by the VA, the whole group would not qualify. [80]

The patient care services must also be billed by the group and paid to the group.[81] This calculation does not apply to Health Professional Shortage Areas (HPSAs), and time spent by group members working in HPSAs does not apply to the 75% total for groups outside of HPSAs, even if the physician is working for the group at the time.[82] For newly-formed groups, there is another exception applicable during the "start-up" period of up to twelve (12) months from the date the group is formed. During this time, the group need only make a good faith effort to comply with the test.[83] Another exception applies when a new member who has relocated to join an existing group, as long as (a) the group would have complied with the test without the addition of the new physician, and (b) the new member's employment is document as of the date they become part of the group.[84]

Members of the group must also perform at least 75% of the "patient encounters" of the group.[85] The term "patient encounters," however, has never been defined in regulations. It also differs considerably from other Medicare language in that it is more narrow than other similar terms. For example, "physician services" is defined as "...where the physician either examines

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[80] To be clear, these restrictions and requirements apply to qualifying under Stark. Physicians may still conduct their businesses in ways which do not comply with Stark, if Stark itself is not relevant to their practices, such as where the practice itself does not provide DHS. If the VA paid the group for his services, then the group would still qualify.

[81] 42 CFR § 411.352(d)(1).

[82] 42 CFR §§ 411.352(d)(2)-(4).

[83] 42 CFR § 411.352(d)(5).

[84] 42 CFR § 411.352(d)(6).

[85] 42 CFR § 411.352(h)(1).

the patient in person 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."[86] However, this description does not describe face-to-face interaction with a patient. Similarly, an interaction with a patient might happen remotely, such as through telemedicine services which, while not face-to-face in the same room, still involve real-time communication with the patient. Likewise, "visits" are usually referred to specifically when referencing a service that would qualify as an evaluation and management (E/M) service with a patient.[87] The requirement that 75% of the "patient encounters" of the group be performed by members also means that independent contractors cannot perform more than 25% of the "patient encounters" of the group.

In addition, the group must distribute overhead, expenses, and income according to one or more methods that are determined prior to receiving payment for services. Compensation methodologies may be adjusted prospectively after that point, however.[88] The group must also operate as a unified business, meaning it at least (a) maintains a centralized decision-making body that is representative of the group's membership which is responsible for setting budgets, deciding compensation and salaries, and otherwise controlling the group's assess and liabilities; and (b) consolidated accounting, billing, and financial reporting.[89] Location and specialty-based compensation practices are allowed under the regulations for revenues not derived from DHS,

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[86] Medicare Benefit Policy Manual, Chapter 15 § 30A.

[87] For more on E/M services, see generally, Medicare Claims Policy Manual Chapter 12 § 30.6.

[88] 42 CFR § 411.352(e).

[89] 42 CFR § 411.352(f)(1).

and may be permitted for revenues which are derived from DHS if they meet the rules for productivity bonuses and/or profit sharing.[90]

With respect to compensation specifically, the statute provides that physician members of the group may not receive compensation which is based on the volume or value of referrals, but may receive productivity bonuses and share in the overall profits of the group.[91] As explained by the regulators, the intention of these rules was to ensure that groups are not simply associations of physicians, formed to make permissible an arrangement which would otherwise violate Stark. For this reason, the definition of a group practice purposefully excludes "a loose confederation of physicians" which is organized "to share profits from referrals."[92] Complying with the group practice definition is critical for groups performing diagnostic tests that wish to protect such arrangements under Stark. Several Stark exceptions rely on first qualifying as a group practice. Compensation for physician members and independent contractors can also be impacted by whether the group actually qualifies as a group in the first place, as discussed further below. Unlike with the federal anti-kickback statute, where the regulations specify safe harbors which – if not met – do not necessarily render the arrangement violative, failure to meet a Stark exception is fatal for arrangements where Stark compliance is required.

B. Stark Exceptions in the Diagnostic Testing Context

The Stark regulations provide for multiple exceptions. Among the most common ones are the exception for certain physician services, and the exception for in-office ancillary services

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[90] 42 CFR § 411.352(f)(2).

[91] 42 CFR § 411.352(g). Discussed in greater detail at Section III.C herein.

[92] 66 Fed. Reg. 897, (January 4, 2001).

(IOAS). With respect to the first exception (generally referred to as the "physician services" exception), the Stark prohibition does not apply to physician services that are furnished personally by another physician who is a member of, or a physician in, the same group practice as the referring physician, or to services that are performed under the supervision of another physician who is a member of the referring physician's practice, or a physician in the group.[93] The physician services referenced in this first exception, however, only mean services which are either personally performed or those services which are performed "incident to" the referring physician's services.[94] In practical terms, within the context of diagnostic testing, this often means that the TC of diagnostic testing falls outside the scope of the physician services exception because diagnostic testing cannot be performed "incident to." Therefore, to meet the "physician services" exception, the TCs must be personally performed by the physicians, which is virtually unheard of in physician practices.

One of the most commonly used exceptions in Stark is the in-office ancillary services (IOAS) exception. This exception looks at three key factors: (1) who provides the service; (2) where the service is provided; and (3) who bills for the service. This exception also relies on meeting the definition of a "group practice" under Stark.

1. The Who

Under the statute, in-office ancillary services must be performed: (1) personally by the ordering physician; (2) personally by another member of the ordering physician's group; or (3) personally by an individual (e.g., a technician) who is supervised by the referring/ordering

[93] 42 CFR § 411.355(a)(1).

[94] 42 CFR § 411.355(a)(2).

physician or a physician in the group.[95] The use of the term "supervision" raises the question of what level of supervision must be provided. To meet the in-office ancillary services exception, the services must be "directly supervised," according to the Stark statute, which, under historical Medicare terms, would mean in the office suite even though x-rays or abnormal films or skeletal films without contrast had always been allowed under "general supervision" and the provision of overall quality control.[96]

In the Stark Phase I rulemaking, CMS clarified that the appropriate level of supervision is "whatever level is required under the applicable Medicare payment and coverage requirements."[97] For diagnostic testing purposes, this means that the appropriate level of supervision required to meet the IOAS exception is the level required for the specific service, as described under the Medicare Physician Fee Schedule. In other words, diagnostic testing providers must determine whether the test to be performed requires general, direct, or personal supervision, likely by consulting the Medicare Physician Fee Schedule Look-Up tool, discussed above.

The Phase I clarification also means that, although the statute may require the service to be "directly supervised," if the required level of supervision under the Medicare Physician Fee Schedule is "general supervision," the supervision need not be provided in the office suite. The one wrinkle in this is when supervision is provided by a physician "in the group." Because a physician "in the group" can only be considered "in the group" when providing services on the

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[95] 42 CFR § 411.355(b)(1). The latter term allows physicians to supervise in the practice's offices.

[96] 42 USCA § 1395nn(2)(A)(i).

[97] 66 Fed. Reg. 875, January 4, 2001.

group's facilities, even if a test only requires "general supervision," the physician "in the group" must provide the test in the group's facilities, which will likely mean that the physician must provide the services under "direct supervision."

2. The Where

In-office ancillary services must be performed in one of two types of locations: (1) the "same building," or (2) a "centralized building." The "same building" applies where a group has offices on multiple floors of the same building but is also sometimes referred to as "shared facilities" in scenarios such as block-time leasing of space, where the group rents space for anywhere between eight and thirty-five hours per week. There are three options to satisfy the "same building" requirement where the building is not the group's primary practice site.

The first "same building" option is where the location used is where the referring physician or a member of the referring physician's group regularly practices for at least thirty-five hours per week, and provides at least thirty hours per week of non-DHS services.[98] Conceptually speaking, this refers an office of a physician practice that has multiple locations but uses the location where IOAS is offered on a full-time basis. Consider an orthopedic group that performs various imaging studies and rents two to three different facilities, only one of which it occupies for thirty-five hours at a time. If a physician member at one of the other offices saw a patient and referred the patient for a DHS diagnostic study to be performed at the group's main office and supervised by another physician member, that would meet the IOAS' "same building" location requirement.

[98] 42 CFR § 411.355(b)(2)(i)(A).

The second "same building" option is a location where the referring physician or his or her group owns or rents an office that is open to their patients for at least eight hours per week, and the referring physician regularly practices medicine and provides services at that location for at least six hours per week, including services that do not include the provision of DHS.[99] Conceptually, this approach involves a group's satellite office where the referring physician works. An example might be a cardiovascular group that has a "hub and spokes" office model with a central office where many patients are seen, and satellite offices where diagnostic tests are performed. If a patient presents at the central office for a visit, and a physician member refers the patient for a cardiac MRI with stress imaging, the "same building" location requirement could be satisfied if the physician spends one day a week at the satellite location, and performs non-DHS services for at least six hours at a time in that location.

The third option for "shared facilities"/"same building" purposes is a location where the referring physician is on-site and orders the DHS during a patient visit in an office that is normally open to the public for at least eight hours per week and where the group provides services for at least 6 hours which do not include DHS.[100] Conceptually, this is a satellite office where the referring physician is simply visiting for the day; the arrangement only works while the referring physician remains on-site. Similar to the example above, consider the same type of setup, only the physician is only in the satellite office to supervise the performance of the MRI, but the group provides services regularly at the office, and those services include non-DHS services.

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[99] 42 CFR § 411.355(b)(2)(i)(B).

[100] 42 CFR § 411.355(b)(2)(i)(C).

The other approach to meeting the locational requirements of the IOAS exception is the "centralized building." This refers to all or part of a building owned or leased on a full-time, 24/7 basis by the group, which is used exclusively by the group, and where the group provides some or all of its DHS.[101] In accordance with the definition, a "centralized building" may not include vans, mobile trailers, or other vehicles, unless they are parked and used exclusively by the group on a 24/7 basis.[102] The definition also does not include parking lots or garages.[103]

In addition, the IOAS exception requires that, for referrals of MRIs, CTs, and PETs, the referring physician must inform the patient at the time of the referral of the availability of another supplier. They must provide the patient with a list of at least five other suppliers of the same service who can be found within a 25-mile radius of the referring physician's office. If there are fewer than five such providers within the 25-mile radius, the referring physician must list all of the other suppliers within that radius, unless there are none.[104] The regulators have not specified the form that such a notice must take, but it is likely advisable to have the notice in a standardized, written form which the patient signs and dates, a copy of which is retained by the referring physician or their group. This approach creates a more reliable paper trail by which to demonstrate compliance with the requirements if such a demonstration is ever needed.

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[101] 42 CFR § 411.355(b)(2)(ii); see also, the definition of "centralized building" at 42 CFR § 411.351.

[102] 42 CFR § 411.351.

[103] 42 CFR § 411.351.

[104] 42 CFR § 411.355(b)(7).

3. Billed by Whom

Finally, in-office ancillary services must be billed either by (1) the physician who performs or supervises the service, (2) the group practice of which the performing or supervising physician is a member, or (3) an entity that is wholly owned by the performing or supervising physician or that physician's group.[105] Third party billing companies may also be used when billing on behalf of the group or entity described above.[106] In most instances, the physician performing the service will belong to a group, and the group will bill for the service under its own name, with the physician reassigning their right to payment to the group. With respect to wholly-owned entities, this could occur in a scenario where a physician in Group A refers to an entity that the group wholly owns, and is not simply owned by the same physicians. To put this in context, if Group A is owned by Drs. Smith, Jones, Patel, Schwartz, Oh, and Qadir, then to qualify for billing they cannot own stock individually in Imaging Services, P.C., even if they own the stock in the same proportions that they do in Group A; instead, Group A must hold 100% of the stock in Imaging Services, P.C.

C. Compensation Concerns

Stark can also interfere with how physicians within groups are compensated, including those groups that provide diagnostic tests which are Stark DHS. The Stark regulations permit two different approaches with respect to compensation: productivity bonuses, and profit sharing.

[105] 42 CFR § 411.355(b)(3).

[106] 42 CFR § 411.355(b)(3)(v).

1. Productivity Bonuses

Productivity bonuses under Stark reward the physician with the fruits of their own labors (as well as "incident to" services). The bonus in question must be calculated in a "reasonable and verifiable manner that is not directly related to the volume or value of the physician's referrals of DHS."[107] The regulations offer three safe harbor methods. Under one option, the bonus may be based on total patient encounters or RVUs.[108] The use of the term "patient encounters" here, again, raises the problem of its ambiguity, as discussed above.[109] Within the diagnostic testing context, it is conceivable that not every service would constitute a "patient encounter," which could in turn negatively impact the productivity bonus for physicians. For example, in a multispecialty group, those physicians who perform diagnostic testing which does not involve "patient encounters" – such as interpretations of remote cardiac monitoring services, or certain pathology services – would fare worse for productivity bonuses under this method than physicians whose practices have them spending more face-to-face time with patients. One would expect, in such circumstances, that the RVU model would be used instead. Alternatively, the bonus may be based on the allocation of the physician's compensation attributable to services which are not DHS (for example, evaluation and management services and non-DHS diagnostic testing) payable by federal health care programs or private payors. Many group practices utilize this approach.[110] Finally, the bonus may be based on revenues which include DHS, but only: (1) when DHS makes up less than 5% of the group's total revenues, and (2) the portion of those

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[107] 42 CFR § 411.352(i)(3).

[108] 42 CFR §411.352(i)(3)(i).

[109] See, Section III.A herein.

[110] 42 CFR § 411.352(i)(3)(ii).

revenues constitutes 5% or less of the physician's total compensation from the group.[111] Unsurprisingly, this last approach is uncommon, and really only applies to group practices where the amount of DHS performed by the group is minimal.

Productivity bonuses also permit for physicians to count services that are performed incident-to their own services in the total calculation. However, because diagnostic testing can never be performed incident-to, physicians cannot count as part of their productivity bonus services where the physician supervises the TC.[112] In the Stark Phase III preface, CMS explained its rationale, stating that the rules regarding "incident-to" services only applied to those services which do not have their own separate benefit category. However, because diagnostic testing does have its own benefit category, it could not be billed incident-to, and therefore could not be counted in productivity bonus calculations.[113]

The federal government has used the issue of productivity bonuses to penalize physician groups as well. For example, in 2014, the Department of Justice (DOJ) entered into the first Stark-related settlement by a cardiology group.[114] Cardiovascular Specialist, P.C., d/b/a/ New York Heart Center, agreed to pay the DOJ over $1.33M for alleged violations of the Federal False Claims Act and Stark. Partner physicians in the group had been paid compensation using a formula which included the volume or value of the physicians' referrals for nuclear and CT

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[111] 42 CFR § 411.352(i)(3)(iii).

[112] The only way the TC itself, if DHS, could be counted towards the physician's productivity bonus is if the physician personally performs the TC.

[113] 72 Fed. Reg. 51016.

[114] "New York Heart Center to Pay More Than $1.33 Million to Settle Allegations of False Claims Act and Stark Law Violations," Dept. of Justice, U.S. Attorney's Office, NDNY (August 14, 2014). https://www.justice.gov/usao-ndny/pr/new-york-heart-center-pay-more-133-million-settle-allegations-false-claims-act-and.

scans, but which did not require them to actually personally perform the scan. In fact, the services in question had been rendered between 2006 and 2007, after the incident-to billing rules had changed. Prior to 2007, the compensation arrangement would have complied with the rules. The settlement underscores that physicians may only be paid productivity bonuses for those services which they personally perform, and for those services which do qualify for incident-to billing. For productivity bonuses derived from diagnostic testing, supervision alone is insufficient.

[This section may need to be revised, depending on what happens with the next wave of Stark regs. Leaving this as a placeholder to remind me to revisit it when the final rule is published.] Under the Stark regulations group practices may also pay physicians compensation based on an overall share of the group's profits.[115] Profits may be divided using the group's total compensation, or on the compensation of sub-groups of at least 5 physicians (often referred to as "pods").[116] The regulators explained their reasoning in using at least 5 physicians per "pod" in response to commentary in the original Phase I rulemaking requesting that 3-physician pods be permitted. In rejecting the request, the regulators stated, "We believe a threshold of at least five physicians is likely to be broad enough to attenuate the ties between compensation and referrals. We are rejecting the suggestion to use a threshold of three physicians because we believe the lesser threshold would result in pooling that would be too narrow and, therefore, potentially too closely related to DHS referrals."[117] Under the current Stark regulations, physician practices may use more than one pod, and physicians may be members of more than one pod.

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[115] 42 CFR § 411.352(i).

[116] 42 CFR § 411.352(i)(2).

[117] 66 Fed. Reg. 909 (January 4, 2001).

The share of the overall profits must not be based on the volume or value of DHS referrals.[118] To meet this requirement, the regulations specify three methods which will be deemed not to reflect the volume or value of DHS referrals. First, profits may be distributed on a per-capita basis.[119] Second, revenue derived from DHS may be distributed on a basis which is unrelated to revenues attributable to DHS that are not payable by any federal health care program or private payor.[120] Third, revenues that derive from DHS make up less than 5% of the group's total revenues, and each physician's allocated portion of those revenues is 5% or less of the physician's total compensation to the group.[121]

These methods are not the only ones available, however; as long as the profits are divided in a reasonable and verifiable manner that does not directly relate to the volume or value of the physician's referrals of DHS, the profit sharing will be permitted.[122] In the Phase I rulemaking, the regulators specifically noted that other methods aside from the three explicitly stated ones were permissible. The regulators stated, "Group practices are not required, however, to use these methods. The regulations clarify that other methods (including distributions based on ownership interests or seniority) are acceptable so long as they are reasonable, objectively verifiable, and indirectly related to referrals. These compensation methods should be adequately documented and supporting information must be made available to the Secretary upon request."[123] We have

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[118] 42 CFR § 411.352(i)(1).

[119] 42 CFR § 411.352(i)(2)(i).

[120] 42 CFR § 411.352(i)(2)(ii).

[121] 42 CFR § 411.352(i)(2)(iii).

[122] 42 CFR § 411.352(i)(2).

[123] 66 Fed. Reg. 909-910 (January 4, 2001).

represented a large multi-specialty group that has multiple pods for different types of providers, such as for clinical laboratory services, diagnostic imaging, and physical therapy, but which bases its profit sharing on historical ordering patterns for low-, medium-, and high-ordering brackets.

Taking into account diagnostic testing revenues can be complicated in profit sharing. A group could decide not to share diagnostic testing profits for those tests where the technical component is DHS. Although, non-DHS diagnostic testing revenue could be shared, such as for Holter studies, electrocardiograms, nerve conduction studies, etc. The group could choose to allocate profits based on ordering of non-DHS diagnostic testing, to meet the requirement that profits not directly reflect the volume or value of ordering DHS services.

Another approach for groups is to use profit sharing to allow physicians to benefit from the performance of DHS diagnostic testing which they do not personally perform. For example, a multispecialty group could allow the physicians who perform E/M services for patients (which results in orders for DHS diagnostic testing, such as ultrasound) to share in the overall profits of the group that include ultrasound studies. In this way, although the ordering physicians do not personally perform the ultrasounds (and therefore cannot take advantage of a productivity bonus), they may still benefit from the performance of the tests. Groups are also free to mix and match productivity bonuses and profit sharing. Thus, the same multispecialty group could reward the physicians who interpret the ultrasounds by providing them with productivity bonuses for their interpretations, while offering profit sharing for all physicians in the group which includes revenues from the TCs of the ultrasounds that the interpreting physicians supervise.

IV. The Anti-Markup Rule

First implemented in its current form in 2009, the anti-markup rule is designed to control Medicare costs, and applies to all "purchased" Medicare diagnostic tests, as categorized under the Medicare Physician Fee Schedule (but not to clinical laboratory testing). Unlike the Stark law, the anti-markup rule does not prohibit payment altogether; rather, it limits the total amount that may be paid for the test itself. A "purchased" test is one where one component of the diagnostic test is ordered by the billing physician (or a related party), and the physician supervising the performance of the TC or performing the PC does not "share a practice with the billing physician."[124] A "related party" is defined as another party with common ownership or control as the physician.[125] If the ordering physician is not also the billing physician or a related party, the anti-markup test does not apply at all.

When the anti-markup rule does apply, the billing physician is limited to charging: (1) the actual amount charged by the performing physician; (2) the MPFS amount for the test (in other words, with no profit made on the purchased test); or (3) the performing physician or supplier's "net charge" to the billing physician, whichever is lowest.[126] The "net charge" is calculated when there is no fixed fee charged by the selling physician for each service. In these circumstances, the billing physician is limited to the salary and benefits paid to the performing supplier for the TC or PC allocated to each service billed. This calculation may not account for overhead, either, and the billing entity is ultimately responsible for determining the amount that

[124] Medicare Claims Processing Manual, Chapter 1 § 30.2.9.

[125] 42 CFR § 414.50(a)(1), referencing the definition of "related party" in 42 CFR § 413.17.

[126] 42 CFR § 414.50(a)(1).

it pays. This can present a major headache for physicians, which is why they attempt to avoid having to calculate the "net charge" if at all possible.

In most cases, this issue is avoided by ensuring that the performing physician "shares a practice" with the billing physician. This may be demonstrated using one of two tests. A performing physician will be deemed to "share a practice" with the billing physician when he or she provides "substantially all" of his or her professional services through the billing physician or supplier.[127] "Substantially all" means at least 75%, although the regulations do not describe how to calculate the 75% figure. Because the anti-markup regulations reference the Stark regulations as standards in other instances, it would be reasonable to use the "substantially all" standard and calculation method described in the Stark regulations.[128] The other test that may be used to demonstrate the performing physician "shares a practice" with the billing physician or supplier is when the TC or PC is performed "in the office of the billing physician or supplier,"[129] meaning the office space where the ordering physician regularly provides patient care, including space where diagnostic testing is provided if the space is located in the "same building" as defined under Stark.[130] If the "billing physician or other supplier" is a physician practice, the "office of the billing physician or other supplier" is the space in which the ordering physician

[127] 42 CFR § 414.50(a)(2)(ii).

[128] At 42 CFR § 411.352(d).

[129] 42 CFR § 414.50(a)(2)(iii).

[130] The definition can be found at 42 CFR § 411.351, and is "a structure or combination of structures that share a single street address, but not including exterior spaces, loading docks, parking garages, mobile vehicles, vans, or trailers."

provides substantially the full range of patient care services that the ordering physician generally provides.[131]

For groups that have multiple office locations, this test can present a problem. We represent a multispecialty group with multiple offices in different locations. The group has several, radiology providers who perform various diagnostic procedures and who are located in one facility. The group's ordering physicians, however, are spread out across multiple other facilities. Unfortunately, the group cannot avoid the anti-markup prohibition with this arrangement, because its ordering physicians do not "share a practice" with the performing physicians, even though they are part of the same legal entity; the definition of "in the office of the billing physician" requires the ordering physicians to provide substantially the full range of the services they generally provide in the office space where the performing physician (in this case the radiation physicians) perform the diagnostic tests. To avoid the limitation, the group would have to have its physicians engage in burdensome travel in one direction or the other: Either the ordering physicians would have to travel to the office of the performing physicians to perform substantially full range of services they perform, or the performing physician would have to travel to the ordering physicians' offices to perform the diagnostic test. Another option would be to refer the patient to a physician in the group at the site of the radiologist; but (1) that physician would have to have a treating relationship with the patient for his order to be legitimate; and (2) the service of the treating physician has to be medically necessary.

The anti-markup rule can also implicate Medicare's diagnostic testing supervision rules when supervision is provided by an independent contractor. Similar to the distinction between a

[131] 42 CFR § 414.50(a)(2)(iii).

"member of the group" and a "physician in the group" under Stark[132], an independent contractor can only be said to "share a practice" with the group if he or she is physically present in the "same building" as the ordering physician to provide supervision of the test. In practice, what this can mean is that, even though a given test might only require general supervision under the MPFS, to satisfy the anti-markup rule, the independent contractor physician will have to be present in the "same building" and perform the test under direct supervision.

In most instances, physician practices wishing to purchase TC services avoid the prohibitions of the anti-markup rule by physically co-locating the ordering and performing/supervising physicians. This may be done by hiring independent contractor physicians or mobile testing companies to come to the ordering physician's office to perform the test. It should also be reiterated that if the billing entity did not order the test itself, the anti-markup rule does not apply. Thus, if a family medicine practice orders a patient to get a stress test from a cardiology group, the anti-markup rule will not apply to the cardiology group's performance of the stress test.

V. Independent Diagnostic Testing Facilities

Before 1997, there was no such thing as an "independent diagnostic testing facility" (IDTF); instead, Medicare created the concept of "independent physiology laboratories" (IPLs) in an Office of General Counsel ruling published in January, 1979, and they were treated differently from clinical laboratories.[133] The Health Care Financing Administration (HCFA)[134],

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[132] Discussed more in depth above at Section III.A herein.

[133] See, "Quality Assurance in Independent Physiological Laboratories," Office of Inspector General Office of Evaluation and Inspections, October 1990. Available at, https://oig.hhs.gov/oei/reports/oei-03-88-01400.pdf.

[134] The agency tasked with administering Medicare and the federal portions of Medicaid before CMS.

however, ultimately abandoned the concept. For example, the term "physiological" itself had no definition, and the "independence" of IPLs was only considered in relation to their operating independently of a hospital, a rural health clinic, or a physician's office and complying with state and local licensure requirements.[135] Rather than attempt to clarify it, HCFA replaced the IPL concept with the much more clearly defined IDTF concept.[136]

Medicare recognizes two general forms for IDTFs: fixed site IDTFs, and mobile IDTFs.[137] A fixed site IDTF is based out of a physical location, such as a building (or portion thereof) or a permanently parked trailer in which diagnostic tests are performed. The fixed site entity may not share space with any other Medicare-enrolled individuals or organizations, and may not lease or sublease its own operations, location, or equipment.[138] Thus, a fixed-site IDTF may not function as a "turnkey" diagnostic testing operation. A mobile IDTF is an IDTF that utilizes portable equipment which is taken from one location to another, or which resides in a van that contains diagnostic equipment. Mobile units must still have a central office, however, to which correspondence may be sent and where the mobile equipment itself is stored; a post office

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[135] 62 Fed. Reg. 59070 (October 31, 1997).

[136] 62 Fed. Reg. 59048 (October 31, 1997). Both IDTFs and IPLs are, fundamentally, Medicare concepts. Many states do not have laws or regulations governing the types of providers who function as IDTFs, and to the extent they do, there may not be a single, broad category of licensure the way that Medicare recognizes IDTFs.

[137] 42 CFR § 410.33(a)(1). An individual NPP may also qualify as an IDTF. The IDTF rules do not apply to the following categories of tests: diagnostic mammographies; audiology tests; diagnostic psychological testing provided by a clinical psychologist or qualified independent psychologist; diagnostic tests performed by a physical therapist certified as a qualified electrophysiological clinical specialist by the American Board of Physical Therapy Specialists and permitted to perform such services under state law.

[138] 42 CFR § 410.33(g)(15).

box will not suffice.[139] In either case, the IDTF must remain independent of a physician office or hospital.[140]

All IDTFs must all have at least one supervising physician, who is competent and trained in the tests performed by the IDTF.[141] However, this requirement can be met by having multiple supervising physicians who are competent and trained in the performance of some of the tests, as long as the constellation of supervising physicians are collectively competent and trained in the performance of all of the tests.[142] Each supervising physician may supervise no more than three IDTF sites at once – including both fixed site IDTFs and mobile units.[143] This requirement also applies across multiple corporate entities; in other words, a physician performing supervision for three fixed site IDTFs run by Company A cannot also provide supervision to Company B. To further complicate matters, the level of supervision required is that specified under the MPFS for the specific diagnostic test(s).[144] In practice, this means that if an IDTF requires personal supervision for some diagnostic tests, the supervising physician must be physically in the room to perform such supervision. However, physicians providing supervision of services requiring direct supervision may provide such supervision for concurrent services. Physicians providing supervision,

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[139] 42 CFR § 410.33(g)(3). That CMS has been required to specify this likely suggests that they have encountered such attempts in the past.

[140] 42 CFR § 410.33(a)(1).

[141] 42 CFR § 410.33(b).

[142] In the manuals, CMS explains that physicians need only meet the proficiency standards for the tests that they supervise. Medicare Program Integrity Manual Chapter 15, Section 15.5.19.5.

[143] 42 CFR § 410.33(b)(1).

[144] 42 CFR § 410.33(b)(2).

> "must evidence proficiency in the performance and interpretation of each type of diagnostic procedure performed by the IDTF. The proficiency may be documented by certification in specific medical specialties or subspecialties or by criteria established by the [MAC]...In the case of a procedure requiring the direct or personal supervision of a physician...the IDTF's supervising physician must personally furnish this level of supervision whether the procedure is performed in the IDTF or, in the case of mobile services, at the remote location."[145]

The IDTF must also maintain documentation substantiating the physician's credentials. Similarly, technicians must also be appropriately certified as required under state law.[146] Specifically, non-physician personnel must demonstrate basic qualifications to perform tests and have training and proficiency as evidenced by licensure/certification by appropriate state health or education dept. If no such authority exists, must be certified by appropriate national credentialing body, and IDTF must maintain documentation for review by CMS to substantiate this.

For multi-state entities, all locations must be enrolled with the appropriate Medicare contractor.[147] The multi-state IDTF must also have documentation that the supervising physician(s) are licensed in each state where the IDTF operates, and the IDTF must operate in compliance with applicable federal, state, and local laws and regulations regarding the health and safety of patients in each applicable state.[148] When the IDTF renders services in different MAC jurisdictions, the point of delivery of the diagnostic service must be the Place of Service (POS) on the submitted claim.[149] When an IDTF performs an entire diagnostic test at a beneficiary's

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[145] 42 CFR 410.33(b)(2).

[146] 42 CFR § 410.33(c).

[147] 42 CFR 410.33(e).

[148] 42 CFR § 410.33(e)(1).

[149] 42 CFR § 410.33(e)(2).

location, the beneficiary's location must be recorded as the POS. However, when one or more aspects of the test are performed at the IDTF, the IDTF is listed as the POS on the claim.[150]

In 2012, we represented an IDTF that performed home sleep services. The IDTF was located in several states, and enrolled in Medicare with each appropriate MAC. The IDTF purchased PCs from a physician who was physically located in a jurisdiction where the IDTF was not enrolled, with the physician reassigning his right to payment to the IDTF. This scenario triggered a chain of confusing interactions with CMS. We asked CMS as to how the IDTF could bill a purchased PC when the PC itself was performed outside of the jurisdiction in which the IDTF was located. Initially, CMS informed us that such an arrangement was essentially impossible; reassignments, we were told, were not permitted across state lines (although we assumed the individual informing us of the decision meant contractor jurisdictions rather than state lines). In support, the CMS representative cited generally to CMS manuals. These manuals, however, stated "In situations where an individual is reassigning benefits to a person/entity, both the reassignor and reassignee must be enrolled with the same contractor."[151]

At the time, our solution was to have the physician enroll in the jurisdiction where the IDTF was located, and then reassign to the IDTF, with the IDTF filing change of enrollment information to list the physician as an interpreting physician. We were then told by a different CMS representative that this was impossible because an enrollment application could not be submitted by a provider unless the provider was physically entering the jurisdiction to render

[150] 42 CFR § 410.33(e)(2).

[151] Medicare Program Integrity Manual, Chapter 15 § 15.5.20A, circa November, 2012. This language has since been changed in the manuals, however.

services. When we asked for a citation to substantiate this position, none was provided. We later learned that the process was being discussed internally at CMS.

Medicare's current policy is listed in a revised section of the Program Integrity Manual, which was changed in February, 2016. At present, the reassigning physician,

> "need not – pursuant to the reassignment – enroll in the reassignee's contractor jurisdiction nor be licensed/authorized to practice in the reassignee's state. If the reassignor will be performing services within the reassignee's state, the reassignor must enroll with the Medicare contractor for – and be license/authorized to practice in – that state."[152]

The manual then describes a scenario in which Dr. Smith is located in Jurisdiction X, and is reassigning benefits to Jones Medical Group in Jurisdiction Y. Jones must enroll with the MAC in both X and Y, but need not be licensed or authorized to perform services in Smith's state. Jones must list Smith's location as one of Jones' practice locations on the CMS-855B enrollment form it submits to the Jurisdiction X MAC.[153] It is unclear, however, whether this implicates CMS' telemedicine coverage rules, discussed further below.

All IDTFs must also provide complete and accurate information on their enrollment applications, including keeping such applications updated with respect to changes of ownership, changes in practice location, changes in general supervision, and adverse legal actions being reported to Medicare within 30 days, and all other changes reported within 90 days.[154]

They must maintain a primary business phone under the name of the IDTF's designated business, with the phone located at the designated site of business or the home office of a mobile

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[152] Medicare Program Integrity Manual, Chapter 15 § 15.5.20.1A.

[153] Medicare Program Integrity Manual, Chapter 15 § 15.5.20.1A.

[154] 42 CFR § 410.33(g)(2).

IDTF. The number itself must be reported in a local directory and be available through directory assistance.[155]

Medicare's regulations prohibit IDTFs from directly soliciting patients, including via telephone, computer, or in-person contacts.[156] An IDTF may only perform a diagnostic test on the order of a treating physician. The supervising physician for the IDTF may not order such tests unless the supervising physician is also the patient's treating physician. The order for the test must be in writing, in contrast to what the manuals generally describe for diagnostic testing orders.[157] However, IDTFs may order subsequent studies based on the outcome of the initial test ordered by the treating physician under certain circumstances.[158]

In a mobile setting, IDTFs often sell their services as part of a "purchase service" arrangement, especially with respect to the sale of TCs. In such circumstances, a mobile unit typically travels to a physician practice's office, where the IDTF's technicians perform the services under the supervision of the physician who ordered the test. The physician practice may then perform its own PC, after which the physician practice submits separate claims for both the PC and TC in the practice's own name. The benefit of such an arrangement is that the practice need not make the investment in equipment or in qualified technicians for services which the

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[155] 42 CFR § 410.33(g)(5).

[156] 42 CFR § 410.33(g)(7).

[157] 42 CFR § 410.33(d).

[158] Specifically, the IDTF may order subsequent tests when six criteria are met: (1) the IDTF cannot reach the treating physician or practitioner to change the order or obtain a new order and this is documented in the medical record for the patient; (2) the IDTF has performed the originally ordered test; (3) the interpreting physician at the IDTF determines and documents that, because of an abnormal result of the test performed, an additional test is medically necessary; (4) delaying the performance of the additional test would have an adverse effect on the beneficiary's care; (5) the result of the test is communicated to and used by the treating physician or practitioner in the patient's treatment; and (6) the interpreting physician at the IDTF documents in his or her report why additional testing was done. Medicare Benefit Policy Manual Chapter 15 § 80.6.3.

practice may not use with enough frequency to justify the additional expense. Such an arrangement also avoids the restrictions of the Medicare anti-markup fee limitation. The ordering physician (usually the practice's physician) provides supervision of the TC, or the IDTF's physician is on-site to provide supervision, thereby meeting the facility requirement for the "shares a practice" analysis. One wrinkle in this is if the test requires only general supervision, in which case, the practice's physician – rather than the IDTF's – will provide supervision to avoid the anti-markup limitation.

This type of arrangement also needs to be reviewed for Stark compliance if the TC is a Stark DHS, and there is a financial relationship between the IDTF and the physician practice. For example, we represented IDTF clients that operate mobile IDTFs housed in tractor-trailers or vans that provided CT scan services. The IDTFs proposed to drive to physician practices for several hours per week (but not on a 24/7 basis) and provide TCs to the practices. This arrangement did not meet the IOAS exception, however, because the physicians for the practice would not come on to the van itself to personally perform or supervise the service, and the van could not count under the "centralized building" definition. To meet the "centralized building" requirement, the van would have to have been parked on a 24/7 basis and leased/used exclusively by the practice. The arrangement would not qualify under the IOAS' "same building" test, either, because the test explicitly excludes mobile units like vans. This type of arrangement typically works better with more portable units like hand-held devices (e.g., ultrasound units) which can be physically brought inside of a practice's offices. It is worth noting, however, that the approach to mobile units using vans can work when the diagnostic testing services are not DHS.

VI. Conclusion

Diagnostic testing in Medicare presents a confusing morass of statutory, regulatory, and administrative rules for physicians and physician practices. These requirements intersect and overlap, and can make analyzing physician arrangements a difficult, multi-layered process. Diagnostic testing, however, is unlikely to go away, and even though utilization trends have declined somewhat in recent years, they still remain high. In light of this, it is likely that Medicare will seek to further limit the utilization of diagnostic testing services, such as by adopting MedPAC recommendations like limiting the availability of the IOAS to only specific services, or making prior authorization requirements more stringent for physicians. One also cannot discount the possibility of additional changes to Stark, which will likely impact diagnostic testing and more. Legal counsel must keep abreast of these changes, and be prepared to assist physician clients in negotiating the twists and turns of an increasingly regulated system.